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29 CFR 1910, 1915 and 1926
Hazard Communication; Final Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

[Docket No. OSHA–H022K–2006–0062 (formerly Docket No. H022K)]

RIN 1218–AC20

Hazard Communication

AGENCY: Occupational Safety and Health Administration (OSHA), DOL.

ACTION: Final rule.

SUMMARY: In this final rule, OSHA is modifying its Hazard Communication Standard (HCS) to conform to the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS). OSHA has determined that the modifications will significantly reduce costs and burdens while also improving the quality and consistency of information provided to employers and employees regarding chemical hazards and associated protective measures. Consistent with the requirements of Executive Order 13563, which calls for assessment and, where appropriate, modification and improvement of existing rules, the Agency has concluded this improved information will enhance the effectiveness of the HCS in ensuring that employees are apprised of the chemical hazards to which they may be exposed, and in reducing the incidence of chemical-related occupational illnesses and injuries.

The modifications to the standard include revised criteria for classification of chemical hazards; revised labeling provisions that include requirements for use of standardized signal words, pictograms, hazard statements, and precautionary statements; a specified format for safety data sheets; and related revisions to definitions of terms used in the standard, and requirements for employee training on labels and safety data sheets. OSHA is also modifying provisions of other standards, including standards for flammable and combustible liquids, process safety management, and most substance-specific health standards, to ensure consistency with the modified HCS requirements. The consequences of these modifications will be to improve safety, to facilitate global harmonization of standards, and to produce hundreds of millions of dollars in annual savings.

DATES: This final rule becomes effective on May 25, 2012 Affected parties do not need to comply with the information collection requirements in the final rule until the Department of Labor publishes in the **Federal Register** the control numbers assigned by the Office of Management and Budget (OMB). Publication of the control numbers notifies the public that OMB has approved these information collection requirements under the Paperwork Reduction Act of 1995.

The incorporation by reference of the specific publications listed in this final rule is approved by the Director of the Federal Register as of May 25, 2012.

ADDRESSES: In compliance with 28 U.S.C. 2112(a), the Agency designates Joseph M. Woodward, 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 standard.

FOR FURTHER INFORMATION CONTACT: *For general information and press inquiries, contact:* Frank Meilinger, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, telephone (202) 693–1999. *For technical information, contact:* Dorothy Dougherty, Director, Directorate of Standards and Guidance, Room N–3718, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1950.

SUPPLEMENTARY INFORMATION: This final rule modifies the Hazard Communication standard (HCS) and aligns it with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as established by the United Nations (UN). This action is consistent with Executive Order 13563 and, in particular, with its requirement of ''retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome.'' The preamble to the final rule provides a synopsis of the events leading up to the establishment of the final rule, a detailed description of OSHA's rationale for the necessity of the modification, and final economic and voluntary flexibility analyses that support the Agency's determinations. Also included are explanations of the specific provisions that are modified in the HCS and other affected OSHA standards and OSHA's responses to comments, testimony, and data submitted during the rulemaking. The discussion follows this outline:

The HCS requires that chemical manufacturers and importers evaluate the chemicals they produce or import and provide hazard information to downstream employers and employees by putting labels on containers and preparing safety data sheets. This final rule modifies the current HCS to align with the provisions of the UN's GHS. The modifications to the HCS will significantly reduce burdens and costs, and also improve the quality and consistency of information provided to employers and employees regarding chemical hazards by providing harmonized criteria for classifying and labeling hazardous chemicals and for preparing safety data sheets for these chemicals.

OSHA is required by the Occupational Safety and Health (OSH) Act of 1970 to assure, as far as possible, safe and healthful working conditions for all working men and women. Section 3(8) of the OSH Act (29 U.S.C. 652(8)) empowers the Secretary of Labor to promulgate standards that are ''reasonably necessary or appropriate to provide safe or healthful employment and places of employment.'' This language has been interpreted by the Supreme Court to require that an OSHA standard address a significant risk and reduce this risk significantly. *See Industrial Union Dep't* v. *American Petroleum Institute,* 448 U.S. 607 (1980). As discussed in Sections IV and V of this preamble, OSHA finds that inadequate communication to employees regarding the hazards of chemicals constitutes a significant risk of harm and estimates that the final rule will reduce this risk significantly.

Section 6(b)(7) of the Act (29 U.S.C. 655(b)(7)) allows OSHA to make appropriate modifications to its hazard communication requirements as new knowledge and techniques are developed. The GHS system is a new approach that has been developed through international negotiations and embodies the knowledge gained in the field of chemical hazard communication since the current rule was first adopted in 1983. As indicated in Section IV of this preamble, OSHA finds that modifying the HCS to align with the GHS will enhance worker protections significantly. As noted in Section VI of this preamble, these modifications to HCS will also result in less expensive chemical hazard management and communication. In this way, the modifications are in line with the requirements of Executive Order 13563 and its call for streamlining of regulatory burdens.

OSHA is also required to determine if its standards are technologically and economically feasible. As discussed in Section VI of this preamble, OSHA has determined that this final standard is technologically and economically feasible.

The Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires OSHA to determine if a regulation will have a significant impact on a substantial number of small entities. As discussed in Section VI, OSHA has determined and certified that this rule will not have a significant impact on a substantial number of small entities.

Executive Orders 13563 and 12866 require OSHA to assess the benefits and costs of final rules and of available regulatory alternatives. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rule has been designated an economically significant regulatory action under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget, and the remainder of this section summarizes the key findings of the analysis with respect to the costs and benefits of the final rule.

Because this final rule modifies the current HCS to align with the provisions of the UN's GHS, the available alternatives to the final rule are somewhat limited. The Agency has qualitatively discussed the two major alternatives to the proposed rule—(1) voluntary adoption of GHS within the existing HCS framework and (2) a limited adoption of specific GHS components—in Section III of this preamble, but quantitative estimates of the costs and benefits of these alternatives could not reasonably be developed. However, OSHA has determined that both of these alternatives would eliminate significant portions of the benefits of the rule, which can only be achieved if the system used in the U.S. is consistently and uniformly applied throughout the nation and in conformance with the internationally harmonized system.

Table SI–1, derived from material presented in Section VI of this preamble, provides a summary of the costs and benefits of the final rule. As shown, the final rule is estimated to prevent 43 fatalities and 521 injuries and illnesses annually. Also as shown, OSHA estimates that the monetized health and safety benefits of the final rule are $250 million annually and that the annualized cost reductions and productivity gains are $507 million annually. In addition, OSHA anticipates that the final rule will generate substantial (but unquantified) savings from simplified hazard communication training and from expanded opportunities for international trade due to a reduction in trade barriers.

The estimated cost of the rule is $201 million annually. As shown in Table SI–1, the major cost elements associated with the final rule include the classification of chemical hazards in accordance with the GHS criteria and the corresponding revision of safety data sheets and labels to meet new format and content requirements ($22.5 million); training for employees to become familiar with new warning symbols and the revised safety data sheet format ($95.4 million); management familiarization and other management-related costs as may be necessary ($59.0 million); and costs to purchase upgraded label printing equipment and supplies or to purchase pre-printed color labels in order to include the hazard warning pictogram enclosed in a red-bordered diamond on the product label ($24.1 million).

The final rule is estimated to generate net monetized benefits of $556 million annually, using a discount rate of 7 percent to annualize costs and benefits. Using a 3 percent discount rate instead would have the effect of lowering the costs to $161 million per year and increasing the gross benefits to $839 million per year. The result would be to increase net benefits from $556 million to $678 million per year.

These estimates are for informational purposes only and have not been used by OSHA as the basis for its decision concerning the requirements for this final rule.

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The point estimates below do not reflect the uncertainties described throughout the analysis. While OSHA is reluctant to provide quantified ranges, OSHA recognizes that these estimates are uncertain. OSHA provides a Sensitivity Analysis on these estimates in Section VI.K of this preamble.

Table SI-1: Annual Benefits, Costs, and Net Benefits of OSHA's Final Hazard Communication Standard (2010 dollars)

Annualized Costs (discounted at 7 percent)	
Reclassification of Chemical Hazards and Revision of SDSs and Labels	$22.5 million
Employee Training	$95.4 million
Management Familiarization and Other Costs	$59.0 million
Printing Packaging and Labels for Hazardous Chemicals in Color	$24.1 million
Total Annualized Costs	$201 million
Annual Health and Safety Benefits	
Number of Non-lost-workday Injuries and Illnesses Prevented	318 (159 -1,590)
Number of Lost Workday Injuries and Illnesses Prevented	203 (101 – 1,015)
Number of Chronic Injuries Prevented	64 (33 – 320)
Number of Fatalities Prevented	43 (22 – 215)
Annualized Benefits	
Monetized Benefits of Reduction in Safety and Health Risks	$250.0 million
Savings from Productivity Improvements for Health and Safety Managers and Logistic Personnel	$475.2 million
Savings from Periodic Updating of SDSs and Labels	$32.2 million
Savings from Simplified Hazard Communication Training	Unquantified
Savings from Reductions in Non-tariff Trade Barriers	Unquantified
OSHA Standards that Are Consistent with International Standards, Consensus Standards, and Standards of Other Federal Agencies	Unquantified
Contribution towards Achieving International Goals Supported by the U.S. Government	Unquantified
Total Annual Monetized Benefits	$757 million ($632 - $1,757 million)
Net Annual Monetized Benefits (Benefits Minus Costs)	$556 million ($431 - $1,556 million)

Source: U.S. Dept. of Labor, OSHA, Directorate of Evaluation and Analysis, Office of Regulatory Analysis, 2011.

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I. Introduction

In the preamble, OSHA refers to supporting materials. References to these materials are given as ''Document ID #'' followed by the last four digits of the document number. The referenced materials are posted in Docket No. OSHA–H022K–2006–0062, which is available at *http://www.regulations.osha.gov;* however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through that Web site. All of the documents are available for inspection and, where permissible, copying at the OSHA Docket Office, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue NW., Washington, DC 20210.

II. Events Leading to the Revised Hazard Communication Standard

The HCS was first promulgated in 1983 and covered the manufacturing sector of industry (48 FR 53280, Nov. 25, 1983). (Please note: The Agency's HCS (29 CFR 1910.1200; 1915.1200; 1917.28; 1918.90; and 1926.59) will be referred to as the ''current HCS'' throughout this rule.) In 1987, the Agency expanded the scope of coverage to all industries where employees are potentially exposed to hazardous chemicals (52 FR 31852, Aug. 24, 1987). Although full implementation in the non-manufacturing sector was delayed by various court and administrative actions, the rule has been fully enforced in all industries regulated by OSHA since March 17, 1989 (54 FR 6886, Feb. 15, 1989) (29 CFR 1910.1200; 1915.1200; 1917.28; 1918.90; and 1926.59). In 1994, OSHA made minor changes and technical amendments to the HCS to help ensure full compliance and achieve better protection of employees (59 FR 6126, Feb. 9, 1994). The development of the HCS is discussed in detail in the preambles to the original and revised final rules (*See* 48 FR at 53280–53281; 52 FR at 31852–31854; and 59 FR at 6127–6131). This discussion will focus on the sequence of events leading to the development of the GHS and the associated modifications to the HCS included in the final rule.

The current HCS requires chemical manufacturers and importers to evaluate the chemicals they produce or import to determine if they are hazardous. The standard provides definitions of health and physical hazards to use as the criteria for determining hazards in the evaluation process. Information about hazards and protective measures is then required to be conveyed to downstream employers and employees through labels on containers and through material safety data sheets, which are now called ''safety data sheets'' (SDS) under the final rule and in this preamble. All employers with hazardous chemicals in their workplaces are required to have a hazard communication program, including container labels, safety data sheets, and employee training. Generally, under the final rule, these obligations on manufacturers, importers, and employers remain, but how hazard communication is to be accomplished has been modified.

To protect employees and members of the public who are potentially exposed to hazardous chemicals during their production, transportation, use, and disposal, a number of countries have developed laws that require information about those chemicals to be prepared and transmitted to affected parties. The laws vary on the scope of chemicals covered, definitions of hazards, the specificity of requirements (*e.g.,* specification of a format for safety data sheets), and the use of symbols and pictograms. The inconsistencies among the laws are substantial enough that different labels and safety data sheets must often be developed for the same product when it is marketed in different nations.

Within the U.S., several regulatory authorities exercise jurisdiction over chemical hazard communication. In addition to OSHA, the Department of Transportation (DOT) regulates chemicals in transport; the Consumer Product Safety Commission (CPSC) regulates consumer products; and the Environmental Protection Agency (EPA) regulates pesticides, as well as exercising other authority over the labeling of chemicals under the Toxic Substances Control Act. Each of these regulatory authorities operates under different statutory mandates, and all have adopted distinct hazard communication requirements.

Tracking and complying with the hazard communication requirements of different regulatory authorities is a burden for manufacturers, importers, distributors, and transporters engaged in commerce in the domestic arena. This burden is magnified by the need to develop multiple sets of labels and safety data sheets for each product in international trade. Small businesses have particular difficulty in coping with the complexities and costs involved. The problems associated with differing national and international requirements were recognized and discussed when the HCS was first promulgated in 1983. At that time, OSHA committed to periodically reviewing the standard in recognition of an interagency trade policy that supported the U.S. pursuing international harmonization of requirements for chemical classification and labeling. The potential benefits of harmonization were noted in the preamble of the 1983 standard:

> * * * [O]SHA acknowledges the long-term benefit of maximum recognition of hazard warnings, especially in the case of containers leaving the workplace which go into interstate and international commerce. The development of internationally agreed standards would make possible the broadest recognition of the identified hazards while avoiding the creation of technical barriers to trade and reducing the costs of dissemination of hazard information by elimination of duplicative requirements which could otherwise apply to a chemical in commerce. As noted previously, these regulations will be reviewed on a regular basis with regard to similar requirements which may be evolving in the United States and in foreign countries. (48 FR at 53287)

OSHA has actively participated in many such efforts in the years since that commitment was made, including trade-related discussions on the need for harmonization with major U.S. trading partners. The Agency issued a Request for Information (RFI) in the **Federal Register** in January 1990, to obtain input regarding international harmonization efforts, and on work being done at that time by the International Labour Organization (ILO) to develop a convention and recommendations on safety in the use of chemicals at work (55 FR 2166, Jan. 22, 1990). On a closely related matter, OSHA published a second RFI in May 1990, requesting comments and information on improving the effectiveness of information transmitted under the HCS (55 FR 20580, May 17, 1990). Possible development of a standardized format or order of information was raised as an issue in the RFI. Nearly 600 comments were received in response to this request. The majority of responses expressed support for a standard safety data sheet format, and the majority of responses that expressed an opinion on the topic favored a standardized format for labels as well.

In June 1992, the United Nations Conference on Environment and Development issued a mandate (Chapter 19 of Agenda 21), supported by the U.S., calling for development of a globally harmonized chemical classification and labeling system:

> A globally harmonized hazard classification and compatible labeling system, including material safety data sheets and easily understandable symbols, should be available, if feasible, by the year 2000.

This international mandate initiated a substantial effort to develop the GHS, involving numerous international organizations, many countries, and extensive stakeholder representation.

A coordinating group comprised of countries, stakeholder representatives, and international organizations was established to manage the work. This group, the Inter-Organization Programme for the Sound Management of Chemicals Coordinating Group for the Harmonization of Chemical Classification Systems, established overall policy for the work and assigned tasks to other organizations. The Coordinating Group then took the work of these organizations and integrated it to form the GHS. OSHA served as chair of the Coordinating Group.

The work was divided into three main parts: classification criteria for physical hazards; classification criteria for health and environmental hazards (including criteria for mixtures); and hazard communication elements, including requirements for labels and safety data sheets. The criteria for physical hazards were developed by a United Nations Sub-committee of Experts on the Transport of Dangerous Goods/ International Labour Organization working group and were based on the already harmonized criteria for the transport sector. The criteria for classification of health and environmental hazards were developed under the auspices of the Organization for Economic Cooperation and Development. The ILO developed the hazard communication elements. OSHA participated in all of this work, and served as U.S. lead on classification of mixtures and hazard communication.

Four major existing systems served as the primary basis for development of the GHS. These systems were the requirements in the U.S. for the workplace, consumers, and pesticides; the requirements of Canada for the workplace, consumers, and pesticides; European Union directives for classification and labeling of substances and preparations; and the United Nations Recommendations on the Transport of Dangerous Goods. The requirements of other systems were also examined as appropriate, and taken into account as the GHS was developed. The primary approach to reconciling these systems involved identifying the relevant provisions in each system; developing background documents that compared, contrasted, and explained the rationale for the provisions; and undertaking negotiations to find an agreed approach that addressed the needs of the countries and stakeholders involved. Principles to guide the work were established, including an agreement that protections of the existing systems would not be reduced as a result of harmonization. Thus, countries could be assured that the existing protections of their systems would be maintained or enhanced in the GHS.

An interagency committee under the auspices of the Department of State coordinated U.S. involvement in the development of the GHS. In addition to OSHA, DOT, CPSC, and EPA, other agencies were involved that had interests related to trade or other aspects of the GHS process. Different agencies took the lead in various parts of the discussions. Positions for the U.S. in these negotiations were coordinated through the interagency committee. Interested stakeholders were kept informed through email dissemination of information, as well as periodic public meetings. In addition, the Department of State published a notice in the **Federal Register** that described the harmonization activities, the agencies involved, the principles of harmonization, and other information, as well as invited public comment on these issues (62 FR 15951, Apr. 3, 1997). Stakeholders also actively participated in the discussions at the international level and were able to present their views directly in the negotiating process. The GHS was formally adopted by the new United Nations Committee of Experts on the Transport of Dangerous Goods and the Globally Harmonized System of Classification and Labelling of Chemicals in December 2002. In 2003, the adoption was endorsed by the Economic and Social Council of the United Nations. Countries were encouraged to implement the GHS as soon as possible, and have fully operational systems by 2008. This goal was adopted by countries in the Intergovernmental Forum on Chemical Safety, and was endorsed by the World Summit on Sustainable Development. The U.S. participated in these groups, and agreed to work toward achieving these goals.

OSHA published an Advance Notice of Proposed Rulemaking (ANPR) on the GHS in September of 2006 (71 FR 53617, Sept. 12, 2006). At the same time the ANPR was published, OSHA made available on its Web site a document summarizing the GHS (*http://www.osha.gov*). The ANPR provided information about the GHS and its potential impact on the HCS, and sought input from the public on issues related to GHS implementation. Over 100 responses were received, and the comments and information provided were taken into account in the development of the modifications to the HCS included in the September 2009 Notice of Proposed Rulemaking (NPRM) (74 FR 50279–50549, Sept. 30, 2009). A notice of correction was published on November 5, 2009, in order to correct misprints in the proposal (74 FR 57278, Nov. 5, 2009). Over 100 comments were received in response to the NPRM. Commenters represented the broad spectrum of affected parties and included government agencies, industries, professional and trade associations, academics, employee organizations and individuals. Public hearings were held in Washington, DC, from March 2 through March 5, 2010, and in Pittsburgh, PA, on March 31, 2010. Over 40 panels participated in the hearings. The comments, testimony, and other data received regarding this rulemaking were overwhelmingly favorable, and will be discussed in detail later in this preamble. The final post-hearing comment period for further submissions and briefs ended and the record was certified by Administrative Law Judge Stephen L. Purcell and closed on May 31, 2010. Executive Order 13563, emphasizing the importance of retrospective analysis of rules, was issued on January 18, 2011.

This final rule is based on Revision 3 of the GHS. The adoption of the GHS will improve OSHA's current HCS standard by providing consistent, standardized hazard communication to downstream users. However, even after the U.S. and other countries implement the GHS, it will continue to be updated in the future. These updates to the GHS will be completed as necessary to reflect new technological and scientific developments as well as provide additional explanatory text. Any future changes to the HCS to adopt subsequent changes to the GHS would require OSHA's rulemaking procedures.

OSHA will remain engaged in activities related to the GHS. The U.S. is a member of the United Nations Committee of Experts on the Transport of Dangerous Goods and the Globally Harmonized System of Classification and Labelling of Chemicals, as well as the Sub-committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals, where OSHA is currently the Head of the U.S. Delegation. These permanent UN bodies have international responsibility for maintaining, updating as necessary, and overseeing the implementation of the GHS. OSHA and other affected Federal agencies actively participate in these UN groups. In addition, OSHA will also continue to participate in the GHS Programme Advisory Group under the United Nations Institute for Training and Research (UNITAR). UNITAR is responsible for helping countries implement the GHS, and has ongoing programs to prepare guidance documents, conduct regional workshops, and implement pilot projects in a number of nations. OSHA will also continue its involvement in interagency discussions related to coordination of domestic implementation of the GHS, and in discussions related to international work to implement and maintain the GHS.

III. Overview of the Final Rule and Alternatives Considered

Based on consideration of the record as a whole, OSHA has modified the HCS to make it consistent with the GHS. OSHA finds that harmonizing the HCS with the GHS will improve worker understanding of the hazardous chemicals they encounter every day. Such harmonization will also reduce costs for employers.

OSHA believes that adopting the GHS will result in a clearer, more effective methodology for conveying information on hazardous chemicals to employers and employees. Commenters overwhelmingly supported the revision, and their submissions form a strong evidentiary basis for this final rule. The American Health Care Association stated that the GHS ''would enhance the effectiveness of the HCS in ensuring that employees are apprised of the chemical hazards to which they might be exposed'' (Document ID #0346). The National Institute of Environmental Health Sciences concurred, and added that adopting the GHS ''would provide better worker health and safety protections'' (Document ID #0347). (*See also* Document ID #0303, 0313, 0322, 0324, 0327, 0328, 0329, 0330, 0331, 0334, 0335, 0336, 0339, 0340, 0341, 0344, 0345, 0346, 0347, 0349, 0350, 0351, 0352, 0353, 0354, 0356, 0357, 0359, 0363, 0365, 0367, 0369, 0370, 0371, 0372, 0374, 0375, 0376, 0377, 0378, 0379, 0381, 0382, 0383, 0385, 0386, 0387, 0388, 0389, 0390, 0392, 0393, 0396, 0397, 0399, 0400, 0402, 0403, 0404, 0405, 0407, 0408, 0409, 0410, 0411, 0412, 0414, 0417, 0453, 0456, 0461, and 0463.)

Consistent with Executive Order 13563, OSHA has concluded that the revision significantly improves the current HCS standard. Moreover, there is widespread agreement that aligning the HCS with the GHS would establish a valuable, systematic approach for employers to evaluate workplace hazards, and provide employees with consistent information regarding the hazards they encounter. A member of the United Steel Workers aptly summed up the revision by stating that ''the HCS in 1983 gave the workers the 'right to know' but the GHS will give the workers the 'right to understand' '' (Document ID #0403). The American Society of Safety Engineers (ASSE) concurred, stating that adoption of the HCS was ''necessary to help this nation's workers deal with the increasingly difficult challenge of understanding the hazards and precautions needed to handle and use chemicals safely in an increasingly connected workplace'' (Document ID #0336). Phlymar, ORC, BCI, 3M, American Iron & Steel Institute, and the North American Metals Council (NAMC) all agreed that the adoption of the GHS would improve the quality and consistency of information and the effectiveness of hazard communication (Documents ID #0322, 0336, 0339, 0370, 0377, 0390, 0405, and 0408). (*See also* Document ID #0327, 0338, 0339, 0346, 0347, 0349, 0351, 0354, 0363, 0365, 0370, 0372, 0374, 0379, 0389, 0390, 0397, 0405, 0408, and 0414.) The evidence supporting the Agency's conclusions is discussed more thoroughly below in Sections IV, V, and VI; the revisions to the HCS are discussed in detail in Section XIII.

This section of the preamble provides an overview of the current HCS and how the adoption of the GHS will change this standard. Moreover, this section will also discuss the alternatives to mandatory implementation and the benefits of the final rule. The specific issues for which OSHA solicited comments in the NPRM will be discussed within their respective sections.

1. The Hazard Communication Standard

The HCS requires a comprehensive hazard evaluation and communication process, aimed at ensuring that the hazards of all chemicals are evaluated, and also requires that the information concerning chemical hazards and necessary protective measures is properly transmitted to employees. The HCS achieves this goal by requiring chemical manufacturers and importers to review available scientific evidence concerning the physical and health hazards of the chemicals they produce or import to determine if they are hazardous. For every chemical found to be hazardous, the chemical manufacturer or importer must develop a container label and an SDS, and provide both documents to downstream users of the chemical. All employers with employees exposed to hazardous chemicals must develop a hazard communication program, and ensure that exposed employees are provided with labels, access to SDSs, and training on the hazardous chemicals in their workplace.

There are three information communication components in this system—labels, SDSs, and employee training, all of which are essential to the effective functioning of the program. Labels provide a brief, but immediate and conspicuous, summary of hazard information at the site where the chemical is used. SDSs provide detailed technical information and serve as a reference source for exposed employees, industrial hygienists, safety professionals, emergency responders, health care professionals, and other interested parties. Training is designed to ensure that employees understand the chemical hazards in their workplace and are aware of protective measures to follow. Labels, SDSs, and training are complementary parts of a comprehensive hazard communication program—each element reinforces the knowledge necessary for effective protection of employees. Information required by the HCS reduces the incidence of chemical-related illnesses and injuries by enabling employers and employees to implement protective measures in the workplace. Employers can select less hazardous chemical alternatives and ensure that appropriate engineering controls, work practices, and personal protective equipment are in place. Improved understanding of chemical hazards by supervisory personnel results in safer handling of hazardous substances, as well as proper storage and housekeeping measures.

Employees provided with information and training on chemical hazards are able to fully participate in the protective measures instituted in their workplaces. Knowledgeable employees can take the steps required to work safely with chemicals, and are able to determine what actions are necessary if an emergency occurs. Information on chronic effects of exposure to hazardous chemicals helps employees recognize signs and symptoms of chronic disease and seek early treatment. Information provided under the HCS also enables health and safety professionals to provide better services to exposed employees. Medical surveillance, exposure monitoring, and other services are enhanced by the ready availability of health and safety information. The modifications that make up this final rule build on these core principles by establishing a more detailed and consistent classification system and requiring uniform labels and SDSs, which will better ensure that workers are informed and adequately protected from chemical exposures.

2. Current HCS Provisions for Classification, Labeling, and SDSs

The current HCS covers a broad range of health and physical hazards. The standard is performance-oriented, providing definitions of hazards and parameters for evaluating the evidence to determine whether a chemical is considered hazardous. The evaluation is based upon evidence that is currently available, and no testing of chemicals is required.

The current standard covers every type of health effect that may occur, including both acute and chronic effects. Definitions of a number of adverse health effects are provided in the standard. These definitions are indicative of the wide range of coverage, but are not exclusive. Mandatory Appendix A of the current standard lists criteria for specific health effects; however, it also notes that these criteria are not intended to be an exclusive categorization scheme, but rather any available scientific data on the chemical must be evaluated to determine whether the chemical presents a health hazard. Any adverse health effect that is substantiated by a study conducted according to established scientific principles, and reporting a statistically significant outcome, is sufficient for determining that a chemical is hazardous under the rule.

Most chemicals in commerce are not present in the pure state (*i.e.,* as individual elements or compounds), but are ingredients in mixtures of chemicals. Evaluation of the health hazards of mixtures is based on data for the mixture as a whole when such data are available. When data on the mixture as a whole are not available, the mixture is considered to present the same health hazards as any ingredients present at a concentration of 1% or greater, or, in the case of carcinogens, concentrations of 0.1% or greater. The current HCS also recognizes that risk may remain at concentrations below these cut-offs, and where there is evidence that that is the case, the mixtures are considered hazardous under the standard.

The current HCS establishes requirements for minimum information that must be included on labels and SDSs, but does not provide specific language to convey the information or a format in which to provide it. When the current HCS was issued in 1983, the public record strongly supported this performance-oriented approach (*See* 48 FR at 53300–53310). Many chemical manufacturers and importers were already providing information voluntarily, and in the absence of specific requirements had developed their own formats and approaches. The record indicated that a performance-oriented approach would reduce the need for chemical manufacturers and importers to revise these existing documents to comply with the HCS, thus reducing the cost impact of the standard.

3. GHS Provisions for Classification, Labeling, and SDSs

The GHS is an internationally harmonized system for classifying chemical hazards and developing labels and safety data sheets. However, the GHS is not a model standard that can be adopted verbatim. Rather, it is a set of criteria and provisions that regulatory authorities can incorporate into existing systems, or use to develop new systems.

The GHS allows a regulatory authority to choose the provisions that are appropriate to its sphere of regulation. This is referred to as the ‘‘building block approach.’’ The GHS includes all of the regulatory components, or building blocks, that might be needed for classification and labeling requirements for chemicals in the workplace, transport, pesticides, and consumer products. This rule only adopts those sections of the GHS that are appropriate to OSHA's regulatory sector. For example, while the GHS includes criteria on classifying chemicals for aquatic toxicity, these provisions were not adopted because OSHA does not have the regulatory authority to address environmental concerns. The building block approach also gives regulatory agencies the authority to select which classification criteria and provisions to adopt. OSHA is adopting the classification criteria and provisions for labels and SDSs, because the current HCS covers these elements. Broad criteria were established for the GHS in order to allow regulatory bodies to apply the same standards to a wide array of hazards. The building block approach may also be applied to the criteria for defining hazard categories. As a result, the GHS criteria are more comprehensive than what was in the current HCS, and OSHA did not need to incorporate all of the GHS hazard categories into this final rule.

Under the GHS, each hazard or endpoint (*e.g.,* Explosives, Carcinogenicity) is considered to be a hazard class. The classes are generally sub-divided into categories of hazard. For example, Carcinogenicity has two hazard categories. Category one is for known or presumed human carcinogens while category two encompasses suspected human carcinogens. The definitions of hazards are specific and detailed. For example, under the current HCS, a chemical is either an explosive or it is not. The GHS has seven categories of explosives, and assignment to these categories is based on the classification criteria provided. In order to determine which hazard class a mixture falls under, the GHS generally applies a tiered approach. When evaluating mixtures, the first step is consideration of data on the mixture as a whole. The second step allows the use of ‘‘bridging principles’’ to estimate the hazards of the mixture based on information about its components. The third step of the tiered approach involves use of cut-off values based on the composition of the mixture or, for acute toxicity, a formula that is used for classification. The approach is generally consistent with the requirements of the pre-modified HCS, but provides more detail and specification and allows for extrapolation of data available on the components of a mixture to a greater extent—particularly for acute effects.

Hazard communication requirements under the GHS are directly linked to the hazard classification. For each class and category of hazard, a harmonized signal word (*e.g.,* Danger), pictogram (*e.g.,* skull and crossbones), and hazard statement (*e.g.,* Fatal if Swallowed) must be specified. These specified elements are referred to as the core information for a chemical. Thus, once a chemical is classified, the GHS provides the specific core information to convey to users of that chemical. The core information allocated to each category generally reflects the degree or severity of the hazard.

Precautionary statements are also required on GHS labels. The GHS provides precautionary statements; while they have been codified (numbered), they are not yet considered formally harmonized. In other words, regulatory authorities may choose to use different language for the precautionary statements and still be considered to be harmonized with the GHS. The GHS has codified these statements (*i.e.,* assigned numbers to them) as well as aligned them with the hazard classes and categories. Codification allows the precautionary statements to be referenced in a shorthand form and makes it easier for authorities using them in regulatory text to organize them. In addition, there are provisions to allow inclusion of supplementary information so that chemical manufacturers can provide data in addition to the specified core information.

The GHS establishes a standardized 16-section format for SDSs to provide a consistent sequence for presentation of information to SDS users. Items of primary interest to exposed employees and emergency responders are presented at the beginning of the document, while more technical information is presented in later sections. Headings for the sections (*e.g.,* First-aid measures, Handling and storage) are standardized to facilitate locating information of interest. The harmonized data sheets are consistent with the order of information included in the voluntary industry consensus standard for safety data sheets (ANSI Z400.1).

4. Revisions to the Hazard Communication Standard

The GHS uses an integrated, comprehensive process of identifying and communicating hazards, and the GHS modifications improve the HCS by providing more extensive criteria for defining the hazards in a consistent manner, as well as standardizing label elements and SDS formats to help to ensure that the information is conveyed consistently. The GHS does not include requirements for a written hazard communication program, and this final rule does not make substantive changes to the current HCS requirements for a written hazard communication program. Nor does the GHS impose employee training requirements; however, OSHA believes that additional training will be necessary to ensure that employees understand the new elements, particularly on the new pictograms. Therefore, modified training requirements have been included in the final rule in order to address the new label elements and SDS format required under this revised standard.

a. Modifications

The revised HCS primarily affects manufacturers and importers of hazardous chemicals. Pursuant to the final rule, chemical manufacturers and importers are required to re-evaluate chemicals according to the new criteria in order to ensure the chemicals are classified appropriately. For health hazards, this will involve assigning the chemical both to the appropriate hazard category and subcategory (called hazard class). For physical hazards, these new criteria are generally consistent with current DOT requirements for transport. Therefore, if the chemicals are transported (*i.e.,* they are not produced and used in the same workplace), this classification should already be done to comply with DOT's transport requirements. This will minimize the work required for classifying physical hazards under the revised rule.

Preparation and distribution of modified labels and safety data sheets by chemical manufacturers and importers will also be required. However, those chemical manufacturers and importers following the ANSI Z400.1 standard for safety data sheets should already have the appropriate format, and will only be required to make some small modifications to the content of the sheets to be in compliance with the final rule.

Using the revised criteria, a chemical will be classified based on the type, the degree, and the severity of the hazard it poses. This information will help employers and employees understand chemical hazards and identify and implement protective measures. The detailed criteria for classification will result in greater accuracy in hazard classification and more consistency among classifiers. Uniformity will be a key benefit; by following the detailed criteria, classifiers are less likely to reach different interpretations of the same data.

b. Specific Changes From the Proposal

Based on comments from the rulemaking effort, OSHA has made some modifications from the proposal to the final rule. These changes were the result of OSHA's analysis of the comments and data received from interested parties who submitted comments or participated in the public hearings. The major changes are summarized below and are discussed in the Summary and Explanation Section of this Preamble (Section XIII).

Safety Data Sheet

In the proposal, OSHA asked interested parties to comment on whether OSHA's permissible exposure limits (PELs) should be included on SDSs, as well as any other exposure limit used or recommended by the chemical manufacturer, importer, or employer who prepares SDSs. After reviewing and analyzing the comments and testimony, OSHA has decided not to modify the HCS with regard to the American Conference of Government Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs) and so will continue to require ACGIH TLVs on SDSs. We have also retained the classification listings of the International Agency for Research on Cancer (IARC) and the National Toxicology Program (NTP) on SDSs. As explained more fully in the Summary and Explanation, OSHA finds that requiring ACGIH TLVs as well as the IARC and NTP classification listings on the SDS will provide employers and employees with useful information to help them assess the hazards presented by their workplaces.

Labels

As discussed in the NPRM, the GHS gives individual countries the option of using black, rather than red, borders around pictograms for labels used in domestic commerce. OSHA proposed requiring red frames for all labels, domestic and international. The final rule carries forward this requirement. As discussed in Sections IV and XIII, studies showed that there is substantial benefit to the use of color on the label. The color red in particular will make the warnings on labels more noticeable, because red borders are generally perceived to reflect the greatest degree of hazard. Further, while commenters who objected to this requirement cited the cost of printing in red ink as a reason to allow domestic use of black borders, OSHA was unconvinced that the costs involved made the provision infeasible, excessively burdensome, or warranted the diminished protection provided by black borders. (*See* Sections VI and XIII below.)

One option suggested by commenters was requiring a red label but allowing manufacturers and importers to use preprinted labels with multiple red frames. This would save costs because the preprinted label stock could be used for different products requiring different pictograms. Use of this option, however, would mean that the label for a particular chemical might have empty red frames if the chemical did not require as many pictograms as there were red frames on the label stock.

As explained in Sections IV and XIII, OSHA has concluded that a red border without a pictogram can create confusion and draw worker attention away from the appropriate hazard warnings (*See* Section IV for more detail). Additionally, OSHA is concerned that empty red borders might be inconsistent with DOT regulations (*See* 49 CFR 172.401). Therefore, while OSHA is not opposed to the use of preprinted stock, OSHA has decided not to allow the use of blank red frames on finished labels.

Hazard Classification

Another change to the final rule is the inclusion of the IARC and NTP as resources for determining carcinogenicity. Commenters generally supported this modification, and OSHA believes the inclusion of this information will assist evaluators with the classification process. Therefore, descriptions of both the IARC and NTP classification criteria have been added to Appendix F, and IARC and NTP classifications may be used to determine whether a chemical should be classified as a carcinogen.

Unclassified Hazards

OSHA has made several modifications to clarify and specify the definition for unclassified hazards, based on the comments provided. Executive Order 13563 states that our regulatory system ''must promote predictability and reduce uncertainty,'' and these efforts at clarification are designed to achieve that goal. OSHA included this definition to preserve existing safeguards under requirements of the HCS for chemical manufacturers and importers to disseminate information on hazardous chemicals to downstream employers, and for all employers to provide such information to potentially exposed employees. Inclusion of the definition does not create new requirements. OSHA has made certain changes to clarify application of the definition, and to ensure that the relevant provisions do not create confusion or impose new burdens.

In order to minimize confusion, OSHA has renamed unclassified hazards, ''hazards not otherwise classified.'' More fundamentally, and in response to the majority of the comments on this issue, OSHA has removed from the coverage of the general definition the hazards identified in the NPRM as not currently classified under the GHS criteria. These hazards are: pyrophoric gases, simple asphyxiants, and combustible dust. As described below, OSHA has added definitions to the final rule for pyrophoric gases and simple asphyxiants, and provided guidance on defining combustible dust for purposes of complying with the HCS. In addition, the Agency has also provided standardized label elements for these hazardous effects.

Precautionary/Hazard Statements

In response to concerns by commenters that, on occasion, a specified precautionary statement might not be appropriate, OSHA modified mandatory Appendix C to provide some added flexibility. Where manufacturers, importers, or responsible parties can show that a particular statement is inappropriate for the product, that precautionary statement may be omitted from the label. This is discussed in more detail in section XIII below.

Other Standards Affected

Changing the HCS to conform to the GHS requires modification of other OSHA standards. For example, modifications have been made to the standards for Flammable and Combustible Liquids in general industry (29 CFR 1910.106) and construction (29 CFR 1926.152) to align the requirements of the standards with the GHS hazard categories for flammable liquids. Modifications to the Process Safety Management of Highly Hazardous Chemicals standard (29 CFR 1910.119) will ensure that the scope of the standard is not changed by the revisions to the HCS. In addition, modifications have been made to most of OSHA's substance-specific health standards, ensuring that requirements for signs and labels and SDSs are consistent with the modified HCS.

Effective Dates

In the proposal, OSHA solicited comments regarding whether it would be feasible for employers to train employees regarding the new labels and SDSs within two years after publication of the final rule. Additionally, OSHA inquired as to whether chemical manufacturers, importers, distributors, and employers would be able to comply with all the provisions of the final rule within three years, and whether a phase-in period was necessary.

OSHA received many comments and heard testimony regarding the effective dates which are discussed in detail in Section XIII below. First, after analysis of the record, the Agency has determined that covered employers must complete all training regarding the new label elements and SDS format by December 1, 2013 since, as supported by record, employees will begin seeing the new style labels considerably earlier than the compliance date for labeling. Second, OSHA is requiring compliance with all of the provisions for preparation of new labels and safety data sheets by June 1, 2015. However, distributors will have an additional six months (by December 1, 2015) to distribute containers with manufacturers' labels in order to accommodate those they receive very close to the compliance date. Employers will also be given an additional year (by June 1, 2016) to update their hazard communication programs or any other workplace signs, if applicable.

Additionally, OSHA has decided not to phase in compliance based on whether a product is a substance or a mixture. OSHA has concluded that adequate information is available for classifiers to use to classify substances and mixtures. Finally, as discussed in the NPRM, employers will be considered to be in compliance with the HCS during the transition period as long as they are complying with either the existing HCS (as it appears in the CFR as of October 1, 2011) or this revised HCS. A detailed discussion regarding the effective dates is in Section XIII.

5. Alternatives of Mandatory Implementation

In the NPRM, OSHA proposed several alternatives to mandatory implementation of the GHS in response to concerns raised by commenters through the ANPR (74 FR at 50289). Commenters generally supported the concept of adopting the GHS as it was proposed. However, a few commenters indicated that they were concerned with what they saw as the cost burden on small businesses that are not involved in international trade. To address these concerns, OSHA solicited comments in the NPRM on several options proposed by the Agency regarding alternatives to mandatory harmonization. The following is a discussion of these alternatives; the potential impact and the response from participants in the rulemaking regarding the relative benefit, feasibility, impact on small business; and the impact on worker safety and health.

The first alternative OSHA proposed was to facilitate voluntary adoption of GHS within the existing HCS framework, and give manufacturers and importers the option to use the current HCS or the GHS system. This option would have permitted companies to decide whether they wanted to comply with the existing standard or with the GHS. A variation of this alternative was also proposed that would have adopted the GHS with an exemption allowing small chemical producers to continue to use the HCS, even after this GHS-modified HCS is promulgated.

The second alternative was a limited adoption of specific GHS components. Under this approach, producers could either comply with the GHS or a modified HCS that would retain the current HCS hazard categories, but require standardized hazard statements, signal words, and precautionary statements. A variation of this alternative would have omitted mandatory precautionary statements.

Commenters almost universally objected to both of the alternatives listed above (Document ID #0324, 0328, 0329, 0330, 0335, 0338, 0339, 0341, 0344, 0351, 0352, 0355, 0365, 0370, 0377, 0381, 0382, 0385, 0387, 0389, 0393, 0495, 0403, 0404, and 0412). American Industrial Hygiene Association (AIHA), in a representative comment, stated that ''permitting voluntary use of some of the system * * * or exempting certain sectors based on business size or other criteria [would] defeat the purpose of revising this standard and of the GHS'' (Document ID #0365). Additionally, the

Compressed Gas Association stated they ''would not support any alternative approach as it would defeat the goal of global hazard communication coordination'' (Document ID #0324).

Many commenters argued that a dual system that permitted businesses to opt out of complying with the GHS would undermine the key benefits of implementation. For example, Ferro Corporation stated that ''for GHS to be effective and efficient in the U.S., implementation should be consistent and congruent'' (Document ID #0363). DuPont Company argued ''dual systems would be confusing for employers'' (Document ID #0329). ORC also rejected voluntary implementation, reasoning that ''consistent requirements for all manufacturers and importers of chemicals [are] needed to maximized efficiency in the chemical supply chain'' (Document ID #0370). Additionally, the AFL–CIO cited consistent hazard information for workers and employers as the core objective of this rulemaking (Document ID #0340).

The commenters who supported GHS as proposed indicated that consistency was an essential aspect of this rule. Stericycle, Inc., stated that SDSs which ''do not follow a consistent format would cause issues in understanding and implementing the controls to limit exposure and protect employee safety and health,'' and argued that exemptions from GHS requirements would ''shift the burden from the chemical industry to all employers'' (Document ID #0338). Additionally, commenters did not support exempting small businesses from adopting the GHS. Ecolab argued that ''large and small businesses use each others' products'' and are inextricably linked, and they indicated that voluntary adoption ''could cause confusion about product hazards if two identical products are labeled differently due solely to the size of the business from which [they are] obtained'' (Document ID #0351).

OSHA agrees that the first alternative is unworkable as even one business's adoption of one of the alternatives would affect other companies. As stated in the comments above, if small businesses do not adopt the GHS, then large businesses or distributors will either have to generate GHS classifications for chemicals purchased, or request that small businesses supply data and labels using GHS classifications. Likewise, chemical producers often provide their products to distributors who then sell them to customers who are unknown to the original producer. This would lead to a plethora of product labels, a situation that is bound to make hazard communication far more difficult.

Commenters specifically cited issues with safety as their basis for rejecting the first proposed alternative. The AIHA (Document ID #0365) stated:

> If employers and employees cannot have confidence that labels and MSDSs provide a consistent safety message superficial standardization will not improve safety. Safety is also seriously compromised if different hazard communication systems are present in the work area. Effective training is not possible if pictograms and hazard statements are not used in a consistent manner * * *. All of the approaches discussed will create competitive pressures that can affect classification decisions and make good and consistent hazard communication more difficult.

North American Metal Council argued that the alternative would penalize workers of small business, and asserted that a ''worker's right to know about chemical hazards, should not depend on the source of a chemical or the size of the worker's employer'' (Document ID #0337).

Moreover, commenters asserted that the benefits derived from the harmonized labeling of chemicals would be significantly diluted if employers were not uniformly required to adopt the GHS. United Steel Workers Union aptly reiterated that the primary benefit of adopting the GHS is not the facilitation of international trade, but rather is the protection of workers, which is ''best accomplished through a uniform system of classification leading to comprehensible hazard information'' (Document ID #0403). (*See also* Document ID #0339, 0351, 0376, 0377, 0382, and 0412.)

Several commenters supported the voluntary adoption of the GHS (Document ID #0355, 0389, and 0502). For example, Intercontinental Chemical Corporation supported voluntary adoption for companies not involved in international trade (Document ID #0502). Additionally, Betco supported allowing ''small businesses that market domestically'' to retain the current HCS and suggested that ''voluntary adoption would not be any less protective for employees or create confusion'' (Document ID #0389).

OSHA acknowledges that small chemical manufacturers will have some burdens associated with the adoption of GHS. However, employees who use products produced by small employers are entitled to the same protections as those who use products produced by companies engaged in international trade. The confusion created by two or more competing systems would undermine the consistency of hazard communication achievable by a GHS-modified HCS. Moreover, whether or not a product will wind up in international trade may not be known to the manufacturer or even the first distributer. A producer may provide a chemical to another company, which then formulates it into a product that is sold internationally. Thus, the original producer is involved in international trade without necessarily realizing it. For these reasons, OSHA has determined that, in order to achieve a national, consistent standard, all businesses must be required to adhere to the revised HCS.

OSHA concludes that the rulemaking record does not support adoption of the first alternative. The majority of private industry, unions, and professional organizations did not support this approach, arguing persuasively that piecemeal adoption would undermine the benefits of harmonization. As discussed above, while improvements to international trade are a benefit of this rulemaking; they are not the primarily intended benefit. OSHA believes that implementation of the GHS, without exceptions based on industry or business size, will enhance worker safety through providing consistent hazard communication and, consequently, safe practices in the workplace. However, as indicated above, OSHA does recognize that there are burdens with any change and as discussed in Section XIII, OSHA will use the input OSHA has received to the record to develop an outreach plan for additional guidance.

The second alternative, a halfway measure allowing businesses to adopt some of the features of a GHS-modified HCS but not requiring adoption of others, drew little interest or comment from the participants. OSHA has concluded that this alternative, which would have led to even more inconsistencies in hazard communication, is not a viable alternative. OSHA's conclusion is supported by the overwhelming number of commenters who spoke out against the first option and strongly supported the proposed standard. Allowing employers to adopt, say, only the provisions for the labels or safety data sheets will result in inconsistent use of the standardized hazard statement, signal word, and precautionary statement without clear direction on when they would be required, a situation that is sure to compromise safety in the workplace. Therefore, OSHA has concluded that implementation of the GHS is also preferable to the second alternative.

Pursuant to its analysis of the entire rulemaking record, OSHA has decided to adopt the GHS as proposed and is not incorporating any of the alternatives into this final rule. The adoption of any of the alternatives would undermine the key benefits associated with the GHS. OSHA has concluded, as discussed in Section V, that the adoption of GHS as proposed will strengthen and refine OSHA's hazard communication system, leading to safer workplaces.

IV. Need and Support for the Modifications to the Hazard Communication Standard

Chemical exposure can cause or contribute to many serious adverse health effects such as cancer, sterility, heart disease, lung damage, and burns. Some chemicals are also physical hazards and have the potential to cause fires, explosions, and other dangerous incidents. It is critically important that employees and employers are apprised of the hazards of chemicals that are used in the workplace, as well as the associated protective measures. This knowledge is needed to understand the precautions necessary for safe handling and use, to recognize signs and symptoms of adverse health effects related to exposure when they do occur, and to identify appropriate measures to be taken in an emergency.

OSHA established the need for disclosure of chemical hazard information when the Hazard Communication Standard (HCS) was issued in 1983 (48 FR 53282–53284, Nov. 25, 1983). As noted in the NPRM (74 FR 50291, Sept. 30, 2009), this need continues to exist. The Agency estimates that 880,000 hazardous chemicals are currently used in the U.S., and over 40 million employees are now potentially exposed to hazardous chemicals in over 5 million workplaces. During the September 29, 2009, press conference announcing the publication of the HCS NPRM, Deputy Assistant Secretary of Labor for Occupational Safety and Health, Jordan Barab, discussed the impact that the HCS has had on reducing injury and illness rates. Mr. Barab stated that, since the HCS's original promulgation in 1983, ''OSHA estimates that chemically-related acute injuries and illness [have] dropped at least 42%.'' Reiterating information from OSHA's preliminary economic analysis in the NPRM, Mr. Barab also stated:

> [T]here are still workers falling ill or dying from exposure to hazardous chemicals. OSHA estimates, based on BLS data, that more than 50,000 workers became ill and 125 workers died due to acute chemical exposure in 2007. These numbers are dwarfed by chronic illnesses and fatalities that are estimated in the tens of thousands.
>
> OSHA believes that aligning the Hazard Communication Standard with the provisions of the GHS will improve the effectiveness of the standard and help to substantially improve worker safety and health. The GHS will provide a common system for classifying chemicals according to their health and physical hazards and it will specify hazard communication elements for labeling and safety data sheets.

Data collected and analyzed by the Agency also reflect this critical need to improve hazard communication. Chemical exposures result in a substantial number of serious injuries and illnesses among exposed employees. The Bureau of Labor Statistics estimates that employees suffered 55,400 illnesses that could be attributed to chemical exposures in 2007, the latest year for which data are available (BLS, 2008). In that same year, 17,340 chemical-source injuries and illnesses involved days away from work (BLS, 2009).

The BLS data, however, do not indicate the full extent of the problem, particularly with regard to illnesses. As noted in the preamble to the HCS in 1983, BLS figures probably only reflect a small percentage of the incidents occurring in exposed employees (48 FR 53284, Nov. 25, 1983). Many occupational illnesses are not reported because they are not recognized as being related to workplace exposures, are subject to long latency periods between exposure and the manifestation of disease, and other factors (*e.g.,* Herbert and Landrigan, 2000, Document ID #0299; Leigh *et al.,* 1997, Document ID #0274; Landrigan and Markowitz, 1989, Document ID #0299).

While the current HCS serves to ensure that information concerning chemical hazards and associated protective measures is provided to employers and employees, the Agency has determined that the revisions adopted in this final rule will substantially improve the quality and consistency of the required information. OSHA believes these revisions to the HCS, which align it with the GHS, will enhance workplace protections significantly. Better information will enable employers and employees to increase their recognition and knowledge of chemical hazards and take measures that will reduce the number and severity of chemical-related injuries and illnesses.

A key foundation underlying this belief relates to the comprehensibility of information conveyed under the GHS. All hazard communication systems deal with complicated scientific information being transmitted to largely non-technical audiences. During the development of the GHS, in order to construct the most effective hazard communication system, information about and experiences with existing systems were sought to help ensure that the best approaches would be used. Ensuring the comprehensibility of the GHS was a key principle during its development. As noted in a **Federal Register** notice published by the U.S. Department of State (62 FR 15956, April 3, 1997): ''A major concern is to ensure that the requirements of the globally harmonized system address issues related to the comprehensibility of the information conveyed.'' This concern is also reflected in the principles of harmonization that were used to guide the negotiations and discussions during the development of the GHS. As described in Section 1.1.1.6(g) of the GHS, the principles included the following: ''[T]he comprehension of chemical hazard information, by the target audience, *e.g.,* workers, consumers and the general public should be addressed.''

As was discussed in the proposal (74 FR 50291), to help in the development of the GHS, OSHA had a review of the literature conducted to identify studies on effective hazard communication, and made the review and the analysis of the studies available to other participants in the GHS process. One such study, prepared by researchers at the University of Maryland, entitled ''Hazard Communication: A Review of the Science Underpinning the Art of Communication for Health and Safety'' (Sattler *et al.,* 1997, Document ID #0191) has also long been available to the public on OSHA's Hazard Communication web page. Additionally, OSHA conducted an updated review of the literature published since the 1997 review. This updated review examined the literature relevant to specific hazard communication provisions of the GHS (ERG, 2007, Document ID #0246).

Further work related to comprehensibility was conducted during the GHS negotiations by researchers in South Africa at the University of Cape Town—the result is an annex to the GHS on comprehensibility testing (*See* GHS Annex 6, Comprehensibility Testing Methodology) (United Nations, 2007, Document ID #0194). Such testing has been conducted in some of the developing countries preparing to implement the GHS, and has provided these countries with information about which areas in the GHS will require more training in their programs to ensure people understand the information. The primary purpose of these activities was to ensure that the system developed was designed in such a way that the messages would be effectively conveyed to the target audiences, with the knowledge that the system would be implemented internationally in different cultures with varying interests and concerns.

Another principle that was established to guide development of the GHS was the agreement that levels of protection offered by an existing hazard communication system should not be reduced as a result of harmonization. Following these principles, the best aspects of existing systems were identified and included in a single, harmonized approach to classification, labeling, and development of SDSs.

The GHS was developed by a large group of experts representing a variety of perspectives. Over 200 experts provided technical input on the project. The United Nations Sub-Committee of Experts on the GHS, the body that formally adopted the GHS and is now responsible for its maintenance, includes 35 member nations as well as 14 observer nations. Authorities from these member states are able to convey the insight and understanding acquired by regulatory authorities in different sectors, and to relate their own experiences in implementation of hazard communication requirements. In addition, over two dozen international and intergovernmental organizations, trade associations, and unions are represented, and their expertise serves to inform the member nations. The GHS consequently represents a consensus recommendation of experts with regard to best practices for effective chemical hazard communication, reflecting the collective knowledge and experience of regulatory authorities in many nations and in different regulatory sectors, as well as other organizations that have expertise in this area.

United States-based scientific and professional associations have endorsed adoption of the GHS since publication of the Advance Notice of Proposed Rulemaking (ANPR) in 2006 (71 FR 53617, Sept. 12, 2006). For example, the American Chemical Society (ACS) indicated its support for the GHS, stating: ''The American Chemical Society strongly supports the adoption of the GHS for hazard communication in general and specifically as outlined in the ANPR'' adding that ''* * * ACS anticipates that OSHA implementation of GHS in the U.S. will enhance protection of human health and the environment through warnings and precautionary language that are consistent across different products and materials as well as across all workplaces'' (Document ID #0165). The American Industrial Hygiene Association (AIHA) affirmed its support for modification of the HCS to adopt the GHS. AIHA maintained that standardized labels and safety data sheets will make hazard information easier to use, thereby improving protection of employees (Document ID #0034). While acknowledging that the GHS presents a number of concerns and challenges, the Society of Toxicology has also expressed its support for the GHS, stating that ''a globally harmonized system for the classification of chemicals is an important step toward creating consistent communications about the hazards of chemicals used around the world'' (Document ID #0304). The American Association of Occupational Health Nurses joined these organizations in advocating adoption of the GHS, arguing that standardization of chemical hazard information is critical to protecting the safety and health of employees (Document ID # 0099). Responders to the 2009 NPRM reiterated their support or, in the case of new commenters, echoed the comments from other scientific and professional associations to the ANPR (*See, e.g.,* Document ID #0338, 0357, 0365, 0393, and 0410). The positions taken by these organizations point to wide support for the GHS among the scientific and professional communities.

Stakeholders representing a wide range of sectors and interests agreed with OSHA that aligning the HCS with the GHS will improve comprehensibility, and thus lead to reductions in chemical source illnesses and injuries. American Society of Safety Engineers, Dow Chemical, and ORC all voiced their support for the proposed rule, citing improved comprehensibility and quality of transmitted information as key benefits (Document ID #0336, 0353, and 0370). Representing union labor, the American Federation of State, County and Municipal Employees (AFSCME) stated that this rulemaking would ''allow critical communication about the hazards of chemicals to be understood by all workers, regardless of their literacy level or primary language * * * [and] will in turn lead to safer, more productive workplaces'' (Document ID #0414). Many stakeholders asserted that adopting the GHS would lead to safer workplaces. The Chamber of Commerce provided its support for the rulemaking, stating that the GHS could ''improve worker safety, and facilitate business growth and international trade'' (Document ID #0397). The American Subcontractors Association, Inc. added that consistent hazard communication is critical to having a safe work program (Document ID #0322). Additionally, North American Metals Council (NAMC), which represents the interests of the metals and mining industry, stated that a single, globally harmonized classification and labeling system is of vital interest to its members (Document ID #0233). The position that GHS would increase worker protection was also raised in testimony during the hearings. Elizabeth Treanor of Phylmar Regulatory Roundtable testified that adopting the GHS would ''enhance the effectiveness of the hazard communication standard by improving the quality and consistency of chemical hazard information that is provided to employees and employers'' (Document ID #0497 Tr. 92).

In addition to the endorsement of the GHS by a group of experts with extensive knowledge and experience in chemical hazard communication, support from scientific and professional associations with expertise in this area, and support from industry and labor stakeholders, a substantial body of evidence indicates that the modifications to the HCS will better protect employees. Specifically, this evidence supports OSHA's findings that: (1) Standardized label elements—signal words, pictograms, hazard statements and precautionary statements—will be more effective in communicating hazard information; (2) standardized headings and a consistent order of information will improve the utility of SDSs; and (3) training will support and enhance the effectiveness of the new label and SDS requirements.

This evidence was obtained from sources predating the ANPR and from more recent data. OSHA commissioned several studies to examine the quality of information on SDSs (Karstadt, 1988, Document ID #0296; Kearney/Centaur 1991a, 1991b, Document ID #0309 and 0310; Lexington Group, 1999, Document ID #0257); the General Accounting Office (GAO) has issued two reports based on its evaluation of certain aspects of the HCS (GAO 1991 and 1992, Document ID #0271 and 0272); a National Advisory Committee on Occupational Safety and Health (NACOSH) workgroup conducted a review of hazard communication and published a report of its findings (NACOSH, 1996, Document ID #0260); and a substantial amount of scientific literature relating to hazard communication has been published. As mentioned previously, OSHA commissioned a review of the literature, and a report based on that review was published in 1997 (Sattler *et al.,* 1997, Document ID #0191). An updated review was conducted in 2007 (ERG, 2007, Document ID #0246). In addition, OSHA conducted a review of the requirements of the HCS and published its findings in March of 2004 (OSHA, 2004, Document ID #0224). Key findings derived from these sources are discussed below.

No commenters questioned the validity of studies presented in the NPRM. Similarly, commenters did not question OSHA's analysis or interpretation of the study findings. Only one commenter suggested that OSHA should adopt more ''conservative expectations for the effects that warning format changes can have on the behavior of end users,'' adding that ''real-world conditions'' must be accounted for when determining the actual responses of users (Document ID #0396). However, the commenter did not disagree with OSHA's overall conclusion that this final rule would improve safety. OSHA agrees that external factors may influence the overall benefits of label elements (this will be addressed in Section VI).

The studies discussed in the NPRM formed the evidentiary basis for the revised HCS. As such, OSHA infers that commenters generally found the studies, as well as OSHA's analysis, to be sound. OSHA's rationale for adopting the GHS is tied to anticipated improvements in the quality and consistency of the information that would be provided to employers and employees. Hazard classification is the foundation for development of this improved information. Indeed, hazard classification is the procedure of identifying and evaluating available scientific evidence in order to determine if a chemical is hazardous, and the degree of hazard, pursuant to the criteria for health and physical hazards set forth in the standard. Hazard classification provides the basis for the hazard information that is provided in labels, SDSs, and employee training. As such, it is critically important that classification be performed accurately and consistently.

The GHS provides detailed scientific criteria to direct the evaluation process. The specificity and detail provided help ensure that different evaluators would reach the same conclusions when evaluating the same chemical. Moreover, the GHS refines the classification process by establishing categories of hazard within most hazard classes. These categories indicate the relative degree of hazard, and thereby provide a basis for determining precise hazard information that is tailored to the level of hazard posed by the chemical. The classification criteria established in the GHS thus provide the necessary basis for development of the specific, detailed hazard information that would enhance the protection of employees.

Labels

Labels serve as immediate visual reminders of chemical hazards, and complement the information presented in training and on SDSs. The current HCS requires that labels on hazardous chemical containers include the identity of the hazardous chemical; appropriate hazard warnings that convey the specific physical and health hazards, including target organ effects; and the name and address of the chemical manufacturer, importer, or other responsible party. The HCS does not specify a standard format or design elements for labels.

In the NPRM, OSHA proposed to improve the HCS by changing the performance requirements for labels to the GHS-specific requirements that labels include four standardized elements: a signal word; hazard statement(s); pictogram(s); and precautionary statement(s) (*See* Section XV for a detailed discussion of the requirements). The appropriate label elements for a chemical are to be determined by the hazard classification. OSHA has concluded that these standardized label elements better convey critically important hazard warnings, and provide useful information regarding precautionary measures that will serve to better protect employees than the performance-oriented approach of the current rule.

This requirement is different from the current HCS in that it will require consistent and detailed information regarding a chemical based on the hazard classification. The current rule does not specify a standard format or design elements for labels. Rather, all that is required in the current HCS is that the label of the hazardous chemical containers include the identity of the hazardous chemical; appropriate hazard warnings that convey the specific physical and health hazards, including target organ effects; and the name and address of the chemical manufacturer, importer, or other responsible party.

Additionally, as discussed in the proposal (74 FR 50291, Sept. 30, 2009), a great deal of literature has been developed that examines the effectiveness of warnings on labels. These studies support OSHA's adoption of standardized warnings on the labels of hazardous chemicals. Although the studies discussed below pertain to prescription and non-prescription medications, alcoholic beverages, or consumer products rather than hazardous chemicals, it does not diminish the importance or relevance of the data. This literature provides a substantial body of information directly applicable and analogous to workplace chemical labels. In spite of the differences in affected populations, workplace chemical labels have many characteristics that are comparable to those found in other sectors. Pharmaceutical labels, for example, are similar to chemical labels in that they often have explicit instructions for use which, if not followed, can cause adverse health effects or death. Designers of pharmaceutical labels also encounter many of the same challenges faced by those who design chemical labels, such as container space limitations and the need to convey information to low-literate or non-English-literate users. In addition, some of the research is not directly related to any particular sector or type of product. Some findings related to use of color, for example, could reasonably be applied to a wide variety of label applications. The studies are discussed below in the specific labeling sections.

Signal Words

A signal word is a word that typically appears near the top of a warning, sometimes in all capital letters. Common examples include DANGER, WARNING, CAUTION, and NOTICE. The signal word is generally understood to serve a dual purpose: Alerting the user to a hazard and indicating a particular level of hazard. For example, users generally perceive the word DEADLY to indicate a far greater degree of hazard than a term like NOTICE.

This final rule requires the use of one of two signal words for labels—DANGER or WARNING—depending on the hazard classification of the substance in question. These are the same two signal words used in the GHS. DANGER is used for the more severe hazard categories, while WARNING denotes a less serious hazard. These signal words are similar to those in other established hazard communication systems, except that some other systems have three or more tiers. For example, ANSI Z129.1 (the American National Standard for Hazardous Industrial Chemicals—Precautionary Labeling) uses DANGER, WARNING, and CAUTION, in descending order of severity (ANSI, 2006, Document ID #0280).

A number of studies have examined how people perceive signal words and, in particular, how they perceive signal words to be different from one another. Overall, this research supports the use of signal words on labels, demonstrating that they can attract attention and help people clearly distinguish between levels of hazard. The research also supports the decision to use only two tiers, as many recent studies have found clear differences between DANGER and WARNING, but little perceived difference between WARNING and CAUTION.

Wogalter *et al.* investigated the influence of signal words on perceptions of hazard for consumer products (Wogalter *et al.,* 1992, Document ID #0300). Under the pretext of a marketing research study, 90 high school and college students rated product labels on variables such as product familiarity, frequency of use, and perceived hazard. Results showed that the presence of a signal word increased perceived hazard compared to its absence. Between extreme terms (*e.g.,* NOTE and DANGER), significant differences were noted.

Seeking to test warning signs in realistic settings, Adams *et al.* tested five industrial warning signs on a group of 40 blue-collar workers employed in heavy industry, as well as a group of students (Adams *et al.,* 1998, Document ID #0235). Signs were manipulated to include four key elements (signal word, hazard statement, consequences statement, and instructions statement) or a subset of those elements. Participants were asked questions to gauge their reaction and behavioral intentions. Overall, 77 percent (66 percent of the worker group) recognized DANGER as the key word when it appeared, and more than 80 percent recognized BEWARE and CAUTION, suggesting that the signal word was generally noticed, and it was recognized as the key alerting element. DANGER was significantly more likely than other words to influence behavioral intentions.

Laughery *et al.* also demonstrated the usefulness of signal words. The authors tested the warnings on alcoholic beverage containers in the U.S., and found that a signal word (WARNING) was one of several factors that decreased the amount of time it took for participants to locate the warning (Laughery *et al.,* 1993, Document ID #0281).

Several studies have tested the arousal strength or perceived hazard of different signal words. *Arousal strength* is a term used to indicate the overall importance of the warning, and incorporates both the likelihood and severity of the potential threat. Silver and Wogalter tested the arousal strength of signal words on college students and found that DANGER connoted greater strength than WARNING and CAUTION (Silver and Wogalter, 1993, Document ID #0308). The results failed to show a difference between WARNING and CAUTION. Among other words tested, DEADLY was seen as having the strongest arousal connotation, and NOTE the least.

Griffith and Leonard asked 80 female undergraduates (who were unlikely to have already received industrial safety training) to rate signal words. Results included a list of terms in order of ''meaningfulness,'' representing conceptual ''distance'' from the neutral term NOTICE (Griffith and Leonard, 1997, Document ID #0250). From most to least meaningful, these terms were reported to be DANGER, URGENT, BEWARE, WARNING, STOP, CAUTION, and IMPORTANT.

Wogalter *et al.* asked over 100 undergraduates and community volunteers to rank signal words (Wogalter *et al.,* 1998, Document ID #0286). DEADLY was perceived as most hazardous, followed by DANGER, WARNING, and CAUTION. All differences were statistically significant. In a follow-up experiment using labels produced in the ANSI Z535.2 (American National Standard for Environmental and Facility Safety Signs), ANSI Z535.4 (American National Standard for Product Safety Signs and Labels), and alternative formats, the authors found a similar rank order for signal words with all labeling systems. Finally, the authors tested the same terms on employees from manufacturing and assembly plants and found the same general order: DEADLY, then DANGER, then WARNING and CAUTION with no significant difference between the last two terms.

In more of a free-form experiment, Young asked 30 subjects to produce warning signs for a set of scenarios, using different sign components available on a computer screen (Young, 1998, Document ID #0289). In roughly 80 percent of the signs, the participant chose to use a signal word. DANGER, DEADLY, and LETHAL were more likely to be used for scenarios with severe hazards; CAUTION and NOTICE for non-severe scenarios. WARNING was used equally in both types of scenarios. The author suggests that these results support a two-tiered system of signal words. In a separate task, users ranked the perceived hazard of signal words, resulting in the following list from most to least severe: DEADLY, LETHAL, DANGER, WARNING, CAUTION, and NOTICE.

While these studies have focused on the relative perceptions of signal words, others have sought to evaluate how the absolute meaning of common signal words is perceived. Drake *et al.* asked a group of students and community volunteers to match signal words with definitions borrowed from consensus standards and other sources (Drake *et al.,* 1998, Document ID #0244). Participants matched DANGER to a correct definition 64 percent of the time, while NOTICE was matched correctly 68 percent of the time. WARNING and CAUTION were matched correctly less than half of the time, suggesting confusion. The authors recommended using WARNING and CAUTION interchangeably. The authors also suggested that a standard set of signal words (but not synonyms) is helpful for users with limited English skills, who can be trained to recognize a few key words.

Signal word perceptions are reported to be consistent among some non-U.S. populations, as well. Hellier *et al.* asked 984 adults in the UK to rate DANGER, WARNING, and CAUTION on a hazard scale from 1 (low) to 10 (high) (Hellier *et al.,* 2000a, Document ID #0252). DANGER was ranked as 8.5, WARNING was ranked as 7.8, while CAUTION was rated as 7.25. These results are consistent with the findings of studies on subjects in the U.S. In a second study published in 2000, Hellier *et al.* asked a mixed-age group of participants in the UK to rate the arousal strength of 84 signal words commonly used in the U.S. (Hellier *et al.,* 2000b, Document ID #0253). The authors found that DANGER is stronger than WARNING, while WARNING and CAUTION are not significantly different from each other.

Similar results were found among workers in Zambia. Banda and Sichilongo tested GHS-style labels using four different signal words (as well as other variables) (Banda and Sichilongo, 2006, Document ID #0237). Among workers in the industrial and transport sectors, DANGER was generally perceived as the most hazardous signal word. WARNING was one of a group of terms that were largely indistinguishable from one another, but distinct from DANGER. The authors support adoption of the GHS, suggesting that having just two possible signal words will lead to ''more impact and less confusion about the extent of hazard.''

In addition, comparable results were found in South Africa (London, 2003, Document ID #0311). In a large study on SDS and label comprehensibility conducted for South Africa's National Economic Development and Labour

Council (NEDLAC), DANGER was generally ranked as more hazardous than WARNING by participants in the four sectors tested: industry, transport, agriculture, and consumers.

Cumulatively, these studies provide a clear indication that signal words are effective in alerting readers that a hazard exists, and in conveying the existence of a particular level of hazard. The studies found a generally consistent hierarchy of signal words with respect to perceived hazard. DANGER and WARNING appear to connote different levels of hazard, while the perceived difference between WARNING and CAUTION is often insignificant.

In response to the NPRM, OSHA received a comment from Croplife America about the impact of using a two-tiered signal word system on pesticide labels (Document ID #0387). Croplife America explained that they believe a three-tiered system (DANGER, WARNING and CAUTION) provides ''a little more distinction in the relative toxicity of a compound'' and ''if everything says 'warning,' we run the risk of diluting the effectiveness of the signal word'' (Document ID #0495 Tr. 251). During the informal public hearings, OSHA requested that Croplife America support their position on why a three-tiered warning system is better than a two-tiered system. To support this assertion, Croplife America submitted a late comment containing an additional paper by Hellier *et al.* which analyzed how signal words are interpreted (Hellier *et al.,* 2007, Document ID #0646).

This paper discusses two studies performed in 2007 to analyze if alternative information is communicated with signal words (Hellier *et al.,* 2007, Document ID #0646). Using 17 signal words, 30 undergraduate students were asked to rate the similarities of paired signal words. In the first study, the result ratings revealed that signal words were interpreted by the participants along three dimensions; dimension one: the level of hazard implied by the signal words, dimension two: the extent to which they explicitly implied a risk, and dimension three': the clarity of the instruction given by the signal word. Using the same signal words as in the first study, the second study explored how these signal words were interpreted by the study participants. Using statistical analysis, the analysis confirmed that the participants were able to discern the levels of hazard implied by the signal words and how it to relates to the explicitness of the implied risk (dimensions one and two). The results of the third dimension were unclear. The studies indicate that the extent to which signal words imply risk is important—people may not respond when repeatedly exposed to warnings that do not explicitly imply a risk. The results support using signal words to denote the level of hazard implied by the situation, and that there might be utility in using signal words to convey both information about a potential risk and the level of hazard.

Even if it had been timely submitted, OSHA is not convinced that this study supplies sufficient evidence that using a two-tiered signal word approach will diminish the chemical user's ability to distinguish hazard severity. In OSHA's opinion, if anything, the Hellier study provides additional support for the use of signal words on labels to attract attention and to identify levels of hazard. Indeed, its results show that the signal word ''caution'' was substantially less connected by participants with communicating hazards than ''warning'' and ''danger,'' which supports OSHA's decision not to use ''caution'' as a signal word. The record supports OSHA's determination that using the signal word in combination with the hazard statement alerts the chemical user to the hazard and allows him or her to distinguish the level of hazard severity posed by hazardous chemicals in the workplace.

Commenting on the studies presented in the proposal, Applied Safety and Ergonomics (ASE) agreed that there are benefits associated with the standardization of warning elements. However, they also urged ''OSHA to adopt more conservative expectations for the effect that warning format changes can have on the behavior of end users'' (Document ID #0396). *See* Section VI of this final rule for a detailed discussion of the benefits of standardized warning elements. OSHA does not disagree with these comments and has determined that requiring the use of the combined labeling elements (pictograms, signal words, hazard statements, and precautionary statements) will result in a uniform and consistent system of identifying and communicating chemical hazards in the workplace. No other comments were received on the studies OSHA used in its discussion of the need for signal words in this revised HCS.

Comments received from stakeholders support the revision of the HCS to include the use of standardized signal words (Document ID #0321, 0338, 0339, and 0349). For example, the Communications Workers of America (CWA) stated: ''Clearly, the Rule's requirements regarding revised SDSs and labeling provisions requiring the use of standardized signal words, pictograms, and hazard and precautionary statements would prove invaluable to affected CWA members whom have been exposed to hazardous chemicals and chemical products that have produced negative health effects and medical problems'' (Document ID #0349). These comments support OSHA's conclusion that signal words alert chemical users to a hazard and indicate a particular level of hazard.

After reviewing the comments received and the evidence presented in the record, OSHA has determined that, in this revised rule, use of the signal words ''DANGER'' and ''WARNING'' is appropriate.

Pictograms

A pictogram is a graphical composition that may include a symbol along with other graphical elements, such as a border or background color. A pictogram is a communication tool and is intended to convey specific information. The proposed rule included requirements for use of eight different pictograms. Each of these pictograms consists of a different symbol in black on a white background within a red square frame set on a point (*i.e.,* a red diamond). The specific pictograms on a label were to be determined based on the hazard classification of the substance in question. OSHA has found ample evidence to support the requirement for pictograms.

A study by Kalsher *et al.* reported that users preferred labels with pictorials. The authors concluded that pictorials focused the attention of the user, helped users who were unable to read the small font size or print on the labels, and were useful for individuals who did not understand English (Kalsher *et al.,* 1996, Document ID #0256). The presence of the symbol can attract attention to the warnings and are more memorable than written warnings (Parsons *et al.,* 1999, Document ID #0262). Symbols serve several important functions in warning labels. As Wogalter *et al.* explained (Wogalter *et al.,* 2006, Document ID #0275), symbols may alert the user to a hazard more effectively than text alone:

> Symbols may be more salient than text because of visual differentiations of shape, size, and color. Usually symbols have unique details and possess more differences in appearance than do the letters of the alphabet. Letters are highly familiar and are more similar to one another than most graphical symbols.

Other investigators have examined the benefits of pictograms for those with low literacy levels and those who do not understand the language in which the label text is written. A study by Parsons *et al.* concluded that nonverbal graphics are especially helpful for ensuring that individuals, who do not speak English or who have limited understanding of English, understand the meaning of the intended warning (Parsons *et al.,* 1999, Document ID #0262). Another study has shown that people with low literacy skills can, with the help of pictographs, recall large amounts of medical information over significant periods of time (Houts *et al.,* 2001, Documents ID #0254).

Several researchers have sought to evaluate how people comprehend symbols, including the symbols that were proposed to be required. Several studies have found that the skull and crossbones icon—one of the symbols proposed and included in the final rule—is among the most recognizable of safety symbols. For example, Wogalter *et al.* asked 112 undergraduates and community volunteers to rank various label elements (Wogalter *et al.,* 1998, Document ID #0244). Among shapes and icons, the skull symbol (in this case, without the crossbones) was rated most hazardous and most noticeable. The skull connoted the greatest hazard among industrial employees as well. Smith-Jackson and Wogalter asked 48 English-speaking workers to rate the perceived hazards of six alerting symbols (Smith-Jackson and Wogalter, 2000, Document ID #0196). The skull was rated significantly higher than all other symbols.

Several studies have examined other pictograms included in the final rule. As part of an experiment to see how individuals comprehend warnings on household chemical labels, Akerboom and Trommelen asked 60 university students whether they understood the meaning of several pictograms, including four that are included in the final rule (Akerboom and Trommelen, 1998, Document ID #0236). The authors reported the following levels of comprehension for these pictograms:

▪ Flame: 93 percent comprehension;
▪ Skull and crossbones: 85 percent comprehension;
▪ Corrosion: 20 percent comprehension; and
▪ Flame over circle: 13 percent comprehension.

Only the flame and skull and crossbones pictograms met the 85 percent comprehension criteria suggested by ANSI Z535.3 (the American National Standard Criteria for Safety Symbols) (ANSI, 2002a, Document ID #0276). The authors recommend that labels present the hazard phrase [statement] and symbol together, along with corresponding precautions, as has been included as a requirement in the final rule.

Banda and Sichilongo tested comprehension of labels among 364 workers in four sectors in Zambia (transport, agriculture, industrial, and household consumers) (Banda and Sichilongo, 2006, Document ID #0237). Within this population, the skull and crossbones symbol was widely understood, as was the ''flame'' symbol. Based on these results, the authors suggest a preference for symbols that depict familiar, meaningful, and recognizable images.

London performed a similar study among the same four sectors in South Africa, finding that the skull and crossbones was understood by at least 96 percent of each sector and ''flame'' by at least 89 percent (London, 2003, Document ID #0311). ''Exploding bomb'' was correctly comprehended by 44 to 71 percent of each sector. On the other hand, many health-related symbols did not fare well, and six symbols had less than 50 percent comprehension across all four sectors. Outside the transport sector, ''Gas cylinder'' was the least comprehended symbol.

These findings indicate that some of the pictograms included in the final rule are already widely recognized by a general audience. Others, however, are not commonly understood. Therefore, simply adding some of the pictograms on labels will not provide useful information unless efforts are also undertaken to ensure that employees understand the meaning of the pictograms. As Wogalter *et al.* noted, some studies have found slower processing, poorer recognition, and greater learning difficulties with symbols versus with text—particularly if the symbols are complex or non-intuitive (Wogalter *et al.,* 2006, Document ID #0275). These results emphasize the need to train employees on the meaning of the pictograms that will be included on chemical labels.

Where pictograms are used and understood, communication of hazards can be improved. Houts *et al.* studied long-term recall of spoken medical instructions when accompanied by a handout with pictograms (Houts *et al.,* 2001, Document ID #0254). Nearly 200 pictograms were tested with 21 low-literate adults (less than grade 5 reading level). Immediately after training, participants recalled the meaning of 85 percent of the pictograms, and they recalled 71 percent after 4 weeks. This study found that recall was better for simple pictograms where there is a direct relationship between the image and its meaning—that is, where no inference is required.

Another body of literature focuses on the utility of symbols in general. Ganier found that people generally construct mental representations faster with pictures than they do with text, supporting earlier findings on the usefulness of symbols (Ganier, 2001, Document ID #0275). Evans *et al.* found similar results with a task in which undergraduates were asked to sort items into categories using either text clues, visual clues, or a combination of pictures and text (Evans *et al.,* 2002; Document ID #0192). When categories were fixed (*i.e.,* sorting instructions were specific), people sorted the cards more consistently with one another when presented with pictures than when presented with text alone.

In a follow-up article on the South African study mentioned previously, Dowse and Ehlers found that patients receiving antibiotics adhered to instructions much better when the instructions included pictograms—(54 percent with high adherence, versus 2 percent when given text-only instructions) (Dowse and Ehlers, 2005, Document ID #0243).

Pictograms also serve to attract attention to the hazard warnings on a label. To examine factors that influence the effectiveness of pharmaceutical labels, Kalsher *et al.* asked subjects to rate the noticeability, ease of reading, and overall appeal of labels with or without pictorials (Kalsher *et al.,* 1996, Document ID #0256). A group of 84 undergraduates gave consistently higher ratings to labels with pictorials. A group of elderly subjects had similar preferences, rating labels with pictorials as significantly more noticeable and likely to be read.

Laughery *et al.* found similar results with a timed test on alcoholic beverage labels (Laughery *et al.,* 1993, Document ID #0281). When a pictorial was present to the left of the warning showing what not to do when drinking, the amount of time it took to find the label was significantly reduced. An icon consisting of the alert symbol (an exclamation mark set within a triangle) and the signal word WARNING also decreased response time. The fastest response time came when four different enhancements (including the pictorial and the icon) were included. In a follow-up exercise, an eye scan test found that the pictorial had a particularly strong influence on reaction time, compared with other enhancements.

Where chemical labels are concerned, London found that symbols tend to be the most easily recalled label elements (London, 2003, Document ID #0311). In the comprehensibility test of labels among South African workers mentioned previously, symbols were the most commonly recalled elements—particularly the skull and crossbones—and people recalled looking at symbols first. Symbols were also cited as by far the most important factor in determining hazard perception. The author concludes that ''Symbols are therefore key to attracting attention and informing risk perception regarding a chemical'' (London, 2003, Document ID #0311).

Wogalter *et al.* found factors other than pictorials influenced workers (Wogalter *et al.,* 1993, Document ID #0285). The authors tested the influence of various warning variables on whether subjects wore proper protective equipment during a task involving measuring and mixing chemicals. Warning location and the amount of clutter around the warning had significant effects on compliance, but the presence or absence of pictorials did not.

Meingast asked subjects to recall warning content after viewing labels that were considered either high quality (with color signal icons, pictorials, and organized text conforming to ANSI Z535.4, the American National Standard for Product Safety Signs and Labels) or low quality (text only) (Meingast, 2001, Document ID #0210). Pictorials were the items remembered most often, accounting for 48 percent of what viewers of high-quality labels recalled. The author suggests that these pictorials also served the role of dual coding, meaning that they help to improve the retention of corresponding text.

Other studies support this dual-coding function of pictorials, finding that symbols tend to be most effective when paired with redundant or reinforcing text. For example, Sojourner and Wogalter asked 35 participants to rate several prescription label formats in terms of ease of reading, ease of understanding, overall effectiveness, likelihood of reading, overall preference, pictorial understanding, and how helpful pictorials are in helping to remember the instructions (Sojourner and Wogalter, 1997, Document ID #0288). The authors found that people prefer fully redundant text and pictorials, which they judged easiest to read, most effective, and preferred overall. Dual-coded pictorials aided understanding and memory more than labels with pictorials only (no text).

In a follow-up study, Sojourner and Wogalter gave undergraduates, young adults, and older adults a free recall test after viewing medication labels (Sojourner and Wogalter, 1998, Document ID #0288). Fully redundant text and pictorials led to significantly greater recall than other formats, and were rated most effective by all age groups.

Similarly, Sansgiry *et al.* found that pictograms on over-the-counter drug labels improved comprehension, but only when they were congruent with the corresponding text (Sansgiry *et al.,* 1997, Document ID #0264). The 96 adults who were tested were less confused, were more satisfied, were more certain about their knowledge, and understood more when shown labels that contained congruent pictures and verbal instructions, versus verbal instructions alone. The results were significantly better with congruent pictures and text than with either pictures alone or incongruent pictures and text.

Some evidence links use of pictograms directly to safer behavior. Jaynes and Boles investigated whether different warning designs, specifically those with symbols, affect compliance rates (Jaynes and Boles, 1990, Document ID #0290). Five conditions were tested: a verbal warning, a pictograph warning with a circle enclosing each graphic, a pictograph warning with a triangle on its vertex enclosing each graphic, a warning with both words and pictographs, and a control (no warning). Participants performed a chemistry laboratory task using a set of instructions that contained one of the five conditions. The warnings instructed them to wear safety goggles, mask, and gloves. All four warning conditions had significantly greater compliance than the no-warning condition. A significant effect was also found for the ''presence of pictographs'' variable, suggesting that the addition of pictographs will increase compliance rates.

NIOSH submitted an additional study at the informal public hearings that analyzed the use of pictograms on labels. In 1997, Wilkinson *et al.* (Document ID #0480.6), interviewed 206 farmers in Victoria Australia. Two widely used agricultural herbicides were used for the basis of the research. The researchers developed three ''mocked-up'' labels for each herbicide—one containing existing warning text, one containing existing text with pictograms of appropriate safety precautions, and one containing text with pictograms that had been tested for recognition and comprehension across a variety of cultures and literacy levels. The interviewees answered questions using a rating scale, which was subjected to a statistical analysis to determine the significance of the responses. The authors concluded that ''the labels with added pictograms were perceived by pesticide users as significantly easier to obtain information from than labels containing text only'' (Document ID #0480.6).

Stakeholders on the whole supported the inclusion of pictograms on the labels of hazardous substances. During the hearings, Chris Trahan of the AFL–CIO voiced support for including pictograms on the labels of hazardous chemicals, and cited construction workers as a group whose safety and health conditions would be greatly improved by OSHA's adoption of ''a system of symbols [workers] can then readily use to make decisions on a daily basis'' (Document ID #0494 Tr. 8).

As discussed in the proposal, a considerable amount of evidence shows that pictograms can serve as useful and effective communication tools. In the final rule, OSHA has decided to adopt the eight GHS pictograms initially proposed in the NPRM. Each of these pictograms consists of a different symbol in black on a white background within a red square frame set on a point (*i.e.,* a red diamond). The specific pictograms that are required on a particular label are to be determined based on the hazard classification of the substance in question.

OSHA finds, based on scores of supporting studies and persuasive testimony that the pictograms will make warnings on labels more noticeable and easier for employees to understand. In particular, symbols will improve comprehension among people with low literacy levels and those who are not literate in the English language. Moreover, pictograms will be used not only in conjunction with other label elements, but also in the context of the hazard communication program as a whole. Training that includes an explanation of labels (included in the final rule) will ensure that the pictograms are understood by employees.

Red Borders

GHS allows regulatory authorities the option of permitting black pictogram borders for labels on domestic products, and in the proposal OSHA requested comment on this issue. Mandating the use of red borders was supported by stakeholders, who argued persuasively that red borders would make labels more noticeable and would make the warnings appear to be more important (Document ID #0339, 0341, 0365, 0383, 0408, 0410, 0412, and 0456). The National Association of Chemical Distributers, in supporting the use of red borders, reasoned that they would be consistent with the overall goal of the

GHS (Document ID #0341). Additionally, the AIHA stated that requiring red borders would promote the safe use of chemicals (Document ID #0365).

Several commenters raised economic concerns, suggesting that because red ink is more expensive, the use of black borders should be permitted (Document ID #0318, 0328, 0370, 0377, 0382, 0393, and 0411). Dow Chemical, Troy Corporation, and several other commenters recommended that red borders should only be required on products that were being exported (Document ID #0352, 0353, 0399, 0405, and 0389). Similarly, API argued that in order to remain consistent with the GHS, OSHA should only require exported chemicals to have a red border (Document ID #0376).

OSHA finds this argument to be unpersuasive. In order to reap the benefits of consistency in warnings, labels must have a degree of sameness and that includes the colors used. Moreover, OSHA analyzed the impact that the use of red borders would have on production costs. While the use of red borders may increase the cost of printing, OSHA has determined that the cost does not render the rule infeasible. This issue is discussed in greater detail in Section VI. Finally, the GHS does not even state a preference for black borders on labels of domestic products; it simply gives the competent authority discretion to allow black borders when the product will not enter into international commence.

Numerous studies have found that substantial benefits exist when color is used on labels. Due to the extensive amount of information that needs to be displayed, warning labels can become cluttered. Swindell found that searching for needed information on a cluttered label is very challenging for the user (Swindell, 1999, Document ID #0284). Her study concluded that minor changes to an extensive warning label, such as the addition of color, can greatly improve the noticeability of the warning, grab the attention of the user faster, and produce quicker reaction times.

Swindell also researched the effect that different colors (red, blue, and black) had on the time it took users to locate and respond to a warning. Red was perceived to indicate the highest degree of hazard and was shown to increase the perceived hazard of a word presented in that color (*e.g.,* DANGER in blue is perceived as less hazardous than WARNING in red).

Swindell's findings echo the results reported by Laughery *et al.,* who found that alcoholic beverage labels were located significantly faster when the text was red instead of black (Laughery *et al.,* 1993, Document ID #0281). These studies involve color on label elements other than the pictogram borders, but the presence of color and the particular color is germane to the red borders of labels.

The primacy of red as an understandable color denoting danger is also supported by these studies.

- Smith-Jackson and Wogalter asked English-speaking community members to rate the perceived hazard of ten ANSI safety colors (Smith-Jackson and Wogalter, 2000, Document ID #0196). Red, yellow, black, and orange were rated the highest (in descending order). Differences were statistically significant except the difference between yellow and black.
- Among 80 college students asked to rate colors by Griffith and Leonard, red was rated the most ''meaningful'' color (*i.e.,* most distinct in meaning from neutral gray), followed by green, orange, black, white, blue, and yellow (Griffith and Leonard, 1997, Document ID #0250).
- Wogalter *et al.* asked Spanish speakers to rank the perceived hazard of ANSI safety colors (Wogalter *et al.,* 1997b, Document ID #0266). Red was ranked highest, followed by orange, black, and yellow.
- Dunlap *et al.* surveyed 1169 subjects across several different language groups including English, German, and Spanish speakers (Dunlap et *al.,* 1986, Document ID #0191). Subjects rated the color words red, orange, yellow, blue, green, and white according to the level of perceived hazard. The results demonstrated that the hazard information communicated by different colors followed a consistent pattern across language groups, with red having the highest hazard ratings.
- Wogalter *et al.* asked undergraduates and community volunteers to rank various warning components (Wogalter *et al.,* 1998, Document ID #0286). Red connoted a significantly greater hazard than other colors, followed by yellow, orange, and black (in that order). A group of industrial workers ranked the colors from greatest to least hazard as follows: red, yellow, black, orange.
- London asked workers in four sectors in South Africa to rank the colors red, yellow, green, and blue in terns of perceived hazard; 95 percent said red represents the greatest hazard, and 58 percent said yellow is the second greatest hazard (London, 2003; Document ID #0311).
- Banda and Sichilongo asked workers in Zambia to rate the perceived hazard of various colors used in chemical labels (Banda and Sichilongo, 2006, Document ID #0237). Red was associated with the greatest hazard, followed by yellow.
- Among a sample of 30 undergraduates who rated the perceived hazard of 105 signal word/color combinations, Braun *et al.* reported that red conveyed the highest level of perceived hazard followed by orange, black, green, and blue (Braun *et al.,* 1994, Document ID #0298).

These reports are consistent in showing that red is commonly understood to be associated with a high level of hazard—the highest of any color.

After reviewing stakeholder comments and studies investigating the benefits of using the color red to signal a hazard, OSHA has decided to require all pictograms to have red borders. OSHA finds that these labels will be more effective in communicating hazards to employees—both by drawing the attention of employees to the label and by indicating the presence of a hazard through non-verbal means. Consistently applying red borders to all labels, regardless of the final destination, will ensure that workers are protected. OSHA has determined that red pictogram borders will maximize recognition of the warning label and ensure consistency; therefore the final rule requires red borders for both domestic and international labeling.

Blank Diamonds

The final rule requires that all red diamonds printed on a label have one of the eight pictograms printed inside the diamond. The prohibition of blank diamonds on labels will ensure that users do not get desensitized to warnings placed on labels. Two commenters proposed alternatives to the prohibition of blank diamonds. The American Chemical Council (ACC) suggested that, because the red diamond border for pictograms are often pre-printed on shipping labels, OSHA allow printing the word ''BLANK'' on, or writing ''pictogram intentionally left blank'' in, the unused diamond (Document ID #0393). Additionally, Michelle Sullivan also suggested writing ''intentionally left blank'' in the empty diamonds (Document ID #0382).

OSHA acknowledges that prohibiting blank diamonds on labels may require an adjustment in practice for entities that use pre-printed labels or require businesses to inventory additional blank stock. OSHA analyzed the impact that prohibiting the use of blank diamonds on labels would have on production costs. While this requirement may increase costs associated with labeling, OSHA has determined that the costs do not render the rule infeasible. This issue is discussed in greater detail in Section VI.

Including diamonds on labels only when a pictogram is required will ensure that such warnings stand out to users. Prohibiting the use of blank diamonds will improve the likelihood that users will notice and react to the warning on the label. Therefore, OSHA has determined that prohibiting the use of blank diamonds on labels is necessary to provide the maximum recognition and impact of warning labels and to ensure that users do not get desensitized to the warnings placed on labels.

Hazard Statements and Precautionary Statements

Hazard statements describe the hazards associated with a chemical. Precautionary statements describe recommended measures that should be taken to protect against hazardous exposures, or improper storage or handling of a chemical. This revised rule replaces the current performance-oriented requirement for ''appropriate hazard warnings'' on labels with a requirement for specific hazard and precautionary statements on labels. The statements are prescribed, based on the hazard classification of the chemical.

Standardized requirements for hazard and precautionary statements provide a degree of consistency that is lacking among current chemical labels. This lack of consistency among current labels makes it difficult for users to understand the nature and degree of hazard associated with a chemical, and to compare chemical hazards. For example, in an article reviewed for the record, Dr. Beach relates experiences from the perspective of a doctor treating occupationally exposed patients (Beach, 2002, Document ID #0238). The author noted that different suppliers use different risk phrases for the same chemical, making it difficult for users to compare relative risks.

ANSI standard Z129.1, Hazardous Industrial Chemicals—Precautionary Labeling (Document ID #0610), was developed to provide a consistent approach to labeling of hazardous chemicals. This standard gives manufacturers and importers guidance on how to provide information on a label, including standardized phrases and other information that can improve the quality of labels. Because it is a voluntary standard, however, not all chemical manufacturers and importers have adopted the ANSI approach. As a result of the diverse formats and language used in the past, a consistent and understandable presentation of information was not fully achieved.

A preference for hazard statements was shown in EPA's Consumer Labeling Initiative (Abt Associates, 1999, Document ID #0209). This study asked consumers about their attitudes toward labels on household chemical products. Overall, consumers indicated that they like to have information that clearly connects consequences with actions, and they prefer to know why they are being instructed to take a particular precaution. A clear hazard statement provides this information.

In some cases, clear and concise precautionary information is necessary to enable employees to identify appropriate protective measures. For example, Frantz *et al.* examined the impact of flame and poison warning symbols prescribed in certain regulations by the Canadian government (Frantz *et al.,* 1994, Document ID #0191). The results suggest that although the generic meanings of these two symbols are well understood, people may have difficulty inferring the specific safety precautions necessary for a particular product.

Other reports indicate that users prefer information that includes both an indication of the hazard and the recommended action (*i.e.,* the precautionary statement). Braun *et al.* examined statements in product instructions for a pool treatment chemical and a polyvinyl chloride (PVC) adhesive, asking subjects to rate the injury risk posed by each product (Braun *et al.,* 1995, Document ID #0246). The experimenters manipulated the instructions to include either recommended actions only, actions followed by consequences, consequences followed by actions, or a simple restatement of the product label. The authors found that actions paired with consequences led to significantly higher risk perception than a restatement of the label or actions alone. Although the preferred wording was longer than the alternatives, subjects did not feel that the instructions were too complex, suggesting that they appreciate having actions and consequences paired together. Freeman echoed these findings in a discussion on communicating health risks to fishermen and farmers, noting that to be useful, risk statements should be balanced with equally strong statements of ways to reduce or avoid the risk (Freeman, 2001, Document ID #0249).

Explicit precautionary statements make it more likely that employees will take appropriate precautions. Bowles *et al.* asked subjects to review product warnings, then either decide what actions they should take or evaluate whether someone else's actions were safe, based on the warning (Bowles *et al.,* 2002, Document ID #0246). In general, situations that required the user to make inferences about a hazard—particularly when they had to come up with their own ideas for protective actions—led to decreased intent to comply. By providing clear precautionary instructions on the label, the revised rule eliminates the need for users to infer protective actions.

Evidence indicates that using key label elements together improves warning performance, compared with labels that only contain a subset of these elements. This is the approach taken in the revised rule, which requires the signal word, pictogram(s), hazard statement(s), and precautionary statement(s) together on the label. In one study, Meingast asked students to recall information from two variations of warning labels: Enhanced warnings with color, signal icons, pictorials, and organized text (following the ANSI Z535.4 standard, American National Standard for Product Safety Signs and Labels); and warnings with text only (Meingast, 2001, Document ID #0246). The authors reported that the enhanced warnings were more noticeable, led to significantly greater recall, and made people report a higher likelihood of compliance.

Other findings agree that improving all label elements can improve warning performance. For example, Lehto tested information retrieval from three chemical label formats and found that subjects generally did best with an ''extensive'' format that included pictograms, paragraphs, and horizontal bars indicating the degree of hazard (Lehto, 1998, Document ID #0258). Subjects were able to answer more questions correctly when the label included a range of content—particularly information on first aid and spill procedures.

Wogalter *et al.* reported similar results in a test of four different signs that discouraged people from using an elevator for short trips (Wogalter *et al.,* 1997a, Document ID #0287). Three signs were text-only. The fourth sign had a signal word panel, icons, a pictorial, and more explicit wording indicating the desired behavior (*i.e.,* ''use the stairs''). Subjects rated the enhanced sign as more understandable, and a field test found that it significantly increased compliance over the other options.

The effectiveness of a combination of elements was also investigated in a study of warnings on alcoholic beverage containers (Laughery *et al.,* 1993, Document ID #0281). Laughery et al. tested warnings to determine which elements influenced notice ability. The authors manipulated labels by adding a pictorial, adding an alert symbol with a signal word, making the text red, and/or adding a border around the warning. The warning was located fastest when all four of these modifications were present, suggesting that the best designs include a combination of enhancements.

The findings of these reports support OSHA's belief that the combined label elements, *i.e.,* pictogram, signal word, hazard and precautionary statements, is more effective in communicating hazard information than the individual elements would be if presented alone. Although the warnings examined in these studies are different than those warnings required in this final rule, they indicate that enhancements such as color and symbols can increase the effectiveness of a label, and that presenting hazard information and corresponding precautions together improves understanding.

Overall, the record shows that the presentation of information on labels through standardized signal words, hazard statements, pictograms, and precautionary statements would provide clearer, more consistent, and more complete information to chemical users. Comments received in response to the ANPR support this view (*e.g.,* Document ID #0032, 0054, 0124, and 0158). For example, the Refractory Ceramic Fibers Coalition (Document ID #0030) pointed to the benefits of this approach, stating:

> Employers and employees would be given the same information on a chemical regardless of the supplier. This consistency should improve communication of the hazards. It may also improve communication for those who are not functionally literate, or who are not literate in the language written on the label. In addition, having the core information developed already, translated into multiple languages, and readily available to whomever wishes to access it, should eliminate the burden on manufacturers and users to develop and maintain their own such systems. Thus the specification approach should be beneficial both to the producers and the users of chemicals.

The majority of comments received in response to the proposal support the use of hazard and precautionary statements on labels (*See, e.g.,* Document ID #0313, 0324, 0327, 0328, 0329, 0330, 0335, 0336, 0338, 0339, 0344, 0347, 0349, 0351, 0352, 0353, 0365, 0370, 0372, 0376, 0377, 0379, 0381, 0382, 0383, 0389, 0393, 0399, 0402, 0405, 0408, 0410, 0412, 0453, 0456, and 0461). No comments or testimony were received that opposed the use of hazard or precautionary statements on labels or safety data sheets.

In response to the proposal, stakeholders commented on the importance of being able to comprehend hazard and precautionary statements (*See, e.g.,* Document ID #0321, 0339, 0349, 0410, and 0412). Morganite Industries, Inc. and Morgan Technical Ceramics USA stated: ''Hazard Statements, by and large, convey fact in simple language'' (Document ID #0321). Commenting on the use of precautionary statements, the Phylmar Group noted that ''clear, concise use of key labeling elements can improve warning performance'' (Document ID #0339). The American Industrial Hygiene Association also supports the use of precautionary statements, stating that they ''should improve comprehensibility and compliance'' (Document ID #0410).

Labels are intended to provide an immediate visual reminder of chemical hazards. Whereas labels in the past could be presented in a variety of formats using inconsistent terminology and visual elements, labels prepared in accordance with the requirements in this final rule will be consistent. Standardized signal words and hazard statements attract attention and communicate the degree of hazard. Pictograms reinforce the message presented in text and enhance communication for low-literacy populations. Precautionary statements provide useful instructions for protecting against chemical-source injuries and illnesses.

A number of stakeholders submitted comments in support of standardized labeling for hazardous chemical containers. Several commenters stated that standardized label elements would better convey critically important hazard warnings, and provide useful information regarding precautionary measures that would serve to better protect employees (Document ID #0313, 0341, 0344, 0365, 0381, 0382, 0402, and 0405). The studies contained in the record reinforce OSHA's position on the use standardized label elements—including the use of standardized pictograms, signal words, and hazard and precautionary statements—to alert and inform chemical users of the hazards posed by hazardous chemicals in the workplace.

OSHA concludes, based on the studies discussed above and supported by the comments submitted to the record that standardizing the labels for hazardous chemicals is an essential step in harmonizing the HCS with the GHS. In addition, OSHA concludes that the labeling requirements in this revised final rule will result in more effective transmittal of information to employees. Therefore, OSHA has adopted the labeling requirements set forth in the NPRM in this final rule.

Safety Data Sheets

The HCS requires chemical manufacturers and importers to develop an SDS for each hazardous chemical they produce or import. SDSs serve as a source of detailed information on chemical hazards and protective measures. Each SDS must indicate the identity of the chemical used on the label; the chemical and common name(s) of hazardous ingredients; physical and chemical characteristics; physical and health hazards; the primary route(s) of entry; exposure limits; generally applicable precautions for safe handling and use; generally applicable control measures; emergency and first aid procedures; the date of preparation of the SDS; and the name, address and telephone number of the party preparing or distributing the SDS. Prior to this final standard, the information was not required to be presented in any particular order or to follow a specific format.

While the effectiveness of SDSs is evident, there are concerns regarding the quality of information provided. In particular, concerns have been raised regarding the accuracy (*i.e.,* the correctness and completeness of the information provided) and comprehensibility (*i.e.,* the ability of users to understand the information presented) of information provided on SDSs. In the NPRM, OSHA proposed requiring the information on SDSs to be presented using consistent headings in the sequence specified in the GHS (*See* Section XV for a detailed discussion of the requirements). The Agency has determined that a standardized order of information will improve the utility of SDSs by making it easier for users to locate and understand the information they are seeking. A standardized format is also expected to improve the accuracy of the information presented on SDSs.

Since the HCS was promulgated in 1983, access to chemical information has improved dramatically due to the availability of SDSs. OSHA believes that adopting a standardized format will build on the demonstrated benefits that have already clearly been established from the use of SDSs. As discussed in the proposal, the General Accounting Office (GAO) issued a report in May 1992 that addressed issues employers had with complying with the HCS (GAO, 1992, Document ID #0292). The findings were based on the results of a national survey of construction, manufacturing, and personal services providers. A total of 1,120 responses were received from employers.

One very important finding of the GAO survey was that almost 30% of employers reported that they had replaced a hazardous chemical with a less hazardous substitute because of information presented on an SDS. With regard to the HCS as a whole, GAO found that over 56% of employers reported ''great'' or ''very great'' improvement in the availability of hazard information in the workplace and in management's awareness of workplace hazards. Forty-five percent of those in compliance with the HCS considered the standard to have a positive effect on employees, compared with only 9% who viewed the effect as negative. The results indicate that when chemical hazard information is provided, the result is generally recognized as beneficial to employees. A number of other studies support this conclusion.

Conklin demonstrated the utility of SDSs among employees of a multinational petrochemical company (Conklin, 2003; Document ID #0245). Across three countries (the U.S., Canada, and the United Kingdom), 98 percent felt that the SDS is a satisfactory information source (the percentage was similar across all three countries). Seventy-two percent said they would request an SDS all or most of the time when introduced to a new chemical, although 46 percent of workers said that SDSs are too long. The author notes that this sample did not include any workers with low literacy.

However, while these studies show a clear benefit related to the use of SDS in the workplace, a number of investigations raise concerns that the information on SDSs is not comprehensible to employees. In 1991, OSHA commissioned a study that evaluated the comprehensibility of SDSs by a group of unionized employees in manufacturing industries located in the state of Maryland (Kearney/Centaur, 1991a, 1991b, Document ID #0309 and 0310). The study assessed the ability of these employees to understand information regarding the route of entry of the substance, the type of health hazard present, appropriate protective measures, and sources of additional help.

Each of the 91 participating workers was provided with and tested on four different SDSs. The workers answered the test questions based on information supplied on each of the SDSs. It should be noted that the employees who volunteered for this study understood that it relied on reading comprehension. This created a selection bias, as employees with reading difficulties would not be likely to volunteer for the study.

The results of the tests indicated that workers on average understood about two-thirds of the health and safety information on the SDSs. The best comprehension was associated with information providing straightforward procedures to follow (*e.g.,* in furnishing first aid, dealing with a fire, or in using personal protective equipment) or descriptions of how a chemical substance can enter the body. Workers had greater difficulty understanding health information addressing different target organs, particularly when more technical language was used. Workers also reportedly had difficulty distinguishing acute from chronic effects based on information presented in the SDSs.

Conklin reported a similar result in a study involving employees of a multinational petrochemical company (Conklin, 2003, Document ID #0245). After viewing information on an unfamiliar chemical in a variety of SDS formats, a questionnaire was administered to workers to gauge their comprehension of the material presented. The workers reportedly answered 65 percent of the questions correctly.

The Printing Industries of America reported a study that examined the comprehensibility of SDSs to master printers in 1990 (PIA, 1990, Document ID #0295). The subjects had an average of 13.9 years of formal education, or approximately two years beyond high school. In this study, 27 SDSs were selected and analyzed for reading levels using a software program, finding an average reading grade level of 14. The investigators found that employees with 15 years of education or more understood 66.2% of the information presented.

Some of the difficulty workers experience in understanding information presented on SDSs may be due to the vocabulary used in the document. Information presented at a reading level that exceeds the capability of the user is unlikely to be well understood. An example of this situation was reported by Frazier *et al.* (Frazier *et al.,* 2001, Document ID #0212). The authors evaluated a sample of SDSs from 30 manufacturers of toluene diisocyanate, a chemical known to cause asthma. Half of the SDSs indicated that asthma was a potential health effect. One SDS made no mention of any respiratory effects, while others used language (*e.g.,* allergic respiratory sensitization) that the authors believed may not clearly communicate that asthma is a risk. However, the more technical language meets the requirements of the HCS.

Other reports substantiate the belief that many SDS users have difficulty understanding the information on the documents. For example, in a study evaluating the comprehensibility of SDSs at a large research laboratory, 39 percent of the workers found SDSs ''difficult to understand'' (Phillips, 1997, Document ID #0263). The study also indicated that a third of the information provided on SDSs was not understood. These results were obtained from a study population of literate, trained workers who spoke English as their first language.

Smith-Jackson and Wogalter corroborated this finding in a study involving 60 undergraduates and community volunteers (Smith-Jackson and Wogalter, 1998, Document ID #0188). The subjects were asked to sort SDS data into a logical order. After completing the task, subjects were asked for their opinions on the difficulty of the content. Overall, 43 percent found the information easy to understand, 42 percent said it was not easy, and the remaining 15 percent felt that only scientists, experts, or very experienced workers would be able to understand the information.

These studies are consistent in reporting that workers have difficulty understanding a substantial portion of the information presented on SDSs. This finding can be explained at least in part by the fact that not all of the information on SDSs is intended for workers. SDSs are intended to provide detailed technical information on a hazardous chemical. While they serve as a reference source for exposed employees, SDSs are meant for other audiences as well. SDSs provide information for the benefit of emergency responders, industrial hygienists, safety professionals, and health care providers. Much of this information may be of a technical nature and would not be readily understood by individuals who do not have training or experience in these areas. For example, language that may be readily understood by a population of firefighters may be poorly understood by chemical workers.

In addition, Title III of the Superfund Amendments and Reauthorization Act (SARA, also known as the Emergency Response and Community Right-to-Know Act of 1986) mandated that SDSs be made available to state emergency response commissions, local emergency planning committees, and fire departments in order to assist in planning and response to emergencies, as well as to provide members of the general public with information about chemicals used in their communities. It is difficult, if not impossible, for a document to meet the informational needs of all of these audiences while being comprehensible to all as well.

Product liability concerns also play a role in the comprehensibility of SDSs. Producers of chemicals may be subject to ''failure to warn'' lawsuits that can have significant financial implications. Attempts to protect themselves against lawsuits can affect the length and complexity of SDSs, as well as the way in which information is presented. In some cases the length and complexity of SDSs reportedly make it difficult to locate desired information on the documents. For example, in testimony before the U.S. Senate Subcommittee on Employment, Safety, and Training, one hospital safety director described a situation in which an employee was unable to find critical information on an SDS in an emergency situation (Hanson, 2004, Document ID #0200):

> * * * two gallons of the chemical xylene spilled in the lab of my hospital. By the time an employee had noticed the spill, the ventilation had already sucked most of the vapors into the HVAC. This, in turn, became suspended in the ceiling tile over our radiology department. Twelve employees were sent to the emergency room. To make the matter worse, the lab employee was frantically searching through the MSDS binder in her area for the xylene MSDS. Once she found it, she had difficulty locating the spill response section. After notifying our engineering department, she began to clean up the spill with solid waste rags, known for spontaneous combustion, and placing the rags into a clear plastic bag for disposal. She did not know that xylene has a flash point of 75 degrees Fahrenheit. She then walked the bag down to our incinerator room and left it there, basically creating a live bomb. Twelve people were treated from this exposure. The lab employee was very upset and concerned about the safety of the affected employees and visitors, and hysterically kept stating that she could not find the necessary spill response information.

SDSs at this particular hospital were reported to range from one page to 65 pages in length.

To accommodate the needs of the diverse groups who rely on SDSs, a standardized format has been viewed as a way to make the information on SDSs easier for users to find, and to segregate technical sections of the document from more basic elements. A standardized format was also thought to facilitate computerized information retrieval systems and to simplify employee training.

The first attempt to establish a format for SDS was made in 1985, when OSHA established a voluntary format to assist manufacturers and importers who desired some guidance in organizing SDS information. This two-page form (OSHA Form 174) includes spaces for each of the items included in the SDS requirements of the standard, to be filled in with the appropriate information as determined by the manufacturer or importer. However, some members of the regulated community desired a more comprehensive, structured approach for developing clear, complete, and consistent SDSs.

In order to develop this structure, the Chemical Manufacturers Association (now known as the American Chemistry Council) formed a committee to establish guidelines for the preparation of SDSs. This effort resulted in the development of American National Standards Institute (ANSI) standard Z400.1, a voluntary consensus standard for the preparation of SDSs. Employers, workers, health care professionals, emergency responders, and other SDS users participated in the development process. The standard established a 16-section format for presenting information as well as standardized headings for sections of the SDS. In 2004, an updated version of the ANSI standard that was consistent with the GHS format was published. This ANSI standard has since been combined with the ANSI Z129 consensus standard on precautionary labeling preparation. The ANSI Z400.1/Z129.1 standard was issued in 2010.

By following the recommended format, the information of greatest concern to employees is featured at the beginning of the document, including information on ingredients and first aid measures. More technical information that addresses topics such as the physical and chemical properties of the material and toxicological data appears later in the document. The ANSI standard also includes guidance on the appearance and reading level of the text in order to provide a document that can be easily understood by readers.

OSHA currently allows the ANSI format to be used as long as the SDS includes all of the information required by the HCS. Because it is a voluntary standard, however, the ANSI format has not been adopted by all chemical manufacturers and importers. As a result, different formats are still used on many SDSs.

The International Organization for Standardization (ISO) has published its own standard for SDS preparation. This standard, ISO 11014–1, has been revised for consistency with the GHS (new version issued in 2009). The standard includes the same 16 sections as the GHS, as well as similar data requirements in each section. These two consensus standards, ANSI Z400.1–2004 and ISO 11014–1 (2009), have essentially the same provisions and are consistent with GHS. There are minor differences, such as units of measure recommended in the national ANSI standard versus the international ISO standard.

Another development has been the creation of International Chemical Safety Cards (ICSCs). The documents, developed by the International Programme on Chemical Safety, summarize essential health and safety information on chemicals for use at the ''shop floor'' level by workers and employers (Niemeier, 1997, Document ID #0191). ICSCs are intended to present information in a concise and simple manner, and they follow a standardized format that is shorter (one double-sided page) and less complex than the ANSI approach. The ICSCs were field tested in their initial stages of development, and new ICSCs are verified and peer reviewed by internationally recognized experts (*id.*). ICSCs have been developed in English for 1,646 chemicals, and are also available in 16 other languages. The ICSCs are being updated to be consistent with the GHS.

A study by Phillips compared the effectiveness of different SDS formats as well as ICSCs among workers at a large national laboratory (Phillips, 1997, Document ID #0191). The employees represented a variety of trades, including painters, carpenters, truck drivers, and general laborers. Each worker was tested for knowledge regarding a hazardous chemical before and after viewing an SDS or ICSC. Three designs were tested: a 9-section OSHA form, the 16-section ANSI Z400.1 format (an earlier and slightly different version of the current ANSI Z400.1 format), and the 9-section ICSC. A subsequent paper described the final results of this study (Phillips, 1999, Document ID #0263). All three formats led to significant improvements in subjects' knowledge, and there was no statistically significant difference among the three formats in terms of total test score. However, there were a few significant differences in how well readers of each SDS format answered specific types of questions:

- The ICSC performed better than the OSHA form regarding chronic and immediate health effects.
- The other two formats performed better than the ANSI format on fire-related questions.
- The OSHA form performed better than the other two formats on spill response questions.

▪ The OSHA form performed better than the ANSI format regarding carcinogenic potential.

The ANSI Z400.1 template has been used by a wide number of employers for creating SDSs. By following the recommended format, the information of greatest concern to employees is featured at the beginning of the document, including information on ingredients and first aid measures. More technical information that addresses topics such as the physical and chemical properties of the material and toxicological data appears later in the document. The ANSI standard also includes guidance on the appearance and reading level of the text in order to provide a document that can be easily understood by readers.

The ANSI format is commonly used. However, because it is a voluntary standard, not all chemical manufacturers and importers have adopted it. As a result, different formats are still used on many SDSs. Of the comments received regarding SDS, none were in favor of allowing voluntary adoption of the SDS format. The California Industrial Hygiene Council (CIHC) (Document ID #0463) reiterated its support for a uniform format, and specifically the implementation of the ANSI format for SDSs. The CIHC also stated that a mandatory format would establish a harmonized structure for all ''global target audiences'' (Document ID #0463).

In a separate comparison, Conklin also found similarities in the overall performance of several standard SDS formats (Conklin, 2003, Document ID #0245). In this study, employees of a multinational petrochemical company were given one of three versions of an SDS for an unfamiliar chemical: A U.S. version (OSHA's required content within an ANSI Z400.1–1998 16-part structure); a Canadian version following the 9-part structure prescribed by Canada's Workplace Hazardous Materials Information System (WHMIS); and a version following the European Union's content and 16-part structure. SDSs were controlled for font, layout, and reading level. Overall, Conklin found no statistically significant difference in mean post-test scores using the three different formats, although there were significant differences on 5 out of 10 questions (no one format was consistently better).

OSHA also examined several studies addressing what sequence of information would prove to be most beneficial for users. Because extensive searching can be a barrier to SDS use, researchers have examined whether there is a preferred order of information that more closely matches users' cognitive expectations. Smith-Jackson and Wogalter asked 60 undergraduates and community volunteers to arrange portions of six SDSs in the order they considered most usable (Smith-Jackson and Wogalter, 1998; Document ID #0188). The authors found a few consistent results:

▪ Information about health hazards, protective equipment, and fire and explosion data tended to be placed toward the beginning.

▪ Physical and reactivity data tended to be placed near the end.

▪ Spill or leak procedures were placed near the beginning or the middle, depending on the type of chemical.

A majority of subjects reported that they had attempted to prioritize the hazard information that needed to be communicated. The participants' suggested order of information generally did not match either the original SDS order or the order listed in the HCS—particularly the subjects' emphasis on health hazard information near the beginning.

In the previously discussed 1991 study that evaluated the comprehensibility of SDSs by a group of 91 unionized workers in manufacturing industries in the state of Maryland, a subset of the group (18 workers) was also tested on an ICSC (Kearney/Centaur, 1991a, 1991b, Document ID #0309 and 0310). While the results indicated that workers on average understood about two-thirds of the health and safety information on SDSs, ICSCs provided better results. The average ICSC test score ranged from 6% to 23% higher than the average test score on the four SDSs evaluated. This finding was considered by the authors to suggest that an improved format for SDSs may serve to increase user comprehension of the information presented.

OSHA believes that a standardized format will improve the effectiveness of SDSs for the following reasons: A consistent format makes it easier for users to find information on an SDS. Headings for SDS sections are standardized, so SDS users know which section to consult for the information they desire. The sections are presented in a consistent, logical sequence to further facilitate locating information of interest. Information commonly desired by exposed employees and of greatest interest to emergency responders (*e.g.,* Hazards Identification; First Aid Measures) is presented in the beginning of the document for easy reference. More technical information (*e.g.,* Stability and Reactivity; Toxicological Information) is presented later.

Specifically, the revised SDS format now segregate more complex information from information that is generally easier to understand. This order of information places basic information in the first sections, allowing SDS users to find basic information about hazardous chemicals without having to sift through a great deal of technical information that may have little meaning to them. In emergency situations, rapid access to information such as first-aid measures, fire-fighting measures, and accidental release measures can be critically important.

Several stakeholders expressed dissatisfaction with the degree that current SDSs vary from manufacturer to manufacturer (Document ID #0330 and 0351). The International Brotherhood of Teamsters stated that the quality and usefulness of SDSs has been grossly inconsistent in terms of content and format, adding that such discrepancies ultimately result ''in a failure to achieve the objective of the standard'' (Document ID #0357). John Schriefer, head of Local 9477, indicated that workers often didn't bother to request SDSs, because they are so complicated (Document ID #0494 Tr. 54–55). He suggested that a simplified, standard format for SDSs would go a long way toward improving worker safety (Document ID #0494 Tr. 63).

Commenters supported putting information targeted to the employees first on the SDS in order to improve how emergency situations are addressed (Document ID #0332, 0386 and 0414). Stericycle, Inc. supported placing hazard identification information in one location rather than ''sprinkling it through the documents, as is sometimes the case with [SDSs]'' (Document ID #0338). United Steelworkers stated that the difficulty in locating information on current SDSs ''is bad enough with routine assessments, but in an emergency situation like a spill, splash or fire it can be deadly'' (Document ID #0402). Additionally, the American Wind Energy Association argued that requiring hazard identification and first aid information to be placed in the first sections of the SDS would serve to ''better assist emergency response teams to more efficiently recognize hazards during incidents'' (Document ID #0386). American Federation of State, County and Municipal Employees (AFSCME) also supported the adoption of a standardized SDS, reasoning that it would enable workers to better understand SDSs, and could ultimately lead to faster responses as well as a reduction in the number of incidents altogether (Document ID #0386).

A standardized format does not address all issues affecting SDS comprehensibility. Reading level and some design elements would continue to vary. In many respects, this is inevitable given the different target audiences that SDSs have, and the varying qualifications of those who prepare SDSs. Nevertheless, OSHA believes that the revisions will result in a substantial improvement in the quality and ease of comprehension of information provided on SDSs.

In addition to the issues regarding comprehensibility, researchers raised concerns that some SDSs may be incomplete or contain erroneous information. The magnitude of the problem is unclear, because only very limited numbers of SDSs have been evaluated in these studies, and in some cases the investigations were performed so long ago that the results may not reflect current practices. Nevertheless, the evidence appears to indicate that a substantial number of SDSs may not contain complete and correct information.

An initial examination of the accuracy of SDSs was commissioned by OSHA shortly after the scope of the rule was expanded to cover all industries in 1987 (Karstadt, 1988, Document ID #0296). The report, which analyzed the content of 196 SDSs for products used in auto repair and body shops, provided a general indication that the content and presentation of information was inconsistent on the SDSs examined. In 1991, OSHA commissioned an additional study that examined the accuracy of SDSs (Kearney/Centaur, 1991a, 1991b, Document ID #0309 and 0310). The study examined information presented in five areas considered crucial to the health of workers potentially exposed to hazardous substances. The five areas assessed were: Chemical identification of ingredients; reported health effects of ingredients; recommended first aid procedures; use of personal protective equipment; and exposure level regulations and guidelines. The evaluation indicated that 37% of the SDSs examined accurately identified health effects data, 76% provided complete and correct first aid procedures, 47% accurately identified proper personal protective equipment, and 47% correctly noted all relevant occupational exposure limits. Only 11% of the SDSs were accurate in all four information areas, but more (51%) were judged accurate, or considered to include both accurate and partially accurate information, than were judged inaccurate (10%). The study also concluded that the more recent SDSs examined (those prepared between 1988 and 1990) appeared to be more accurate than those prepared earlier.

This belief that some SDSs are not complete and correct was corroborated by an examination of SDSs for lead and ethylene glycol ethers (Paul and Kurtz, 1994, Document ID #0302). Although these substances are known reproductive and developmental toxicants, researchers found that 421 of 678 SDSs examined (62%) made no mention of effects on the reproductive system. OSHA also commissioned a study, completed in 1999, focusing specifically on the accuracy of first aid information provided on SDSs (Lexington Group, 1999, Document ID #0257). A total of 56 SDSs for seven chemicals were examined. First aid information on the SDSs was compared with information from established references. The researchers reported that nearly all of the SDSs reviewed had at least minor inaccuracies.

A standardized format does not directly address the concerns that have been raised regarding the accuracy of information present on SDSs. However, standardization would improve the accuracy of chemical hazard information indirectly. With consistent presentation of information, the task of reviewing SDSs and labels to ensure accuracy will be simplified. Individuals preparing and reviewing these documents should find it easier to identify any missing elements and compare information presented on an SDS to reference sources and other SDSs. OSHA enforcement personnel will be able to more efficiently examine SDSs when conducting inspections. The detailed entries for SDSs are particularly noteworthy in this regard. The sub-headings provide an organized and detailed list of pertinent information to be included under the headings on the SDS. For example, while the HCS currently requires physical and chemical characteristics of a hazardous chemical to be included on the SDS, the final rule provides a list of 18 properties for Section 9 of the SDS. The party preparing the SDS must either include the relevant information for these entries, or indicate that the information is not available or not applicable. This approach provides both a reminder to the party preparing the SDS regarding the information required and a convenient means of reviewing the section to ensure that relevant information is included and is accurate.

Additionally, several stakeholders agreed that standardization would result in improved accuracy of the information on SDSs. For example, Ecolab, Inc. stated that a uniform approach to hazard classification and labeling would improve the accuracy of the information presented on labels and SDSs and reduce ''the currently observed variability among suppliers in chemical classification and presentation of that information'' (Document ID #0351). Additionally, American Iron and Steel Works noted that ''standardized criteria to evaluate and communicate hazards via SDSs * * * should assure consistent communication and lower the likelihood of miscommunication and misinterpretation'' (Document ID #0408). Alliance for Hazardous Materials Professionals also indicated that the standardization of SDSs is likely to ''resolve language and content inconsistencies among similar product providers'' (Document ID #0327).

OSHA concludes that the classification criteria included in the final rule will also improve the accuracy and precision of information on SDSs. The detailed criteria provided will direct evaluators to the appropriate classification for a chemical. For example, while directing the evaluator to use expert judgment in taking all existing hazard information into account, the criteria for serious eye damage/eye irritation is tied to specific results found in animal testing. In addition, assignment to hazard categories would lead to provision of detailed information that would be specific to the degree of hazard presented by the chemical.

Classification of hazards will play an important role in increasing the usefulness of SDSs under the final rule. By including the classification of the substance on the SDS, employers will be in a much better position to compare the hazards of different chemicals. Hazard categories generally give an indication of the severity of the hazard associated with a chemical. For example, all other things being equal, a chemical classified for skin corrosion/irritation in category 1 as a skin corrosive would be more hazardous than a chemical classified in category 2 as a skin irritant. If chemicals are classified into hazard categories, this information can be used to simplify the process of comparing chemicals. As noted previously, employers use SDSs as a means of comparing chemical hazards to select less hazardous alternatives. Thus, it is reasonable to conclude that this final rule will result in more effective use of the SDS as an instrument for identifying less hazardous substitutes for hazardous chemicals.

Stakeholders have expressed support for a standard SDS format. The development of an industry consensus standard for preparation of SDSs, ANSI

Z400.1, in itself, shows a desire on the part of many parties for a consistent approach to SDSs. The final rule follows the same section and sequence as the ANSI Z400.1, which was updated in 2004 and combined with the ANSI 129 standard in 2010.

A report drafted by the GAO recommended that OSHA clearly specify the language and presentation of information on SDSs (GAO, 1991, Document ID #0292). In addition, the report of the National Advisory Committee for Occupational Safety and Health Review of Hazard Communication (September 12, 1996) indicated that during the public presentations and workgroup discussions, there was general agreement that a uniform format should be encouraged, and most workgroup members agreed that OSHA should endorse use of the ANSI Z400.1 format (NACOSH, 1996, Document ID #0260).

Comments received in response to the ANPR indicated widespread support for a standard format for SDS (*See, e.g.,* Document ID #0030, 0054, 0064, 0124, and 0158). The American Foundry Society, for example, said that consistent SDSs make it easier for users to find information and compare products (Document ID #0158). The Jefferson County Local Emergency Planning Committee maintained that critical information can be missed by first responders due to the current lack of consistency in presentation of information on SDSs, stating: ''It is not overreaching for us to say that lives will be saved through harmonization'' (Document ID #0037).

Moreover, stakeholder response to the NPRM also overwhelmingly supported requiring a consistent, standardized format for SDSs (Document ID #0307, 0313, 0321, 0322, 0328, 0329, 0330, 0335, 0341, 0344, 0349, 0352, 0357, 0365, 0372, 0374, 0381, 0382, 0383, 0386, 0389, 0392, 0393, 0403, 0404, 0405, 0410, 0415, 0456, and 0463). American Subcontractors of America stated that a standardized format would make SDSs a more effective resource and better educational tool (Document ID #0322). Additionally, the Communications Workers of America asserted that standardizing SDSs would be an invaluable solution for addressing current inconsistencies and quality issues on SDSs (Document ID #0349).

Based on the studies and comments in the record, OSHA has concluded that not only will the standardized SDS format indirectly improve the quality of information provided on SDSs, but that it is in the format that stakeholders already know and overwhelmingly prefer.

Training

Along with labels on containers and SDSs, employee training is one of three core components of a comprehensive hazard communication program. Training is needed to explain and reinforce the information presented on labels and SDSs, to ensure that employees understand the chemical hazards in their workplace and are aware of the protective measures they need to follow. The final rule includes a relatively minor revision to the existing HCS training requirements for employers to train employees on the label elements and SDS format. This revision is intended to ensure that labels and SDSs are adequately explained to employees (*See* Section XIII for a detailed discussion of the training requirements). In light of the evidence discussed and new information submitted to the record related to label and SDS comprehension, the importance of training should not be underestimated.

Training is necessary to ensure that employees understand the standardized headings and sequence of information on SDSs. Likewise, employees must be able to understand the meaning of the standardized label elements in order for them to be effective. In certain instances, label elements already appear to be fairly well understood. For example, ''Danger'' appears to be generally recognized to represent a higher degree of hazard than ''Warning.'' Other label elements, particularly some pictograms, are less well understood. This finding is not surprising given the limited amount of exposure that most of the population has had to some of these pictograms.

A relatively high level of understanding is generally recommended for pictograms. For example, ANSI Z535.3, the American National Standard that addresses criteria for safety symbols (Document ID #0276), contains a test method for determining the effectiveness of a pictogram. The criterion for a successful, effective pictogram is 85% correct responses, with no more than 5% critical confusion. (Critical confusion refers to when the message conveyed is the opposite of the intended message.) A score below 85% does not mean the pictogram should not be used, but rather that it should not be used without some additional element, such as written text. The International Standards Organization has similar criteria in ISO 9186, Procedures for the Development and Testing of Public Information Symbols (Document ID #0255). This standard recommends testing methodologies to evaluate symbols intended to be used internationally. It sets a somewhat lower level of acceptability (66%) than the ANSI standard.

While initial understanding of some pictograms may not be satisfactory, research shows that training can improve comprehension. In one study, Wogalter *et al.* tested how well undergraduate subjects comprehended a set of 40 pharmaceutical and industrial safety pictorials before and after training (Wogalter *et al.,* 1997c, Document ID #0288). Training led to a significant increase in pictorial comprehension. The improvement was greatest for the most complex symbols. Training was equally effective whether the subject was given a simple printed label (*e.g.,* ''Danger, cancer-causing substance'') or a label with additional explanatory text.

Lesch conducted a similar study, testing how well workers recognized a set of 31 chemical and physical safety symbols before and after training (Lesch, 2002, Document ID #0246; Lesch, 2003, Document ID #0282). Training significantly improved comprehension, which remained higher up to 8 weeks later. As in the Wogalter *et al.* study described above, Lesch found little difference in performance whether training took the form of a written label assigned to each symbol, a label plus explanatory text, or an accident scenario. Training also improved response speed.

In a survey of South African workers, London examined the impact of brief training on the meaning of symbols and hazard phrases (London, 2003, Document ID #0311). Here, the author found no statistical difference in comprehensibility of four familiar hazard symbols, but did find that training improved comprehension of one symbol (the GHS health hazard symbol), and it also reduced the overall incidence of critical confusion. This study also found that workers with previous workplace training were more likely to understand label text and some pictograms, and were better able to identify the active ingredient. Banda and Sichilongo reported a similar result in their evaluation of GHS labels in Zambia. The authors found that ''correct responses to label elements were not a result of social class and/or age but appeared to be influenced by extent of duration of exposure either through specialized training or acquaintance'' (Banda and Sichilongo, 2006, Document ID #0237). Recognizing that symbols are the items most often recalled from a label, London advised a strong emphasis on training for GHS symbols, particularly the ''flame over circle'' and ''flame'' symbols—which were reported to be easily confused—and other symbols that may generate critical confusion (London, 2003, Document ID #0311).

NIOSH, in its post-hearing comments, provided the following additional studies. These studies support OSHA's position that training ensures the understanding of standardized label elements (pictograms, signal words, hazard statement, and precautionary statements) and is an essential part of an effective hazard communication program.

Burt *et al.* (1999, Document ID #0480.1) conducted an ergonomic study of correct lifting posture. The project included three separate studies: using 135 undergraduate students, Study 1 consisted of a questionnaire to evaluate nine symbols to select the most appropriate symbols to encourage correct lifting posture. Four of the symbols used in Study 1 met the appropriateness criteria and were used in Study 2 by 21 city council workers to test their understanding of each symbol. Using 100 random subjects, Study 3 was a field test that examined the effect of the best performing symbol (from Study 2) on subjects when asked to lift a box. Burt *et al.* found that once trained on the meaning of a label, the presence of a standard recognized label prompted the test subject to take the proper action. The author also found significant increases in correct lifting posture when a symbol was present compared with a control condition in which people were trained in correct lifting techniques, but did not see the symbol as a reminder.

In 2007, Lesch (Document ID #0480.3) conducted a study looking at different training conditions. During the training, warning symbols with labels (to better explain the meaning of the symbol) were paired with accident scenarios. The accident scenarios illustrated the nature of the hazard, the required or prohibited actions, and the possible consequences of failing to comply with the warning. The participants were tested before and following the training (immediately after and two weeks later). The results showed the benefits of training—improved comprehension, reduced reaction times, and an improved confidence in their responses—and illustrated that, by strengthening the connections between the warning symbol and its associated meaning, accident scenario training can be used to prevent accidents and injuries.

In 2007, Su and Hsu (Document ID #0480.5) tested 1,000 college students on their perception of GHS labels and traffic safety signs. The study found that students who had taken training did better in perceiving various traffic safety signs than those who did not. With regards to chemical labeling, students who had taken hazard communication training had better perception ratings than those without training. Analysis showed that 17 out of 27 hazards had perception ratings lower than 66%, the ISO suggested acceptable rate for a good sign. The statistical analysis used in the study indicated that pictograms should not be used alone but accompanied by warning statements or other kinds of textual materials. The study also suggested that training on pictograms and warning statements should be integrated into school curriculum.

Rother (2008, Document ID #0480.4) conducted a study to assess how South African farm workers interpret the pictograms used in the pesticide industry. Administered to 115 farm workers from commercial vineyards in Western Cape, South Africa, this study used a questionnaire designed to interpret the workers' understanding of 10 pictograms commonly used in the pesticide industry. Fifty percent or more of the study participants had misleading, incorrect, or critically confused interpretations of the label pictograms. The study identified a response as critically confused when a farm worker incorrectly interpreted a pictogram to require an action or behavior that would increase his or her health risks. OSHA agrees with NIOSH's interpretation that the study ''found that lack of training severely affected farm worker's abilities to correctly interpret pesticide pictogram warning labels'' (Document ID #0470).

These reports reinforce OSHA's longstanding belief that labels, SDSs, and training are complementary parts of a comprehensive hazard communication program—each element reinforces the knowledge necessary for effective protection of employees. The need for training to ensure comprehension of hazard information is widely recognized. Annex A of ANSI Z535.2 (the American National Standard for Environmental and Facility Safety Signs) (Document ID #0277), for example, recommends training on the meaning of standard safety symbols and signal words, and ANSI Z535.4 (Document ID #0278) contains similar guidance.

OSHA received many comments supporting the importance of training (*See, e.g.,* Document ID #0329, 0331, 0347, 0370, 0382, 0387, 0412, 0527, 0640, 0644, and 0647). The National Institute of Occupational Safety and Health (NIOSH) (Document ID #0412) stated:

> Training is key to ensuring effective hazard communication. Although written information is important, training is an opportunity to explain the data and helps to ensure that the messages are being received accurately so they can be acted on appropriately.

The USW stated that ''there is no question good training greatly improves the ability to understand chemical labeling and safety data sheets. Unfortunately, the OSHA standard is vague * * *'' (Document ID #0403). Several organizations, including Western Region Universities Consortium, ORC Worldwide, SOCMA, NIOSH, Building & Construction Trades Department of AFL–CIO, NIEHS, and USW (*e.g.,* Document ID #0331, 0370, 0402, 0412, 0527, 0640, and 0647) stated that training, though essential, is often not done well, and urged OSHA to ''strengthen training requirements and worker protection'' (Document ID #0331).

Others, such as DuPont, API, Michelle Sullivan, ACC, and American Iron and Steel Institute/American Coke & Coal Chemicals Institute, stated that the standardized SDS and label format should facilitate training efforts and the overall effectiveness of hazard communication in industry (Document ID #0329, 0376, 0382, 0393, and 0408). The American Iron and Steel Institute stated: ''Standardized criteria to evaluate chemicals should facilitate training. With a single teaching format for SDSs and Labels, understanding, regardless of an employee's educational background, should be improved'' (Document ID #0408).

OSHA not only received many comments indicating that the training requirements in the HCS are not adequate, several organizations requested that OSHA either add regulatory text or a mandatory appendix specifying training content, frequency, and methods of evaluation (Document ID #0331, 0340, 0347, 0349, 0357, 0403, 0414, 0456, 0640, and 0647). For example, the National Institute of Environmental Health Sciences Worker Education and Training Program (NIEHS WETP) (Document ID #0347 and, 0516) provided training information, including a training program guidance manual, and an outline detailing specific training topics for the HCS.

OSHA agrees that training is important for ensuring effective hazard communication. However, OSHA did not propose to change the training provisions in the HCS other than initial training on the new GHS elements.

Similarly, the GHS discusses the importance of training, but does not contain specific training requirements. Since the purpose of this rulemaking is to align with the requirements of the GHS, OSHA did not propose modifications that were outside of those necessary to maintain alignment with the GHS. OSHA has decided to stay within the scope of the rulemaking and retain the proposed training provisions in the HCS final rule. *See* Section XIII for a more detailed discussion on training.

Conclusion

It is a longstanding Agency position that employees have the ''right to know'' and understand the hazards of chemicals they are exposed to in the workplace (53 FR 29826, Aug. 8, 1988; 59 FR 6126, Feb. 9, 1994). This knowledge is needed in order to take the precautions necessary for safe handling and use, to recognize adverse health effects associated with chemical exposure, and to respond appropriately in emergency situations.

Equally important in terms of employee protection is that employers have access to chemical hazard information as well. Chemical information is the foundation of workplace chemical safety programs—without it, sound management of chemicals is impossible. By ensuring that emergency responders, physicians, nurses, industrial hygienists, safety engineers and other professionals have the information they need, the HCS reduces the likelihood of chemical source illnesses and injuries. Selection of appropriate engineering controls, work practices, and personal protective equipment is predicated upon knowing the chemicals that are present, the form they are present in, and their hazardous properties.

In his testimony at the informal public hearings, Mr. David Irby, a union safety representative at the Severstal Steel Plant in Sparrows Point, Maryland, expressed the importance of the right to understand SDSs, stating that employees ''need an easy-to read format written in a clear, precise and understandable manner in our workplace'' (Document ID #0494 Tr. 55–57). OSHA agrees that employees must be able to read and comprehend the information presented on both labels and SDSs so that they can respond accordingly. Therefore, OSHA has determined that the provisions in this final rule—the standardized label elements (including pictograms, signal words, and hazard and precautionary statements), a standardized 16-section SDS, and the requisite training provisions—provide the necessary conventions to support understanding the hazards posed by chemicals in the workplace and that this final rule provides employees not only with the ''right to know'' but also the ''right to understand.''

OSHA concludes that aligning the HCS with the GHS will improve the quality and consistency of the chemical hazard information provided to employers and employees. A combination of label elements—signal word, hazard statement(s), pictogram(s), and precautionary statement(s)—is expected to make label warnings more noticeable and easier to understand, and will better communicate hazard and precautionary information. Standardized headings and a consistent order of information are anticipated to make it easier for users to find information on SDSs, improve their accuracy, and better enable users to compare the relative hazards of different substances. Along with effective training in the context of a comprehensive chemical hazard communication program, OSHA has determined that these revisions will more adequately inform employees of chemical hazards, and lead to better protections in the workplace.

V. Pertinent Legal Authority

The primary purpose of the Occupational Safety and Health Act (the ''OSH Act'' or ''Act'') (29 U.S.C. 651 *et seq.*) is to assure, so far as possible, safe and healthful working conditions for every American employee over the period of his or her working lifetime. One means prescribed by Congress to achieve this goal is the mandate given to, and the authority vested in, the Secretary of Labor to ''promulgate, modify, or revoke'' mandatory occupational safety and health standards. OSH Act § 6(b), 29 U.S.C. 655(b).

An occupational safety and health standard is defined under the Act as:

> [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.

OSH Act § 3(8), 29 U.S.C. 652(8). The Supreme Court has interpreted this provision as requiring OSHA to determine, before promulgating a permanent standard under section 6(b) of the Act, that the standard is reasonably necessary and appropriate to remedy a significant risk of material health impairment. *Indus. Union Dep't* v. *Am. Petroleum Inst.,* 448 U.S. 607, 642 (1980) (''*Benzene*''). This ''significant risk'' determination constitutes a finding that, absent the change in practices mandated by the standard, the workplace in question would be ''unsafe'' in the sense that employees would be threatened with a significant risk of harm. *Id.*

Section 6(b)(5) provides that:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall 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. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

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 a proposed standard, section 6(b)(5) requires it 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 * * * plac[ed] the 'benefit' of 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*''). Where, however, there are two equally effective methods of reducing significant risk to the most protective feasible level, OSHA must choose the less costly method. *See Cotton Dust,* 452 U.S. 490, 513 n.32; *Int'l Union, UAW* v. *OSHA,* 37 F.3d 665, 668 (D.C. Cir. 1994).

In addition, section 6(b)(7) of the Act provides in part that:

> Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure.

29 U.S.C. 655(b)(7). Section 6(b)(7)'s labeling and employee warning

requirements provide basic protections for employees in the absence of specific permissible exposure limits, particularly by providing employers and employees with information necessary to design work processes that protect employees against exposure to hazardous chemicals in the first instance. The Supreme Court has recognized such protective measures that may be imposed in workplaces where chemical exposure levels are below that for which OSHA has found a significant risk. *Benzene,* 448 U.S. at 657–58 & n.66. In *Benzene,* the Court relied on section 6(b)(7) to sanction OSHA's requirements for monitoring and medical testing when it sets a permissible exposure limit ''in reliance on less-than-perfect methods.'' *Id.* These requirements serve as a ''backstop,'' the Court said, allowing OSHA to check the validity of its assumptions in developing the PEL, and employers to remove particularly susceptible workers before they suffered any permanent damage. *Id.* at 657–58; *See also Nat'l Cottonseed Products Ass'n* v. *Brock,* 825 F.2d 482, 485–87 (D.C. Cir. 1987) (upholding decision to retain medical monitoring requirement while revoking PEL to ''provide a backstop if that judgment is incorrect and this surveillance will protect the health of the employees'').

In promulgating a standard under the Act, OSHA's determinations will be deemed conclusive if they are ''supported by substantial evidence in the record considered as a whole.'' OSH Act § 6(f), 29 U.S.C. 655(f). When the standard deals with toxic materials or harmful physical agents, OSHA must use the ''best available evidence.'' Such evidence includes ''the latest 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.'' OSH Act § 6(b)(5), 29 U.S.C. 655(b)(5). The Supreme Court has held that OSHA is not required to support its finding of significant risk of material health impairment ''with anything approaching scientific certainty'' and that the determination of whether a level of particular risk is '''significant' will be based largely on policy considerations.'' *Benzene,* 448 U.S. at 655–56 & n.62.

The OSH Act allows the Secretary to ''modify'' and ''revoke'' existing occupational safety or health standards. OSH Act § 6(b)(2); 29 U.S.C. 655(b)(2). In passing the 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* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 42 (1983) (internal quotation marks and citations omitted).

A. Legal Authority for the Current HCS

OSHA's Hazard Communication Standard (''HCS'') is a standard promulgated under the authority of sections 6(b)(5) and 6(b)(7) of the Act (29 U.S.C. 655(b)(5) and 655(b)(7)). *See Associated Builders and Contractors, Inc.* v. *Brock,* 862 F.2d 63, 67–68 (3rd Cir. 1988); *United Steelworkers of Am.* v. *Auchter,* 763 F.2d 728, 738 (3rd Cir. 1985); *United Steelworkers of Am.* v. *Auchter,* 819 F.2d 1263, 1267 (3rd Cir. 1987). Authority for the HCS may also be found in section 8(c) and 8(g) of the Act, 29 U.S.C. 657(c) and 657(g). Section 8(c)(1) of the Act requires employers to make, keep, and preserve records regarding activities related to the Act and to make such records available to the Secretary pursuant to regulations that the Secretary may prescribe. 29 U.S.C. 657(c)(1). Section 8(g)(2) of the Act authorizes the Secretary to ''prescribe such rules and regulations as [she] may deem necessary to carry out [her] responsibilities under this Act * * *.'' 29 U.S.C. 657(g)(2).

As a 6(b)(5) standard, OSHA was required to establish that the HCS would substantially reduce a significant risk of material harm. Some OSHA standards protect employees from exposure to a concentration of a hazardous substance that OSHA has found to create a significant risk of material health impairment. Thus, in making the significant risk determination in these cases, OSHA is concerned with determining the level at which a significant risk arises.

OSHA took a different approach to its significant risk determinations in promulgating the HCS in 1983 and revising it in 1994. The agency relied on NIOSH data showing that about 25 million, or about 25% 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 workplace exposure to hazardous chemicals. 48 FR 53280, 53282 (Nov. 25, 1983). It then noted the consensus evident in the record among labor, industry, health professionals, and government that an ''effective federal 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. *Id.* at 53283.

Thus, OSHA found that because:

> * * * inadequate communication about serious chemical hazards endangers workers and that the practices required by this standard are necessary or appropriate to the elimination or mitigation of these hazards, the Secretary is hereby able to make the threshold ''significant risk'' determination that is an essential attribute of all permanent standards.

Id. at 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* v. *Auchter,* 763 F.2d at 735. The Third Circuit has upheld OSHA's finding of significant risk as sufficient to justify the HCS on several occasions. *See Associated Builders and Contractors,* 862 F.2d at 67 (discussing the history of its review of the issue). OSHA reaffirmed its finding of significant risk in adopting revisions to the HCS in 1994. 59 FR 6126, 6136–40 (Feb. 9, 1994).

A characteristic of hazard communication that OSHA confronted in adopting the HCS is that information about the hazards associated with a particular chemical, and the exposures associated with its use, is not uniformly distributed across industry. That is, chemical manufacturers and importers tend to have greater knowledge and scientific expertise with respect to the composition of the chemicals they make or import than do downstream employers. *See* 48 FR at 53322 (Nov. 25, 1983). Therefore, manufacturers and importers are usually in the best position to assess the inherent hazards associated with them. *Id.* However, it is the downstream users and their employees who tend to have the best information about the means and methods of exposure, and are therefore usually in the best position to determine the risk arising from the use of the chemical in their workplaces. *See* 48 FR at 53307 (Nov. 25, 1983); 59 FR at 6132–33 (Feb. 9, 1994).

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. 29 CFR 1910.1200(b)(2).

In previous rulemakings, OSHA rejected suggestions that the hazard assessment and communication obligations should arise only where the downstream use creates a significant risk because it is difficult, if not impossible, for OSHA or manufacturers and importers to know where these risks might occur before the fact. 48 FR at 53295, 53296, 53307 (Nov. 25, 1983; 59 FR at 6132 (Feb. 9, 1994). Further, it is only by the provision of hazard information that downstream employers and employees can determine how to use the chemical so that exposure and risk may be minimized. *Id.* Thus, the HCS protects employees from significant risk by requiring communications about all chemicals that may present a hazard to employees, regardless of the exposure or risk levels any particular downstream user might actually experience. *See Durez Div. of Occidental Chem. Corp.* v. *OSHA,* 906 F.2d 1, 3–4 (D.C. Cir. 1990); *General Carbon Co.* v. *OSHRC,* 860 F.2d 479, 484–85 (D.C. Cir. 1988).

For these reasons, hazard communication—as opposed to risk communication—''most adequately assures'' employee protection from the significant risk of material impairment of health arising from the use of hazardous chemicals in the workplace for purposes of OSHA's authority under section 6(b)(5) of the Act. In addition, the HCS is authorized under section 6(b)(7), which requires OSHA to prescribe ''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). As noted above, the *Benzene* case recognizes 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. In this way, the HCS ensures that employers and employees have the information they need to avoid situations of exposure in the workplace even before the employee is exposed to a hazardous chemical. As OSHA explained in the preamble to the 1994 HCS amendments: ''OSHA has concluded that imposing informational requirements is necessary and appropriate to protect workers even when OSHA has not determined that the level of risk at a particular worksite warrants a substance-specific standard that would employ more elaborate types of controls.'' 59 FR at 6132 (Feb. 9, 1994).

B. Authority for the Final Rule

1. Section 6(b)(7) Authority. OSHA has authority to adopt the revisions to the HCS made in the final rule under the last sentence of section 6(b)(7) of the Act, which provides that:

> The Secretary, in consultation with the Secretary of Health and Human Services, may by rule promulgated pursuant to section 553 of title 5, United States Code, make appropriate modifications in the foregoing requirements relating to the use of labels or other forms of warning, monitoring or measuring, and medical examinations as may be warranted by experience, information, or medical or technological developments acquired subsequent to the promulgation of the relevant standard.

29 U.S.C. 655(b)(7).

This provision exempts modifications to hazard communication, monitoring, and medical examination requirements from the standard-setting requirements of section 6(b), and so evidences Congress's intent to provide OSHA with an expedited procedure to update these requirements. OSHA believes that exercise of this authority does not require a new finding of significant risk. As noted above, the ''backstop'' 6(b)(7) requirements of hazard communication, exposure monitoring, and medical surveillance may be imposed even in the absence of a significant risk finding. *See Benzene,* 448 U.S. at 657–58; *Nat'l Cottonseed Products Ass'n,* 825 F.2d at 485–87. 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.

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.

OSHA has used the authority of section 6(b)(7) in the past to revise its standards. *See, e.g.,* Standards Improvement Project-Phase II, 70 FR 1112 (Jan. 5, 2005); Standards Improvement (Miscellaneous Changes) for General Industry and Construction Standards, 63 FR 33450, 33458 (June 18, 1998). For example, it used this authority to revise the inorganic arsenic and coke oven emissions standards to eliminate the requirement of sputum cytology testing and to reduce the required frequency of mandatory chest x-rays from semi-annual to annual. 63 FR at 33458 (June 18, 1998). OSHA justified these changes on the grounds that studies reported after the promulgation of the relevant standards showed that sputum cytology did not improve employee survival rates and that the survival rates when semi-annual x-rays were used were not higher than when annual exams were administered. 63 FR at 33458–59 (June 18, 1998). In addition, OSHA has used its section 6(b)(7) authority to authorize new respirator fit protocols under its respiratory protection standard. 69 FR 46986 (Aug. 4, 2004); *See generally* 29 CFR 1910.134 App. A, Pt. II. On neither occasion has OSHA made new findings about significant risk.

The final rule fits well within the authority granted by the last sentence of section 6(b)(7). Adoption of GHS provisions constitutes a ''modification[]'' of the HCS regarding ''the use of labels or other forms of employee warning.'' For the reasons summarized above and explained more fully elsewhere in this preamble, OSHA believes that the adoption of GHS is ''appropriate'' based on ''experience, information, or medical or technological developments acquired subsequent to the promulgation of the relevant standard.'' The formulation of GHS may also be considered a ''technological development'' that has occurred since the promulgation of the original standard in 1983. 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* Parts III and XIII of this preamble; 74 FR 50280, 2085–86 (Sept. 30, 2009); 71 FR 53617, 53618–19 (Sept. 12, 2006). Indeed, OSHA noted the possibility of a future internationally harmonized standard in the preamble accompanying the original HCS rule. *See* 48 FR at 53287 (Nov. 25, 1983).

The last sentence of section 6(b)(7) also requires consultation with the Secretary of Health and Human Services. As detailed in the NPRM, NIOSH was involved in the development of the proposal through briefings and review of the proposed rule before publication. *See* 74 FR at 50306 (Sept. 30, 2009). NIOSH strongly supported the proposal in comments and hearing testimony (Document ID #0412, 0470, 0472, and 0497) and has actively supported the development of the GHS. *See* 74 FR at 50306 (Sept. 30, 2009).

Paul A. Shulte, Ph.D., testified on behalf of NIOSH that:

> [A] significant advantage of the proposed standard is the detailed technically sound criteria for classification that will improve accuracy and consistency in the information provided to employers and employees on chemical hazards and protective measures * * *. In summary, the proposed standard will serve as a powerful tool for the protection of working people.

(Document ID #0497 Tr. 36–37). OSHA has consulted with HHS in accordance with section 6(b)(7). For all the reasons set forth above, revision of the HCS through adoption of the GHS as proposed by OSHA is authorized by section 6(b)(7) of the OSH Act, 29 U.S.C. 655(b)(7).

2. Section 6(b)(5) Authority. OSHA also has authority to adopt the proposal under section 6(b)(5) of the Act, 29 U.S.C. 655(b)(5). As noted above, section 6(b) explicitly allows OSHA to ''modify'' standards, and adoption of the GHS is justified because it ''most adequately assures'' employee protection for purposes of section 6(b)(5) for the reasons detailed in parts IV and XIII of this preamble.

HCS is a 6(b)(5) standard since it acts to mitigate the significant health risk of using dangerous chemicals without adequate hazard communication. *See Int'l Union, UAW* v. *OSHA,* 938 F.2d 1310, 1313 (D.C. Cir. 1991). The Society of the Plastics Industry, Inc. (SPI), however, argues that because the rule also addresses physical hazards, ''the agency must comply with the more demanding burden of proof at least with respect to the safety hazards,'' and that some form of cost-benefit analysis is required (Document ID #0392). OSHA disagrees. Safety standards must be ''highly protective,'' which means OSHA may ''deviate only slightly from the stringency required by section 6(b)(5).'' *Int'l Union, UAW* v. *OSHA,* 37 F.3d 665, 669 (D.C. Cir. 1994). The burden of proof for safety standards is therefore not more demanding than that required for 6(b)(5) standards, as SPI argues. Nor does OSHA believe that the OSH Act requires a cost-benefit analysis in setting safety standards. *See Control of Hazardous Energy Sources, Supplemental Statement of Reasons,* 58 FR 16612, 16621–23 (Mar. 30, 1993). However, as discussed in Section VI, Final Economic Analysis, OSHA has examined the costs and benefits of the final rule, and found that the benefits exceed costs by a large margin. In any event, OSHA believes that the more protective requirements of section 6(b)(5) apply to this standard because the standard addresses health hazards.

Standards adopted under the authority of section 6(b)(5) must be supported by a finding of significant risk. However, as explained elsewhere, the GHS is an improved method of communicating chemical hazards to employers and employees over the current standard, and therefore the final rule, which incorporates the GHS, is now the ''standard that most adequately assures'' worker protection. OSH Act § 6(b)(5); 29 U.S.C. 655(b)(5). Adoption of GHS will substantially reduce the significant risk of inadequate communication workers face. As discussed above, OSHA supported the current rule with a finding, affirmed by the Third Circuit, that ''inadequate communication about serious chemical hazards endangers workers'' and that the HCS will mitigate this risk. 48 FR 53321 (Nov. 25, 1983); *United Steelworkers* v. *Auchter,* 763 F.2d at 735; *See also* 59 FR 6126, 6127, 6129, 6132–38 (Feb. 9, 1994). The record shows that this significant risk of inadequate communication was not eliminated by the current standard.

As discussed in Section IV, several studies show that employees do not understand approximately one-third of the safety and health information listed on SDSs prepared in accordance with the current standard (Document ID #0245, 0263, 0295, 0309, and 0310). Studies also report that roughly 40% of persons reviewing SDSs found them difficult to understand (Document ID #0188 and 0262). The results from these studies probably overstate the level of comprehension in the workforce, because the studies had a selection bias towards employees who have stronger English reading skills. These findings are corroborated by worker testimony stating that they and their coworkers find SDSs ''difficult and confusing,'' ''inadequate and incomprehensible,'' and a ''nightmare.'' One witness stated that employees he works with would not ask to see SDSs because they were too complicated, and as a result, the employees unwittingly expose themselves to chemical hazards (Document ID #0494 Tr. 50, 54–55; and 0499 Tr. 134, 147–48, 151, 162, 165–66, and 167).

Moreover, the evidence in the record shows workers who read SDSs prepared in a standardized format have substantially improved comprehension of the information they present (Document ID #0191, 0263, 0309, and 0310). Indeed, standards specifying uniform formats for SDSs have been adopted by ANSI and other standards bodies, indicating a consensus that standardized SDSs will more effectively communicate chemical hazards to workers and employers. Moreover, commenters overwhelmingly agreed that standardizing SDSs would improve hazard communication. (*See, e.g.,* Document ID #0330, 0335, 0336, 0341, 0344, 0348, 0357, 0370, 0372, 0376, 0381, 0410, 0414, and 0415).

Likewise, the record shows that the current HCS's performance-oriented labeling requirements result in inadequate communication. Research conducted over the last twenty years and summarized in section IV of this preamble shows that use of the signal words ''Danger'' and ''Warning,'' pictograms, red borders, and standardized hazard warnings and precautionary statements better convey information about chemical hazards. Studies show that the information conveyed by these techniques is better understood, especially among low literacy populations, better remembered, and more likely to be acted upon. Again, commenters agreed that the current performance-oriented labeling requirement leads to worker confusion, and that the standardized GHS labeling requirements would minimize that confusion. (*See, e.g.,* Document ID #0313, 0327, 0335, 0336, 0341, 0344, 0348, 0351, 0365, 0370, 0410, 0412, and 0644.)

Finally, employees still continue to suffer chemical-related injuries, illnesses and deaths. As discussed in more detail in Section VI, Final Economic Analysis, of the preamble, OSHA estimates that over 40 million employees are potentially exposed to hazardous chemicals. BLS data show that in 2007, there were approximately 55,400 illnesses related to hazardous chemical exposures and 125 chemical-related fatalities. These statistics probably represent only a small portion of the illnesses experienced by exposed employees; most occupational illnesses are not reported because they are not recognized as being related to workplace exposures and are subject to long latency periods between exposure and the manifestation of disease. The most recent nationwide study of chronic illness estimated that in 1992, there were between 46,900 to 73,700 fatalities from chronic illnesses related to occupational exposures to chemicals (Document ID #0274). In addition, a 2004 study of chronic occupational illness in California reported that more than 200,000 workers were diagnosed with serious chronic diseases attributable to chemical exposures in the workplace, and that an additional 4,400 workers in California died during that year from chemical exposures in the workplace (Document ID #0269).

These data corroborate the idea that currently there is inadequate communication of chemical hazards in the workplace. Further, they show that the use of chemical hazards in the workplace creates a significant risk to employees. For the reasons explained above and in sections IV and XIII of the preamble, OSHA believes that the final rule will reduce the risk to employees by providing better and more easily understood information to employees and employers about the hazards of the chemicals they use, which in turn will allow precautionary measures to be taken.

In its post-hearing comment, the Styrene Information and Research Council (SIRC) argued that OSHA should also have examined injury and illness rates in the EU. It states that ''the GHS is substantially the system that has been in place in the EU for the last 40 years'' for substances covered by the EU Dangerous Substances Directive and for the 10 years for mixtures covered by the EU Dangerous Preparations Directive (Document ID #0642). OSHA disagrees with SIRC's premise. There are significant differences between the GHS and the relevant EU directives. These differences include the criteria for classifying hazards, as well as the label elements used to communicate the hazardous effects. In addition, even if the EU's hazard communications obligations were substantially similar to the GHS, there are technical hurdles that would have to be overcome before such a study could yield useful information. There are significant differences in the way that statistics for occupational illness and injuries collected by the US and the EU (and its members) that make direct comparisons difficult. Furthermore, the regulatory structure for mitigating the hazards identified and communicated in varying systems also differ significantly, and this would confound any effort to compare illness and injury rates in the two jurisdictions. In any event, OSHA need not wait for scientific certainty to update its regulations, but rather it must rely on the best available evidence, and may use conservative assumptions in interpreting the evidence. OSH Act § 6(b)(5), 29 U.S.C. 655(b)(5); *Benzene,* 448 U.S. at 655–56 & n.62. As discussed above and in Sections IV and XIII, the best available evidence indicates that a significant risk continues to exist under the current standard and that the final rule will improve chemical hazard communications, thereby reducing the risk of injury, illness or death associated with the use of hazardous chemicals in the workplace.

C. Feasibility

OSHA standards must be feasible, which means ''capable of being done, executed or effected.'' *Cotton Dust,* 452 U.S. at 508–09. Feasibility has two aspects, economic and technological. *United Steelworkers of Am.* v. *Marshall,* 647 F.2d 1189, 1264 (D.C. Cir. 1981) (''*Lead I''*). 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. *Id.* at 1272. A standard is economically feasible if industry can absorb or pass on the cost of compliance without threatening its longer term profitability or competitive structure. (*See Cotton Dust,* 452 U.S. at 530 n.55; *Lead I,* 647 F.2d at 1265.)

In addressing feasibility in the 1994 HCS revisions, OSHA found that:

> The feasibility question raised by the HCS is not difficult to resolve. This standard does not relate to activities on the frontiers of scientific knowledge; the requirements are not the sorts of obligations that approach the limits of feasibility. *Associated Builders & Contractors,* 862 F.2d at 68. The record on which the original and expanded HCS's were based did not contain credible evidence that the HCS would be technologically or economically infeasible for any industrial sector, *id.,* and there was substantial evidence of feasibility, 52 FR 31855–58.

59 FR at 6133 (Feb. 9, 1994). OSHA has repeatedly found that the requirements of the HCS are technologically feasible. *See* 52 FR at 31855–57 (Aug. 24, 1987); 59 FR at 6133 (Feb. 9, 1994). While the GHS modifications to HCS impose more specific requirements for hazard classification, labeling, and safety data sheets, employers may use the same expertise and methods to meet these requirements as they are already utilizing to comply with the requirements of HCS.

As discussed below and in section VI.E of this preamble, OSHA believes the final rule poses no technological feasibility issues. The most important resource employers will need in order to comply with the GHS modifications to HCS is technical expertise in hazard classification and the communication of those hazards. OSHA found that such expertise was already available in promulgating the initial HCS rule in 1983. 48 FR at 53296–99 (Nov. 25, 1983). OSHA believes that the availability of professionals with this expertise has only increased in the intervening time. The GHS has already been implemented, in whole or in part, by a number of major U.S. trading partners, including Japan and the EU. Companies that export to these jurisdictions should already have developed expertise in the GHS, and there are a number of GHS training resources developed on the international level (Document ID #0405, 0410, and 0514). At least one professional organization currently provides GHS training in hazard communication to professionals and businesses in the United States (Document ID #0021 and 0145). Through OSHA's Alliance with the Society for Chemical Hazard Communication, training to small businesses in the requirements of hazard communication and information about the GHS modifications has been made available. *See http://www.osha.gov/dcsp/alliances/schc/schc.html.* NIOSH is preparing a program for employers to use in training their employees in the new labeling scheme (Document ID #0412). OSHA received numerous comments discussing the professionals and tools (both manual and electronic) that employers have available to comply with current hazard communication requirements. (*See, e.g.,* Document ID #0015, 0024, 0026, 0036, 0038, 0042, 0046, 0050, 0053, 0072, 0077, 0107, 0108, 0116, 0123, 0128, 0141, 0144, 0145, 0154, 0155, 0163, 0330, 0352, and 0389.) The Agency has been engaged on several fronts to facilitate the transition from the current standard to the GHS modifications. For instance, the United Nations Institute for Training and Research is developing basic and more advanced training courses for the GHS, and OSHA has been involved with and committed resources to this effort. As discussed in more detail below in the Summary and Explanation, OSHA plans to issue a number of outreach and compliance assistance materials. Additionally, NIOSH testified that the World Health Organization has started the process to convert International Safety Cards to GHS and as of March 2010; approximately 249 (15%) have already been converted (Document ID #0497 Tr. 46). OSHA believes that adopting the GHS modifications poses no technological feasibility issues.

Likewise, for the reasons more fully discussed in Section VI, Final Economic Analysis, OSHA believes that the adoption of GHS will not pose economic feasibility issues. Again, OSHA previously found that the implementation of HCS would have no such effect. *See* 52 FR at 31855–57 (Aug. 24, 1987); 59 FR at 6133 (Feb. 9, 1994). As discussed in Section VI, OSHA has found that, once conversion to the new system is completed, compliance with the GHS-modified HCS will not be more expensive than compliance with the current HCS and will result in savings for employers. While industry will incur the cost of converting to the new system, OSHA does not believe that this cost is so substantial as to threaten long term profitability or the competitive structure of any industry.

VI. Final Economic Analysis and Voluntary Regulatory Flexibility Analysis

A. Introduction and Summary

Introduction

OSHA is required by the Occupational Safety and Health (OSH) Act of 1970 to ensure and demonstrate that standards promulgated under the Act are reasonably necessary and appropriate, as well as technologically and economically feasible. Executive Orders 12866 and 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act also require OSHA to estimate the costs, assess the benefits, and analyze the impacts of certain rules that the Agency promulgates. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. OSHA has determined that this action is ''economically significant'' within the meaning of 3(f)(1) of the executive order because it is likely to have an effect on the economy of $100 million or more in any one year. Accordingly, the rule has been reviewed by OMB.

Accordingly, OSHA has prepared this Final Economic Analysis (FEA), including a Final Regulatory Flexibility Screening Analysis (FRFSA), for the modifications to the Hazard Communication Standard (HCS). The OSHA FEA is based largely on research conducted for the Preliminary Economic Analysis (PEA) by Policy, Planning, and Evaluation, Inc. (PP&E), as presented in its revised final report, ''Data and Analysis in Support of an Economic Analysis of Proposed Changes to the OSHA Hazard Communication Standard,'' prepared under contract to OSHA, and on research conducted for purposes of completing this FEA by Eastern Research Group (ERG). ERG and OSHA analyses updated both costs and benefits. The materials prepared by PP&E, 2009 (Document ID #0273) and ERG (2010, 2011, and 2012) [1] are available in the public docket for this rulemaking, OSHA–H022K–2006–0062, through *www.regulations.gov.*

Need for Regulation

Employees in work environments covered by the HCS are exposed to a variety of significant hazards that can and do cause serious injury and death. The HCS serves to ensure that both employers and employees are provided needed information about chemical hazards that was not provided by markets in the absence of such a standard. The HCS also facilitates interstate commerce by promoting consistency among federal and individual state requirements.

The changes to the HCS will create a uniformity standard for the presentation of hazard information and, as such, will serve to improve the efficiency and effectiveness of the existing hazard communication system in the U.S., and to reduce unnecessary barriers to trade. Hazard communication is currently addressed by many different international, national, and State authorities. As described in Section IV of this preamble, these existing requirements are not always consistent and often contain different definitions of hazards and varying provisions for what information is required on labels and safety data sheets. Complying with these different rules results in increased costs for employers with hazardous chemicals in their workplace and for chemical manufacturers, distributors, and transporters involved in international trade. In addition to these effects on businesses, the different existing requirements result in workplaces receiving chemicals with varying information, with potential adverse impacts on the safety and health of employees. The revisions to the OSHA HCS will standardize the hazard communication requirements for products used in U.S. workplaces, and thus provide employees with uniform and consistent hazard communication information. Secondarily, because these revisions will harmonize the U.S. system with international norms, they will facilitate international trade.

Affected Industries

The revisions would affect employers and employees in many different industries across the economy. Based on ERG (2012), OSHA estimates that the HCS covers over five million workplaces in which employees are potentially exposed to hazardous chemicals (*see* Table VI–3).

For establishments with employees whose only exposures to hazardous chemicals result from their use of the chemical products, the revisions to the HCS would generally involve minor effects, such as familiarization with new warning labels. For establishments producing hazardous chemicals, which are generally part of the chemical manufacturing industry, the revisions to the standard would involve reclassifying chemicals in accordance with the new classification system and revising safety data sheets (SDSs) and labels associated with hazardous chemicals. OSHA has judged that SDSs for imported chemicals would normally be produced in the country of origin, and thus would not represent expenses for importers. OSHA solicited comment on this judgment in the PEA and did not receive any contrary testimony or evidence.

Benefits

There is ample evidence of the substantial risks of chemical exposure in the workplace. In 2007, according to the Bureau of Labor Statistics, employees suffered an estimated 55,400 illnesses attributable to chemical exposures (BLS, 2008), and some 17,340 chemical-source injuries and illnesses involved days away from work (BLS, 2009). However, as noted in the preamble to the HCS in 1983, BLS

[1] Eastern Research Group (ERG, 2010). Harmonization of Hazard Communication: Labeling Costs. Final Report. Submitted to Occupational Safety And Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis, Contract No. GS–10–F–0125P. April 28, 2010. Eastern Research Group (ERG, 2011). Harmonization of Hazard Communication: Summary of Labeling Costs. Final Report. Submitted to Occupational Safety And Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis, Contract No. GS–10–F–0125P. March 23, 2011.

Eastern Research Group (ERG, 2012). Excel Spreadsheets in Support of OSHA Final Economic Analysis for GHS Rule. Submitted to Occupational Safety And Health Administration, Directorate of Evaluation and Analysis, Office of Regulatory Analysis, Contract No. GS–10–F–0125P. January 20, 2012.

estimates probably only reflect a small percentage of occupational illnesses (48 FR 53284, Nov. 25, 1983) because most occupational illnesses are not reported. The principal reasons are that they are not recognized as being related to workplace exposures and are subject to long latency periods between exposure and the manifestation of disease. The key study of the issue of the number of fatalities from chronic illnesses, not recorded in any way by BLS, is Leigh *et al.,* 1997 (Document ID#0274). That study found that in 1992, there were from 46,900 to 73,700 fatalities from chronic illnesses related to occupational exposures to chemicals. This critical category dwarfs all acute injuries and illnesses due to chemicals recorded by BLS.[2]

Section IV of this preamble describes some of the incidents that may have been related to the non-standardized approach to SDSs in the current HCS, including xylene exposure at a hospital when an employee was unable to find critical information on an SDS in an emergency spill situation (Document ID #0251). As a result, twelve employees required emergency room treatment. Were the information on SDSs more uniformly formatted and comprehensible, as required under the modifications to HCS, incidents such as this would be less likely to occur.

In general, the modifications to the HCS are expected to result in increased safety and health for the affected employees and to reduce the numbers of accidents, fatalities, injuries, and illnesses associated with exposures to hazardous chemicals.

It is difficult to quantify precisely how many injuries, illnesses, and fatalities would be prevented due to the revisions to the HCS.[3] The benefits associated with the current HCS may indirectly help provide a general sense of the potential magnitude of the benefits of the revisions to the HCS.

OSHA estimates that if the rule could capture one percent of the benefits estimated for the original 1983 and 1987 HCS rules, the revisions would result in the prevention of 318 non-lost-workday injuries and illnesses, 203 lost-workday injuries and illnesses, 64 chronic illnesses, and 43 fatalities annually. The monetized value of the corresponding reduction in occupational risks among the affected employees is an estimated $250 million on an annualized basis.

The harmonization of hazard classifications, safety data sheet formats, and warning labels for affected chemicals and products would also yield substantial savings to businesses. Fewer different SDSs would have to be produced for affected chemicals, and many SDSs would be able to be produced at lower cost due to harmonization and standardization. The benefits represented by these cost reductions would primarily affect businesses involved in chemical manufacturing. In addition, businesses that purchase or use hazardous chemicals can expect reductions in operating costs as a result of the promulgation and implementation of the modifications to the HCS due the standardization of SDSs, which will make it easier to locate information and determine handling requirements, and other factors related to simplification and uniformity which will improve workplace efficiency.

In 2008, in preparation for OSHA's Notice of Proposed Rulemaking, PP&E conducted extensive research on the processes that companies use to classify chemical hazards, to develop SDSs and labels, and to handle, store, and use hazardous chemicals. PP&E evaluated how these processes would be affected by the revisions to the HCS and analyzed the potential savings that would be realized as a result of adopting these revisions. Using the parameters estimated by PP&E through its research and employing updated data on wages and the number of affected establishments and employees, OSHA has concluded that the annual cost savings for these companies would be an estimated $507.4 million.

OSHA also expects the revised HCS will reduce the costs of providing hazard communication training to employees in future periods. Stakeholders largely corroborated that expectation. Standardized SDS and label formats will reduce the amount of time needed to familiarize employees with the HCS, which will reduce the training time for all employees once the final rule is fully implemented. OSHA did not monetize these estimated cost savings, but anticipates that they will be substantial.

As an additional benefit, the modification of the HCS by the inclusion of the globally harmonized system (GHS) of classification and labeling of chemicals would be expected to facilitate international trade, increasing 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 both the direct savings resulting from harmonization and the increased competitiveness, prices for the affected chemicals and products, and the corresponding goods and services using them, would be lowered.

Finally, the GHS modifications to the OSHA HCS would meet the international goals for adoption and implementation of the GHS that have been supported by the U.S. government. Implementing GHS in U.S. federal laws and policies through appropriate legislative and regulatory action was anticipated by the U.S. support of 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 Chemicals Management, a policy framework that the U.S. helped to craft (*See http://www.chem.unep.ch/saicm/*).

Compliance Costs

The estimated compliance costs for the revisions to the HCS represent the additional costs necessary for employers to achieve full compliance. They do not include costs associated with current compliance that has already been achieved; nor do they include costs necessary to achieve compliance with existing requirements, to the extent that some employers may currently not be fully complying with applicable regulatory requirements.

The majority of the costs associated with compliance with the revisions to the HCS would generally be incurred by the affected industries as one-time transitional costs over the phase-in period of four years including the costs to reclassify chemical hazards and revise SDSs and labels, to train workers, and for management to familiarize itself with the requirements of the final rule. There will be additional ongoing annual compliance costs associated with the revisions to the HCS due to the cost to purchase and maintain color printing ink or cartridges or to purchase pre-printed color labels in order to comply

[2] A more recent study prepared by the University of California Centers for Occupational and Environmental Health, and commissioned by the California Environmental Protection Agency, suggests that fatalities from chronic illnesses remain an important problem (University of California COEH, 2008 p. 18). That study estimated that, in 2004, more than 200,000 workers, in California alone, were diagnosed with serious chronic diseases (encompassing cancer, COPD, asthma, pneumoconiosis, chronic renal failure, and Parkinson's disease) attributable to chemical exposures in the workplace, and that an additional 4,400 workers in California died during that year from chemical exposures in the workplace.

[3] While comments in the record did not attempt to estimate the magnitude of these safety and health benefits, they largely supported the conclusion that these revisions would yield increased protection for workers. For additional discussion of the comments regarding OSHA's estimate of benefits, see Section VI:D Benefits in this preamble.

with the requirement that the GHS hazard warning pictogram be presented with a red border. However, OSHA's analysis has found that these costs will not be substantial relative to the other costs of the rule.

The compliance costs are expressed as an annualized cost for purposes of assessing the cost-effectiveness of the revisions, in order to be able to compare the economic impact of the rulemaking with other regulatory actions, and to be able to add and track federal regulatory compliance costs and economic impacts in a consistent manner. Annualized costs also represent a better measure for assessing the longer-term potential impacts of the rulemaking. A seven percent discount rate was applied to costs incurred in future years to calculate the present value of these costs 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 20-year period,[4] to calculate the annualized cost.

[4] OSHA annualized costs for this rule over a 20-year period in accordance with Executive Order 13563, which directs agencies "to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible." In addition, OMB Circular A–4 states that analysis should include all future costs and benefits using a "rule of reason" to consider for how long it can reasonably predict the future and should limit its analysis to this time period. The choice of a 20-year period is designed to capture out-year benefits given a 4-year phase-in period. A shorter period would place too much emphasis on the phase-in period, where benefits would not be accruing. A longer discount period might over-emphasize the long-term benefits since net benefits increase with the length of the annualization period. As a comparison, the life of OSHA's original hazard communication rule was 1987 to 2011, a 24-year period, suggesting that 20 years is a reasonable estimate.

The total annualized cost of compliance with the final rule is estimated to be about $201 million. The major cost elements associated with the revisions to the standard include the classification of chemical hazards in accordance with the GHS criteria and the corresponding revision of safety data sheets and labels to meet new format and content requirements ($22.5 million); training for employees to become familiar with new warning symbols and the revised safety data sheet format ($95.4 million); management familiarization and other management-related costs as may be necessary ($59.0 million); and costs to purchase upgraded label printing equipment and supplies or to purchase pre-printed color labels in order to include the hazard warning pictogram enclosed in a red-bordered diamond on the product label ($24.1 million).

Net Benefits, Cost-Effectiveness, and Regulatory Alternatives

Table VI–1 provides a summary of the costs and benefits of the modifications to the OSHA HCS, and it shows the net benefits of the modifications to the standard are estimated to be $556 million annually, using a discount rate of 7 percent to annualize costs and benefits. (Using a 3 percent discount rate instead would have the effect of lowering the costs to $161 million per year and increasing the gross benefits to $839 million per year. The result would be to increase net benefits from $556 million to $674 million per year.) Because compliance with the standard would result in cost savings that exceed costs, OSHA has not provided estimates of costs per life saved or other metrics of cost-effectiveness. However, it should be noted that the estimated benefits exceed costs by more than a factor of three.

In response to comments on the proposed rule, OSHA has made the following changes to the economic analysis from the PEA to the FEA:

(1) Increased by 100 percent the amount of training time necessary to train employees on the revised HCS during the transition period—from 30 minutes to 60 minutes;

(2) Increased by over 60 percent the number of SDSs (with corresponding labels) covered by the rule—from approximately 0.9 million to over 1.4 million;

(3) Added annualized costs of $24.1 million to print product labels in color; and

(4) Incorporated updated economic data on the number of establishments, number of employees, annual revenues, annual profits, etc. and adjusted estimates from 2007 dollars to 2010 dollars.

The change from 2007 to 2010 dollars using the GDP deflator (for non-wage-related costs and benefits) increased affected costs and benefits by about 4 percent. The rule changes that increased the phase-in period reduced the annualization factors and the associated costs and benefits by about 9.6 percent. All other changes to costs and benefits were the result of updated economic data, including wages, and revised cost factors (e.g., number of SDSs, number of affected employees) in response to comments on the proposed rule.

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Table VI-1: Net Benefits

The point estimates below do not reflect the uncertainties described throughout the analysis. While OSHA is reluctant to provide quantified ranges, OSHA recognizes that these estimates are uncertain. OSHA provides a Sensitivity Analysis on these estimates in the final section of the FEA.

Annualized Costs	
Reclassification of Chemical Hazards and Revision of SDSs and Labels	$22.5 million
Employee Training	$95.4 million
Management Familiarization and Other Costs	$59.0 million
Additional Label Printing Costs	$24.1 million
Total Annualized Costs:	$201 million
Annual Benefits	
Number of Non-lost-workday Injuries and Illnesses Prevented	318 (159 - 1,590)
Number of Lost Workday Injuries and Illnesses Prevented	203 (101 - 1,015)
Number of Chronic Injuries Prevented	64 (32 - 302)
Number of Fatalities Prevented	43 (22 - 215)
Monetized Benefits of Reduction in Safety and Health Risks	$250 ($125 - $1,250) million
Savings from Productivity Improvements for Health and Safety Managers and Logistics Personnel	$475.2 million
Savings during Periodic Updating of SDSs and Labels	$32.2 million
Savings from Simplified Hazard Communication Training	unquantified
Reductions in non-tariff trade barriers	unquantified
OSHA standards that are consistent with international standards, consensus standards, and standards of other federal regulatory agencies	unquantified
Contribution towards achieving international goals supported by the U.S. government	unquantified
Total Annual Monetized Benefits:	$757 ($632 - $1,757) million
Net Annual Monetized Benefits (Benefits Minus Costs):	$556 ($431-1,556) million

Note: Costs and benefits are expressed in 2010 dollars and are discounted at a 7% discount rate.

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As discussed in Section III of this preamble, the available alternatives to the final rule are somewhat limited since this final rule modifies the current HCS in order to align with the provisions of the UN's GHS. In Section III, the Agency qualitatively discussed the two major alternatives presented during this rulemaking process—(1) voluntary adoption of GHS within the existing HCS framework and (2) a limited adoption of specific GHS components and a variation on (1) that would require compliance with GHS but allow an exemption for small businesses to comply with either the current HCS or with the GHS-compliant HCS. All of these alternatives were soundly rejected by stakeholders. To allow certain parties to follow an alternative system or to allow voluntary adoption of the elements of a uniformity standard does nothing to reduce confusion, improve efficiency, or simplify processes. In order for those benefits to be realized, all elements must apply to all affected parties. OSHA has determined that both of the alternatives presented above would eliminate significant portions of the benefits of the rule.

OSHA did not attempt to evaluate the costs and benefits for the regulatory alternatives that involved partial or voluntary adoption of the GHS. The Agency did evaluate two alternatives where the effective dates were altered. In the first alternative considered, all elements of the revised HCS would be required to be implemented within two years. Under this alternative, all transitional costs would be incurred in two years and benefits would be realized beginning in the third year. The second alternative that OSHA evaluated extended the timeline for training to be completed. For this alternative, all elements of the revised HCS (including training) would be required to be implemented by June 1, 2016. Under this alternative, training costs would not be realized for four and a half years (as opposed to the two year requirement for training in the final version of this rule) while benefits would not be realized for five years (unchanged from the final rule). The results of these evaluations are presented in Table VI–2 below and are discussed in further detail, *including significant qualifications,* in Section VI:G Net Benefits, Cost Effectiveness, and Regulatory Alternatives in this preamble. Although both alternatives show greater net benefits, the Agency concludes that the timing of the final rule is preferable because of additional (but unquantified) compliance costs and reduced (but unquantified) benefits under the first alternative and because of reduced (but unquantified) worker health and safety benefits under the second alternative. In addition, OSHA expects that the final rule offers coordination benefits in that its requirements will fully take effect at the same time as the EU completes its transition.

Table VI-2
Regulatory Alternatives

	Years After Promulgation								
	To Complete Training	For Full Implementation	Until Benefits are Realized	Annualized Benefits	Annualized Costs	Annualized Net Benefits	Benefits Relative to Final Rule Implementation Timeline	Costs Relative to Final Rule Implementation Timeline	Net Benefits Relative to Final Rule Implementation Timeline
Alternative 1									
	2 years	2 years	3 years	$923 million	$206 million	$717 million	+ $166 million	+ $5 million	+ $161 million
Final Rule Implementation Timeline									
	2 years	4.5 years	5 years	$757 million	$201 million	$556 million	--	--	--
Alternative 2									
	4.5 years	4.5 years	5 years	$756 million	$189 million	$568 million	--	-$12 million	+ $12 million

Source: Office of Regulatory Analysis, OSHA

Economic Impacts

To assess the nature and magnitude of the economic impacts associated with compliance with the final rule, OSHA developed quantitative estimates of the potential economic impact of the new requirements on entities in each of the affected industry sectors. The estimated compliance costs were compared with industry revenues and profits to provide an assessment of the economic feasibility of complying with the final rule and an evaluation of the potential economic impacts.

Only the compliance costs were considered for purposes of assessing the potential economic impacts and economic feasibility of the revisions. As described in Section VI.G: Net Benefits, Cost-effectiveness, and Regulatory Alternatives, in this preamble, the overall economic impacts associated with this rulemaking are expected to result in significant net benefits to employers, employees, and the economy generally.

As described in greater detail in Section VI.F: Costs of Compliance in this preamble, the costs of compliance with the rulemaking are not large in relation to the corresponding annual financial flows associated with each of the affected industry sectors. The estimated costs of compliance represent about 0.001 percent of revenues and about 0.011 percent of profits, on average, across all entities; compliance costs represent less than 0.09 percent of revenues or, with the exception of three chemical manufacturing industries, less than 0.9 percent of profits in any individual industry sector. These three chemical manufacturing industries are NAICS 325181 Alkalies & chlorine manufacturing, NAICS 325191 Gum & wood chemical manufacturing, and NAICS 325992 Photographic film, paper, plate, & chemical manufacturing, and their compliance costs as a percentage of profits are 4.3 percent, 2.1 percent, and 2.4 percent, respectively. The higher percentage of profits for these three industries are mainly the result of low profit margins, low baseline estimates of the number of color printers currently employed in these industries (causing higher costs of compliance with the color printing requirements), and a large estimated number of labels produced by these industries.

The economic impact of achieving compliance with the final rule, without considering the associated benefits, is most likely to consist of an extremely small increase in prices of about 0.001 percent, on average, for affected hazardous chemicals. It is highly unlikely that a price increase of this magnitude would significantly alter the types or amounts of goods and services demanded by the public or any other affected customers or intermediaries. If the compliance costs of the final rule can be substantially recouped with a minimal increase in prices, there may be little or no effect on profits.

In general, for most establishments, it would be very unlikely that none of the compliance costs could be passed along in the form of increased prices. In the event that a price increase of 0.001 percent were not possible, profits in the affected industries would be reduced by an average of about 0.011 percent.

Given the minimal potential impact on prices or profits in the affected industries, OSHA has concluded that compliance with the requirements of the rulemaking would be economically feasible in every affected industry sector.

In addition, based on an analysis of the costs and economic impacts associated with this rulemaking, OSHA concludes that the effect of the final rule on employment, wages, and economic growth for the United States would be negligible. The effect on international trade is likely to be beneficial and similar to the effect of a small reduction in non-tariff trade barriers.

Final Regulatory Flexibility Screening Analysis

OSHA has analyzed the potential impact of the final rule on small entities, and has prepared a Final Regulatory Flexibility Screening Analysis (FRFSA) in conjunction with this rulemaking to describe the potential effects on small entities. The FRFSA is included as a part of this preamble in Section VI:I.

As a result of the analysis of the potential impact on small entities, OSHA concludes and certifies that the rulemaking would not have a significant impact on a substantial number of small entities. Therefore, a Final Regulatory Flexibility Analysis (FRFA) is not required for this rulemaking. Nevertheless, OSHA has voluntarily provided the elements of the FRFA as part of the FRFSA presented in Section VI:I: Final Regulatory Flexibility Screening Analysis in this preamble. As part of this rulemaking, OSHA has fulfilled its requirements under the Regulatory Flexibility Act and under the Small Business Regulatory Enforcement Fairness Act, as applicable, to ensure that no unnecessary burdens are imposed on small businesses.

The remainder of this FEA includes the following sections:

B. Need for Regulation
C. Profile of Affected Industries
D. Benefits
E. Technological Feasibility
F. Costs of Compliance
G. Net Benefits, Cost-Effectiveness, and Regulatory Alternatives
H. Economic Feasibility and Impacts
I. Final Regulatory Flexibility Screening Analysis
J. Environmental Impacts
K. Unfunded Mandates Reform Act Analysis
L. Sensitivity Analysis

B. Market Failure and the Need for Regulation

Employees in work environments addressed by OSHA's hazard communication standard (HCS) are exposed to a variety of significant hazards associated with chemicals used in the workplace that can and do cause serious injury and death. OSHA's HCS was designed to ensure that employers and employees are provided the information they need about the hazards in chemical products both to make informed purchases and to provide for safe use. The current HCS contains a set of requirements for chemical products, including mandatory hazard determination, labeling, and detailed information (in safety data sheets). Based on evidence presented in the record,[5] OSHA determined that the revisions to the HCS will make employers' hazard communication programs more worker-protective, efficient, and effective. In addition, the revisions will have the effect of harmonizing hazard communication to facilitate international trade by replacing a plethora of national rules with a single international system.

The standard, through conformance with GHS (as explained in Section IV and XIII of this preamble), contains a number of changes to improve the performance of the U.S. hazard communication system:

- Revised criteria for more consistent classification of chemical hazards;
- Standardized signal words, pictograms, hazard statements, and precautionary statements on labels; and
- A standardized format for SDSs.

In short, GHS is a ''uniformity standard'' for the presentation of hazard information (Hemenway, 1975, Document ID #0293, Tr. 8). And much

[5] *See* Document ID #0303, 0313, 0322, 0324, 0327, 0328, 0329, 0330, 0331, 0334, 0335, 0336, 0339, 0340, 0341, 0344, 0345, 0346, 0347, 0349, 0350, 0351, 0352, 0353, 0354, 0356, 0357, 0359, 0363, 0365, 0367, 0369, 0370, 0371, 0372, 0374, 0375, 0376, 0377, 0378, 0379, 0381, 0382, 0383, 0385, 0386, 0387, 0388, 0389, 0390, 0392, 0393, 0396, 0397, 0399, 0400, 0402, 0403, 0404, 0405, 0407, 0408, 0409, 0410, 0411, 0412, 0414, 0417, 0453, 0456, 0461, and 0463 and additional discussion in Section III of this preamble.

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, GHS will provide significant efficiencies and economies.[6] In the case of GHS, manufacturers will be able to produce SDSs at lower cost, and users of SDSs will be able to more fully and quickly utilize the information contained in the SDSs, thereby reducing costs and, more importantly, better protect workers against chemical hazards.[7]

Since publication of the current HCS, there has been some movement by industry toward standardization, consistent with the revisions. However, OSHA does not believe that full and comprehensive standardization as required under the revisions, or the goal of harmonizing the U.S. system with the international one, can be achieved voluntarily in the absence of regulation.

First, in a basic sense, GHS cannot simply be implemented by the market. Some aspects of GHS, such as the reorganization of SDSs, would be allowed under the current OSHA standard, but other aspects, such as the classifications system, would not be. Use of differing classification criteria would lead to label warnings that are not consistent with current HCS requirements in some situations. Thus, at a minimum, OSHA would need to modify HCS to allow the use of GHS in the U.S. OSHA cannot simply provide a compliance interpretation that labels and safety data sheets prepared in accordance with the GHS meet the HCS requirements because the requirements of a standard cannot be changed through a compliance interpretation. While there is considerable overlap between the HCS and the GHS in terms of coverage, there are differences in the criteria used to classify both substances and mixtures that can result in different hazards being covered in some situations. This is particularly true in the area of acute toxicity, where OSHA is covering more substances under the modified rule than the current HCS, but potentially fewer mixtures.[8]

Second, it is important to understand that while the costs of creating SDSs and labels under GHS are borne directly by the chemical producers, the bulk of the benefits of adopting GHS accrue to the users. The set of all users includes employers who are direct customers of a chemical manufacturer, employees who use or are exposed to workplace chemicals, and emergency responders who typically have no market relationship with the producers of the chemical. Even if one thought that market forces might ensure the socially optimal approach to SDSs between manufacturers of chemicals and their customers, there are limited market forces at work between the chemical manufacturer and these two other sets of users—the employees and the emergency response community. Therefore, the benefits achieved by a uniformity standard, such as GHS, cannot be obtained in the private market, without regulation.

OSHA does anticipate that there will be some increased market pressure to comply with GHS that will affect some firms that may think that they have no need to switch to the GHS system because they do not ship their products internationally. Many small firms do not realize the extent to which they are involved in international trade. There are probably few companies who have products that are never involved in international trade, or who never import chemical products and need hazard communication information for them. Many chemical producers ship their products to distributors and are unaware of where their products are ultimately used. OSHA can envision a likely scenario in which these distributors put pressure on their suppliers to become GHS-compliant. Further, small companies sell products to larger companies. The larger companies may use those products to prepare goods that are exported. These larger companies might also be expected to pressure their small-firm suppliers to be GHS-compliant. Nevertheless, such an approach would surely involve a long transition period, with attendant losses in worker protection and production efficiencies, and it is doubtful that market pressure alone would achieve full compliance.

The changes made by GHS will involve costs for all parties. Producers of chemicals will incur substantial costs, but will also achieve benefits—in part because they themselves benefit as both producers and users, and in part, as a result of foreign trade benefits that OSHA has not quantified. Some producers may not see these types of trade benefits unless they engage in chemical export. However, many small companies are currently prevented from engaging in international trade because of the substantial burdens of complying with many different countries' requirements. International harmonization of hazard communication requirements would enable these small companies to become involved in international trade if they so desire.

Of more significance to the concerns of the OSH Act, the changes also provide substantial benefits to users, including:

- Fewer worker illnesses, injuries, fatalities, and accidents due to a more consistent and comprehensible system that does not require English literacy to obtain some minimal hazard information;
- Greater ease of use of SDSs; and
- Less time needed to train workers due to a clearer and more uniform system.

Because many of these benefits require uniformity, and the benefits are dispersed throughout a network of producers and users, only some of which have direct market relationships with each other, OSHA believes that only a single, uniform standard can achieve the full net benefits available to a hazard communications system.

C. Profile of Affected Industries

The revisions to the HCS would affect establishments in a variety of different industries in which employees are exposed to hazardous chemicals or in which hazardous chemicals are produced. Every workplace in OSHA's jurisdiction in which employees are exposed to hazardous chemicals is covered by the HCS and is required to have a hazard communication program.

The revisions to the HCS are not anticipated to either increase or

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[6] In contrast to a uniformity standard, 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, only a specification standard would guarantee that employees are protected 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 this rule) 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 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 non-existent or minuscule.

[7] On the ability of individuals to more fully and effectively utilize knowledge when uniformity requirements are present, see Hemenway, 1975 (Document ID #0293), pp. 34–35.

[8] The coverage of fewer mixtures is due to the bridging principles and formula being applied to the mixtures' classification, rather than being based strictly on a 1 percent cut-off.

decrease the scope of affected industries or establishments. 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 requirements of the standard is not substantially different from the previous version of HCS. Therefore, the revisions should have little or no effect on whether an entire establishment falls within the scope of the standard. OSHA solicited comment on this determination and received no comment in the record presenting contrary evidence.

For establishments with employees exposed to hazardous chemicals, the revisions to the HCS will generally involve management becoming familiar with and employees receiving training on the new warning labels and the new format of the SDSs. For establishments producing or importing hazardous chemicals, generally as part of the chemical manufacturing industry, these revisions to the standard will involve reclassifying chemicals in accordance with the new classification system and revising safety data sheets and labels associated with hazardous chemicals.

OSHA's estimates of the number of employees covered by the standard are based on the determination that all production employees in manufacturing will be covered, and that, in addition, employees in other industries working in any of the occupations specified in the PP&E (2009) report would also be exposed to hazardous chemicals.

Table VI–3 provides an overview of the industries and estimated numbers of employees potentially affected by the HCS. The data in this table update the estimates provided in the PEA in support of the proposed rule. They rely on the most recent data from the U.S. Census Bureau (2007a, 2007b).[9]

The industries and establishments affected by the revisions can be divided into two categories. The first category contains establishments that are required to produce labels and SDSs; the second category contains establishments that do not produce labels or SDSs but are required to provide employee access to labels and SDSs, supplied by others, for the chemicals to which their employees may be exposed in the workplace. As noted in the introduction to this FEA, OSHA has judged that SDSs and labels for imported chemicals would normally be produced in the country of origin, and thus would not represent expenses for importers or other US firms.

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[9] U.S. Census Bureau (2007a). County Business Patterns, 2007. U.S. Department of Commerce. Available at: *http://www.census.gov/econ/cbp/*. U.S. Census Bureau (2007b). 2007 Economic Census. U.S. Department of Commerce. Available at: *http://www.census.gov/econ/census07/*.

Table VI-3.
Industry Profile

NAICS Code	Industry	Total Number of Firms	Number of Affected Firms	Total Number of Establishments	Number of Affected Establishments	Total Employees	Employees to be Trained	Number of SDSs Produced
11	**Agriculture, Forestry, Fishing & Hunting**							
113	Forestry & Logging	10,303	10,303	10,491	10,491	64,445	17,638	0
114	Fishing, Hunting and Trappinig	2,380	856	2,389	862	9,244	1,637	0
115	Support Activities for Ag & Forestry	10,271	4,412	10,765	4,895	100,513	12,278	0
211	**Oil and Gas Extraction**							
211111	Crude petroleum & natural gas extraction	6,424	6,424	7,221	7,221	133,286	82,953	56,995
211112	Natural gas liquid extraction	139	130	321	311	8,218	6,919	6,145
212	Mining (except Oil & Gas)	4,465	4,465	7,008	7,008	218,044	174,991	0
213	Support Activities for Mining	9,809	9,809	11,652	11,652	341,034	252,262	0
22	**Utilities**							
2211	Electric Power Gen, Trans & Distrib	1,687	1,687	9,611	9,611	503,134	315,623	0
2212	Natural Gas Distribution	507	507	2,283	2,283	79,354	34,240	0
2213	Water, Sewage, & Other Systems	3,998	3,998	4,780	4,780	40,269	21,875	0
23	**Construction**							
236	Construction of Buildings	242,322	242,322	244,862	244,862	1,672,254	1,148,424	0
237	Heavy Construction	49,228	49,228	51,421	51,421	1,016,407	617,651	0
238	Special Trade Contractors	508,722	508,722	515,169	515,169	4,579,222	3,610,532	0
31	**Manufacturing**							
311	Food Manufacturing	21,591	21,591	25,796	25,796	1,439,266	1,116,334	0
312	Beverage &Tobacco Prod. Manuf.	3,466	3,466	4,069	4,069	156,114	90,970	0
313	Textile Mills	2,690	2,690	3,092	3,092	164,082	138,640	0
314	Textile Product Mills	6,471	6,471	6,732	6,732	152,978	124,024	0
315	Apparel Manufacturing	10,151	10,151	10,368	10,368	350,439	275,995	0
316	Leather & Allied Product Manufac.	1,348	1,348	1,392	1,392	36,671	29,133	0
321	Wood Product Manufacturing	14,608	14,608	16,622	16,622	527,565	429,838	0
322	Paper Manufacturing	3,259	3,259	5,037	5,037	425,096	329,797	0
323	Printing and Related Support	31,655	31,655	33,281	33,281	631,771	461,828	0
324	**Petroleum & Coal Prod. Manufac.**							
324110	Petroleum refineries	258	258	374	374	64,263	39,080	26,740
324121	Asphalt paving mixture & block mfg	481	481	1,386	1,386	14,457	10,739	132,545

Table VI-3.
Industry Profile (continued)

NAICS Code	Industry	Total Number of Firms	Number of Affected Firms	Total Number of Establishments	Number of Affected Establishments	Total Employees	Employees to be Trained	Number of SDSs Produced
324	**Petroleum & Coal Prod. Manufac.**							
324122	Asphalt shingle & coating materials mfg	126	126	229	229	11,598	8,503	18,415
324191	Petroleum lubricating oil & grease m	290	290	329	329	10,136	5,426	559,300
324199	All other petroleum & coal products mfg	72	72	90	90	3,123	2,370	5,030
325	**Chemical Manufacturing**							
325110	Petrochemical mfg	41	39	58	55	8,393	4,123	4,498
325120	Industrial gas mfg	89	60	553	60	304	192	4,877
325131	Inorganic dye & pigment mfg	71	59	92	65	2,649	1,713	833
325132	Synthetic organic dye & pigment mfg	90	90	107	107	5,128	2,867	2,308
325181	Alkalies & chlorine mfg	33	33	49	49	4,483	2,748	374
325182	Carbon black mfg	10	10	30	30	1,708	121	222
325188	All other basic inorganic chemical mfg	383	383	612	612	42,063	25,891	16,038
325191	Gum & wood chemical mfg	43	43	51	51	2,139	1,128	2,505
325192	Cyclic crude & intermediate mfg	26	26	31	31	5,074	2,979	356
325193	Ethyl alcohol mfg	222	222	245	245	5,957	4,334	2,545
325199	All other basic organic chemical mfg	541	541	712	712	68,867	39,150	25,119
325211	Plastics material & resin mfg	561	561	799	799	61,199	38,855	84,337
325212	Synthetic rubber mfg	127	127	150	150	8,455	6,053	1,801
325221	Cellulosic organic fiber mfg	16	16	17	17	2,365	1,876	21
325222	Noncellulosic organic fiber mfg	85	85	110	110	24,214	13,956	0
325311	Nitrogenous fertilizer mfg	132	132	157	157	1,117	772	202
325312	Phosphatic fertilizer mfg	30	30	41	41	688	483	65
325314	Fertilizer (mixing only) mfg	341	341	467	467	8,551	5,313	3,871
325320	Pesticide & other agricultural chemical mfg	185	185	241	241	10,668	5,868	5,758
325411	Medicinal & botanical mfg	342	342	366	366	27,475	13,584	3,610
325412	Pharmaceutical preparation mfg	798	798	1,002	1,002	158,124	68,144	12,765
325413	In-vitro diagnostic substance mfg	199	199	244	244	27,215	10,254	26,620
325414	Biological product (except diagnostic) mfg	221	221	314	314	28,525	13,544	3,236
325510	Paint & coating mfg	1,081	1,081	1,318	1,318	41,177	17,728	83,050
325520	Adhesive mfg	446	446	588	588	21,316	13,117	27,450

Table VI-3.
Industry Profile (continued)

NAICS Code	Industry	Total Number of Firms	Number of Affected Firms	Total Number of Establishments	Number of Affected Establishments	Total Employees	Employees to be Trained	Number of SDSs Produced
325	**Chemical Manufacturing**							
325611	Soap & other detergent mfg	649	649	710	710	23,660	14,519	15,825
325612	Polish & other sanitation good mfg	507	507	551	551	16,670	9,207	11,014
325613	Surface active agent mfg	130	130	154	154	6,135	2,706	5,795
325620	Toilet preparation mfg	767	767	826	826	57,957	37,288	17,586
325910	Printing ink mfg	250	250	482	482	12,821	6,224	48,172
325920	Explosives mfg	50	50	77	77	5,431	4,236	2,204
325991	Custom compounding of purchased resin	477	477	588	588	21,942	13,686	5,169
325992	Photographic film, paper, plate, & chemical mfg	384	368	407	407	7,319	4,177	2,667
325998	All other miscellaneous chemical product & preparation mfg	1,091	1,091	1,246	1,246	35,765	20,617	48,145
326	Plastics and Rubber Products Man.	11,187	11,187	14,233	14,233	855,483	667,348	36,591
327	Nonmetallic Mineral Prod. Manufac.	11,351	11,351	17,472	17,472	472,128	370,139	45,544
331	Primary Metal Manufacturing	4,304	4,304	5,267	5,267	438,921	344,209	13,396
332	Fabricated Metal Prod. Manufac.	55,545	55,545	59,637	59,637	1,565,866	1,163,554	0
333	Machinery Manufacturing	23,736	23,736	26,198	26,198	1,137,540	701,517	0
334	Computer & Electronic Prod Man.	12,689	12,689	14,478	14,478	1,043,288	463,175	0
335	Electric Equipment, Appliance Man.	5,291	5,291	6,144	6,144	406,259	292,852	0
336	Transportation Equip. Manufacturing	10,708	10,708	12,857	12,857	1,574,147	1,127,395	0
337	Furniture & Related Product Man.	20,952	20,952	21,717	21,717	517,401	408,165	0
339	Miscellaneous Manufacturing	29,816	29,816	31,160	31,160	680,848	430,024	44,897
42	**Wholesale Trade**							
423	Durable Goods	178,898	178,898	247,339	247,339	3,395,277	956,215	0
424	Nondurable Goods	102,988	102,988	130,640	130,640	2,228,049	835,103	0
42469	Other Chemicals & AlliedProducts	6,169	6,169	9,647	9,647	103,928	38,954	0
4247	Petroleum & petroleum Products	4,890	4,890	7,024	7,024	94,845	35,549	0
42495	Paint, Varnish, & Supplies	1,207	1,207	2,183	2,183	19,875	7,449	0
44-45	**Retail Trade**							
441	Motor vehicle & parts dealers	94,291	94,291	127,331	127,331	1,938,266	660,987	0
442	Furniture & home furnishings stores	46,532	45,755	65,485	63,265	596,538	129,479	0

Table VI-3.
Industry Profile (continued)

NAICS Code	Industry	Total Number of Firms	Number of Affected Firms	Total Number of Establishments	Number of Affected Establishments	Total Employees	Employees to be Trained	Number of SDSs Produced
44-45	**Retail Trade**							
443	Electronics & appliance stores	30,657	12,356	52,470	32,940	500,780	44,615	0
444	Building material & garden equipment & supplies dealers	62,011	62,011	88,304	88,304	1,373,961	284,191	0
445	Food & beverage stores	116,280	67,664	151,031	101,410	2,881,783	389,067	0
446	Health & personal care stores	43,864	43,864	89,406	89,406	1,069,187	423,319	0
447	Gasoline stations	66,431	39,008	115,533	86,524	888,705	96,582	0
448	Clothing & clothing accessories stores	67,035	6,754	155,371	29,316	1,648,157	29,316	0
451	Sporting goods, hobby, book, & music stores	41,057	10,899	60,145	28,027	639,694	34,108	0
452	General merchandise stores	10,460	3,163	47,456	40,015	2,897,472	198,992	0
453	Miscellaneous store retailers	97,730	43,045	123,374	66,575	813,827	87,799	0
454	Nonstore retailers	40,168	32,492	47,723	39,680	511,558	105,840	0
48-49	**Transportation & Warehousing**							
481	Air transportation	2,929	1,775	5,730	4,537	480,648	67,816	0
483	Water transportation	1,476	1,476	1,928	1,928	68,947	43,190	0
484	Truck transportation	106,632	106,632	121,419	121,419	1,476,397	1,191,682	0
485	Transit & ground passenger transportation	15,536	7,500	18,322	10,265	440,623	38,072	0
486	Pipeline transportation	241	241	2,775	2,775	42,445	20,810	0
487	Scenic & sightseeing transportation	2,680	1,944	2,781	1,979	17,747	4,351	0
488	Support activities for transportation	30,332	30,332	38,566	38,566	610,641	295,204	0
492	Couriers & messengers	8,073	8,073	13,845	13,845	569,190	367,737	0
493	Warehousing & storage	7,410	7,410	14,440	14,440	679,077	415,296	0
51	**Information**							
511	Publishing industries	22,876	16,911	31,508	25,398	1,034,709	152,798	0
512	Motion picture & sound recording industries	21,258	3,565	24,883	7,091	320,647	12,811	0
515	Broadcasting (except Internet)	5,108	2,098	10,415	7,292	293,968	11,379	0
516	Internet Publishing and Broadcasting	9,590	2,753	50,078	43,091	1,201,922	46,525	0
517	Telecommunications	2,400	426	2,746	731	46,627	977	0
518	Internet Service Providers, Web Search Portals, and Data Processing Services	11,613	2,669	19,922	8,960	446,781	9,362	0
519	Other Information Services	3,408	611	4,227	1,130	54,659	1,145	0

Table VI-3.
Industry Profile (continued)

NAICS Code	Industry	Total Number of Firms	Number of Affected Firms	Total Number of Establishments	Number of Affected Establishments	Total Employees	Employees to be Trained	Number of SDSs Produced
52	**Finance & Insurance**							
521	Monetary authorities - central bank	68	27	104	62	19,919	567	0
522	Credit intermediation & related activities	66,462	6,003	232,716	15,948	3,226,219	15,948	0
523	Securities intermediation & related activities	57,933	2,107	90,065	4,566	942,086	4,566	0
524	Insurance carriers & related activities	138,876	14,205	181,528	48,000	2,326,944	48,000	0
525	Funds, trusts, & other financial vehicles (part)	2,213	389	3,678	1,038	33,396	1,098	0
53	**Real Estate & Rental and Leasing**							
531	Real estate	270,268	218,115	312,524	257,057	1,554,163	482,590	0
532	Rental & leasing services	28,435	28,435	65,046	65,046	638,277	183,927	0
533	Lessors of intangible assets, except copyrighted works	2,476	802	2,568	888	31,735	1,687	0
54	**Professional, Technical & Technical**							
5411	Legal services	181,525	4,757	191,351	5,435	1,206,577	5,435	0
5412	Accounting, tax return prep, bookkeeping, & payroll services	108,428	12,421	123,415	24,952	1,357,368	27,843	0
5413	Architectural, engineering, & related services	101,108	26,500	117,115	42,049	1,434,803	64,179	0
5414	Specialized design services	34,485	10,849	34,783	11,089	134,739	14,769	0
5415	Computer systems design & related services	104,469	6,144	116,769	11,112	1,297,710	11,112	0
5416	Management, scientific, & technical consulting services	143,228	26,431	151,766	34,479	1,015,109	63,181	0
5417	Scientific R&D Serv.	14,009	5,971	17,787	9,640	688,052	47,136	0
5418	Advertising & related services	36,980	13,199	40,275	16,329	445,590	37,736	0
5419	Other professional, scientific, & technical services	64,704	64,704	74,295	74,295	599,993	214,139	0
55	**Management of Companies**							
551111	Offices of bank holding companies	1,049	777	1,313	1,032	20,046	2,065	0
551112	Offices of other holding companies	7,438	4,423	8,238	5,198	178,577	18,393	0
551114	Corporate, subsidiary, & regional managing offices	20,807	19,949	41,092	40,201	2,922,779	301,043	0
56	**Adm and Support & Waste Managmt**							
561	Administrative and Support Serv.	311,675	311,675	363,043	363,043	9,628,468	4,589,001	0
562	Wastemanagement & Remediation Serv.	17,156	17,156	21,458	21,458	355,193	248,661	0
61	**Educational Services**							
6111	Elementary & secondary schools	18,666	15,913	21,066	18,291	827,165	69,423	0
6112	Junior colleges	468	346	862	740	80,568	4,642	0

Table VI-3.
Industry Profile (continued)

NAICS Code	Industry	Total Number of Firms	Number of Affected Firms	Total Number of Establishments	Number of Affected Establishments	Total Employees	Employees to be Trained	Number of SDSs Produced
6113	Colleges, universities, & profesional schools	2,456	2,091	4,022	3,657	1,572,333	185,456	0
6114	Business schools, & computer & management training	6,995	649	7,640	857	65,818	857	0
6115	Technical & trade schools	6,681	2,476	8,019	3,741	119,020	6,307	0
6116	Other schools & instruction	35,969	4,555	38,506	5,477	302,908	5,477	0
6117	Educational support services	6,071	973	6,781	1,557	71,573	1,814	0
62	**Healthcare and Social Assistance**							
621	Ambulatory health care services	467,925	467,925	547,183	547,183	5,817,039	3,423,528	0
622	Hospitals	4,164	4,164	7,352	7,352	5,477,818	3,846,705	0
623	Nursing & residential care facilities	34,648	34,648	75,606	75,606	3,043,133	1,941,252	0
624	Social assistance	113,068	88,641	154,090	129,034	2,459,657	332,342	0
71	**Arts, Entertainment & Recreation**							
711	Performing arts, spectator sports, & related industries	43,415	14,721	44,260	15,491	436,072	52,870	0
712	Museums, historical sites, & similar institutions	6,823	3,905	7,312	4,358	128,539	14,892	0
713	Amusement, gambling, & recreation industries	66,499	54,547	73,650	61,474	1,443,956	251,213	0
72	**Accommodation & Food Services**							
721	Accommodation	53,300	53,300	63,903	63,903	1,907,554	658,752	0
722	Foodservices & drinking places	423,999	71,510	568,586	127,312	9,657,310	127,312	0
81	**Other Services**							
811	Repair & maintenance	208,647	208,647	226,131	226,131	1,322,952	909,073	0
811121	Automotive body, paint, & interior repair & maintenance	34,683	34,683	35,850	35,850	222,381	152,810	0
812	Personal & laundry services	172,890	132,555	212,530	169,669	1,380,284	272,379	0
812320	Drycleaning & laundry services (except coin-operated)	23,180	20,821	26,370	23,120	167,447	33,043	0
812921	Photofinishing laboratories (except one-hour)	1,050	928	1,139	964	10,647	2,101	0
813	Religious/grantmaking/civic/professional & similar org	296,045	125,355	305,591	134,330	2,816,537	228,997	0
99	**State and Local Government**							
9992	State Government	n.a.	n.a.	n.a.	n.a.	2,242,536	324,618	0
9993	Local Government	n.a.	n.a.	n.a.	n.a.	6,706,471	1,841,671	0
Total		**6,146,382**	**4,223,431**	**7,720,753**	**5,403,278**	**129,924,808**	**43,840,000**	**1,414,636**
Total for firms producing SDSs		**74,781**	**74,616**	**91,367**	**90,628**	**3,423,801**	**2,358,340**	**1,414,636**
Total for firms not producing SDSs		**6,071,601**	**4,148,815**	**7,629,386**	**5,312,650**	**126,501,007**	**41,481,660**	**0**

Note: Costs are expressed in 2010 dollars

Source: Office of Regulatory Analysis, OSHA based on PP&E (2009) and ERG (2012)

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As shown in Table VI–3, approximately 75,000 firms, in over 90,000 establishments, create hazardous chemicals (*i.e.,* products, substances, or mixtures) for which a label and SDS are required in accordance with the OSHA HCS. In response to testimony presented on the proposed rule, OSHA has revised its estimate of the number of SDSs (and corresponding container labels) potentially affected by the revisions to the HCS from approximately 0.9 million SDSs to approximately 1.4 million SDSs.[10] OSHA estimates that the adoption of GHS will not significantly change the numbers of labels and SDSs produced.

In many instances, firms may be already producing several different versions of SDSs and labels for the same product to satisfy different regulatory requirements in different jurisdictions, including SDSs and labels consistent with GHS criteria. For these products, the revisions to the OSHA HCS will be satisfied relatively easily and may result in a reduction in overall compliance costs by reducing the number of different labels and SDSs needed for each affected product.

The second category of industries and establishments affected by the revisions contains those that do not produce labels or SDSs but are required to provide their employees with access to SDSs supplied by others as part of a hazard communication program covering chemicals to which employees may be exposed in the workplace. The effects on these establishments will generally involve promoting employee awareness of and management familiarization with the revisions to SDSs and labels.

As shown in Table VI–3, an estimated 41 million employees are potentially exposed to hazardous chemicals in these workplaces and are covered by the OSHA HCS. Including employees working in establishments that produce labels and SDSs, a total of 44 million employees would potentially need to become familiar with the revisions to SDSs and labels. The estimated number of employees to be trained, as shown in Table VI–3, is equal to the number of production employees in all affected industries. As also shown in Table VI–3, OSHA estimates that there are over five million workplaces where employees may be potentially exposed to hazardous chemicals.

OSHA received comment from the American Wind Energy Association and Duke Energy Business Services, LLC that asserted that the Agency had underestimated the number of employees that would need to be trained in the electric power generation industry (Document ID #0386 and 0453). OSHA estimated that approximately 49 percent of employees were production employees in this industry who would need to be trained to familiarize them with the revisions to the HCS and that an additional 11,000 managers and logistic personnel would receive training as well. The commenters felt that 60 to 70 percent of employees would need to be trained. OSHA evaluated the concerns of the AWEA and Duke Energy and has decided to defer to their expertise on the subject and adopt their recommendation (by changing the percentage of employees who would need to be trained in NAICS 2211 Electric power generation, transmission and distribution to 65 percent). The change from 49 percent of employees to 65 percent of employees to be trained results in a negligible change to the costs to this industry. Increasing the number of production employees needing training from 245,715 to 315,623 results in an increase of about $39 per firm in annualized costs to this industry, and the costs as a percent of revenues would increase from 0.0052 percent to 0.0060 percent.

D. Benefits

OSHA estimates that the promulgation of the revisions to the HCS will result in substantial benefits from a variety of sources. OSHA's estimates of the benefits include improvements in occupational safety and health and a corresponding reduction in the annual number of injuries, illnesses, and fatalities sustained by employees from exposure to hazardous chemicals; cost reductions for producers of hazardous chemicals; increased efficiencies in the handling and use of hazardous chemicals; reduced costs to provide HCS training to new employees; and other benefits as described in this section.

OSHA expects the revisions to the HCS will result in an increased degree of safety and health for affected employees and a reduction in the numbers of accidents, fatalities, injuries, and illnesses associated with exposures to hazardous chemicals.

As explained in detail in Sections IV and XIII of this preamble, the design of GHS was based on years of extensive research that demonstrated the effectiveness of pictograms, specific signal words, and a standardized format.[11] As a result of this research, OSHA is confident that the GHS revisions to the HCS for labeling and safety data sheets will enable employees exposed to workplace chemicals to more quickly obtain and more easily understand information about the hazards associated with those chemicals. Warning labels on products covered by the standard, which provide an immediate visual reminder of the chemical hazards involved, would be made more intuitive, self-explanatory, and logical, and the nature and extent of any associated hazards would be more readily understood as a result of the training required under the standard. Relatedly, the revisions are expected to improve the use of appropriate exposure controls and work practices that can reduce the safety and health risks associated with exposure to hazardous chemicals.

In addition, the standardized format of the safety data sheets would enable critical information to be accessed more easily and quickly during emergencies. This can reduce the risk of injury, illness, and death to exposed employees and to rescue personnel and can also reduce property damage.

It is difficult to quantify precisely how many injuries, illnesses, and fatalities will be prevented due to the revisions to the HCS. The benefits associated with the current HCS may help provide a general sense of the potential magnitude of the benefits of these revisions. A discussion and analysis of the benefits that would result from the implementation of the current OSHA HCS were included as part of the rulemaking process for the promulgation of the current standard in the 1980s.

The current HCS was originally promulgated in two parts. First, a final rule covering the manufacturing industry was published in the **Federal Register** in 1983 (48 FR 53280, Nov. 25, 1983); a second final rule covering other general industries, maritime industries, construction industries, and agricultural industries was published in the **Federal Register** in 1987 (52 FR 31852, Aug. 24, 1987).

For both of these final rules, OSHA conducted research specifically

[10] A representative from the Independent Lubricant Manufacturers Association suggested that OSHA had underestimated the number of SDSs produced per firm in the lubricating oils industry and that the average firm in the industry produces approximately 1,700 lubricating products requiring an SDS. OSHA has considered this testimony and accepted the estimate of 1,700 SDSs produced per firm in NAICS 324191: Petroleum lubricating oil & grease manufacturing. With 329 affected establishments in this industry, OSHA's estimate of the number of affected SDSs has increased by approximately 0.4 million SDSs in the FEA (as compared to the PEA). The industry profile has been revised accordingly (Document ID #0495 Tr. 296–7).

[11] See Sections IV and XIII of this preamble for a discussion of the studies related to these issues.

regarding the benefits that could be expected from the promulgation of these standards, as described in the preambles to the final rules. In addition, through the rulemaking process, OSHA evaluated the best available evidence, including the data and comments submitted by the public.

The information, data sources, analyses, and findings related to the estimation of the benefits associated with these standards are included in the public records for the rulemakings. The complete rulemaking records for these standards can be found in OSHA public dockets H–022B and H–022D.

The estimated benefits associated with the Hazard Communication Standards were published in the **Federal Register** with the promulgation of the final standards (48 FR 53329, Nov. 25, 1983 and 52 FR 31872, Aug. 24, 1987). OSHA estimated that compliance with the various Hazard Communication Standards would produce annual benefits that would include the prevention of 31,841 non-lost-workday injuries and illnesses, 20,263 lost-workday injuries and illnesses, 6,410 chronic illnesses, and 4,260 fatalities.

Using a willingness-to-pay approach for valuing these benefits, OSHA determined that the annual safety and health benefits would be over $18.2 billion annually, expressed in 1985 dollars. Applying the BLS inflation calculator, the $18.2 billion of benefits in 1985 is equivalent to $36.7 billion of benefits in 2010 after adjusting for inflation of 102 percent of the period.[12] [13]

Based on the material presented in this preamble, OSHA expects that the revisions to the HCS will result in incremental improvements in employee health and safety above that already achieved under the current HCS. In the PEA, OSHA estimated that compliance with the revisions to the HCS would result in benefits equal to 1 percent of the health and safety benefits attributed to the current HCS. It is conceivable that actual benefits might be somewhat lower, but because 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.[14] OSHA solicited comment on the anticipated health and safety benefits of the revisions to the HCS and received numerous comments indicating that stakeholders anticipate increased worker protection as a result of the revisions. The Alliance of Hazardous Materials Professionals responded that they believed that these revisions to the HCS would yield ''benefits in preventing injuries and illnesses'' (Document ID #0327) and DuPont Company reported that they ''believe domestic implementation of the GHS will serve to further enhance worker protection through a more standardized approach to hazard classification and communication'' (Document ID #0329). The National Association of Chemical Distributors said that their association members ''believe that there are benefits associated with preventing injuries, illnesses and fatalities through clearer and more accessible information'' (Document ID #0341) and likewise, the Communications Workers of America reported that they believed that application of the elements of the revised HCS ''would lead to a reduction in the incidence of workplace injuries, illnesses, and fatalities'' (Document ID #0349). This sentiment was echoed by the American Health Care Association, National Center for Assisted Living who felt that the revised HCS will ''reduce incidence of chemical-related illnesses and injuries'' (Document ID #0346), and the Associated General Contractors of America who felt that the revisions ''will allow employees to easier understand hazard information and will assist in better job planning and injury prevention'' and that they ''should reduce eye and skin contact injuries'' (Document ID #0404). The U.S. Chamber of Commerce stated that they ''(b)elieve * * * the new rule will improve workplace safety'' (Document ID #0397). One commenter (Document ID #0033), representing an organization whose membership includes first responders and emergency management, wrote the following in response to the Advance Notice of Proposed Rulemaking (ANPR):

> The emergency planning and first responder community depends upon MSDS information for life and safety. The ability to immediately examine an MSDS and glean hazard and response information at the scene of an incident is critically important. The lives of first responders, employees of the facility and the public depend upon the accuracy and ease of use of the MSDS.

Some stakeholders questioned whether the revisions would result in any health and safety benefits. For example, the Society of Plastics Industries, Inc. felt that there was a ''serious question as to what improvements to workplace safety and health can reasonably be expected'' (Document ID #0392), and the U.S. Chamber of Commerce was concerned that OSHA ''overestimated the utility and benefits of this proposed revision to the HCS'' (Document ID #0397). However, even this commenter suggested the rule '' ''* * * will promote consistency in the identification, classification, and labeling of chemicals, improve workplace safety, and facilitate business growth and international trade.'' (Document ID #0392). The Agency feels that the record supports that these revisions to the HCS will reduce confusion and lead to better hazard communication, which will translate into fewer accidents, illness, injuries, and fatalities. OSHA's estimate that these revisions will provide one percent of the benefits attributed to the original HCS rulemaking represents a very small and easily realized improvement of workplace safety and health. The Agency did not receive additional comments on what level of benefits commenters believed would be more reasonable or accurate and therefore OSHA has retained the estimated health and safety benefits as part of the FEA. OSHA is confident that its initial estimates of the reductions in injuries, illnesses, and fatalities is a minimal estimate given the general agreement by almost all parties that the rule will have safety and health benefits.

OSHA prepared a sensitivity analysis to test the effect of variations in its estimates and found that, even if the estimated health and safety benefits were overstated by a factor of 2 (or even if the health and safety benefits were omitted altogether—see Table VI–1), the benefits would still exceed the costs of the final rule. Those results can be seen in Section VI.L: Sensitivity Analysis in this preamble.

Using the 1 percent estimate, OSHA anticipates that once all requirements take effect for the final rule, 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. The monetized value of these health and safety benefits is an estimated $367 million annually in 2010 dollars.

[12] *http://data.bls.gov/cgi-bin/cpicalc.pl.* The BLS inflation calculator was used on January 18, 2011.

[13] Using OSHA's current willingness-to-pay estimates of $8.7 million per life saved and $62,000 per injury avoided, those benefits are equivalent to about $38.7 billion worth of benefits in 2010 dollars. OSHA decided to use the lower benefits estimate in the text ($36.7 billion), which is consistent with the estimation procedure used for the proposed rule.

[14] 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. These ranges are considered in the sensitivity analysis presented in Section VI.L of this preamble.

In order to obtain a sense of how realistic these estimated safety and health benefits are in light of the current level of occupational injuries, illnesses, and fatalities that are chemically related, OSHA reviewed relevant BLS data for the periods 1992–2007. OSHA's examination of these data shows a 42 percent decline in chemically related acute injuries and illnesses over the period, but both remain significant problems—55,400 chemically related illnesses and 125 chemically related fatalities in 2007. However these readily measurable reported acute illnesses and fatalities are dwarfed by chronic illnesses and fatalities. For chronic illness fatalities, there is little information available, and certainly no annual time-series data. The most recent estimate is that there were 46,900 to 73,700 fatalities due to occupational illnesses in 1992 (Document ID #0274). OSHA believes these more recent data from 1992–2007 suggest that the HCS has had a desirable effect on chemically related illnesses and injuries, but there remains a very significant role for further and better hazard information, as would be provided by aligning the current HCS with the GHS.

The annual health and safety benefits associated with the revisions to the OSHA HCS are estimated to begin after full implementation of the changes and associated employee training. The phase-in period for the main provisions of the final rule is approximately four years from the date of publication. Thus, in order to calculate the estimated annualized health and safety benefits over a twenty-year period associated with this rule in a manner that would be comparable to the corresponding annualized costs, the delay in the realization of the benefits was incorporated into the calculation. Using a discount rate of 7 percent, the estimated annual benefits of $367 million, beginning four years after the effective date of the final rule, were multiplied by 0.6803 to calculate the annualized benefits over a twenty-year period beginning with the effective date of the final rule.[15] Thus, the annualized monetized benefits associated with the reduction in safety and health risks attributable to the revisions to the HCS are an estimated $250 million.

Other substantial benefits, in addition to the improved occupational safety and health of affected employees, are also expected to result from this rulemaking, as discussed in the following paragraphs.

The harmonization of hazard classifications, safety data sheet formats, and warning labels for affected chemicals and products would yield substantial savings to the businesses involved in these activities. Fewer different SDSs would have to be produced for affected chemicals, and many SDSs would be able to be produced at lower cost due to harmonization and standardization. The record supports these savings with comment from Stericycle, Inc. stating that they anticipate that ''less time will be spent in reviewing new chemicals due to the changed format and better characterizations of the hazard'' (Document ID #0338), from the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD), which felt that these revisions to the HCS would ''ultimately increase efficiency and reduce time needed to prepare labels and SDSs'' (Document ID #0374), and from ORC Worldwide, which said that the ''use of one harmonized classification system is expected to significantly reduce the time needed to classify global products'' (Document ID #0123). The American Chemistry Council reported that they would ''expect a positive economic and time impact on developing and reviewing SDSs'' (Document ID #0393) as a result of these revisions to the HCS. Troy Corporation reported that they believed that ''providing harmonized SDSs will reduce development and maintenance time'' (Document ID #0352) and that there ''will be tangible savings when materials only have to be classified once instead of multiple times'' (Document ID #0128). Two commenters suggested that harmonization could lead to a 50 percent time savings in classification (Document ID #0313 and 0327). The benefits represented by these cost reductions would primarily affect businesses involved in chemical manufacturing.

In addition, reductions in operating costs are also expected as a result of the promulgation of the revisions to the HCS for many businesses that purchase or use hazardous chemicals. The current non-uniformity of SDSs and labels received by establishments in many industries requires employees and managers to spend additional time on a daily basis to ascertain the appropriate way to handle and store the hazardous chemicals in their workplaces. Under the revised standard, the presence of uniform and consistent information would help employers and employees to make decisions more efficiently and save substantial time. There is ample evidence in the record that stakeholders anticipate that the revisions to the HCS will improve the quality of the SDSs and labels and that the standardization of the SDS and label elements will increase the consistency of the hazard information and better communicate the hazards to users (*See* Document ID #0313, 0327, 0329, 0334, 0335, 0336, #0339, 0341, 0344, 0347, 0351, 0352, 0354, 0357, 0363, 0365, 0370, 0372, 0374, 0377, 0379, 0382, 0386, 0389, 0390, 0399, 0404, 0405, 0408, 0409, 0410, and 0414). Stakeholders reported that they expected that simplification and reduction in ''the number of documents that we manage * * * will reduce expenses'' (Document ID #0018), and Tom Duffy testified on behalf of the United Steelworkers of America at the Pittsburgh, PA, public hearing that a uniform system for SDSs would result in time savings (Document ID #0499 Tr. 171–72). These sentiments were echoed by Gary Valasek, who represented the Intercontinental Chemical Corporation (Document ID #0499 Tr. 63–64), the National Association of Chemical Distributors, which stated that standardized SDSs and labels would ''create a more efficient process for chemical distributors'' (Document ID #0341), and Wacker Chemical Company, which reported ''that uniformity in SDS and labels will help employees and customers * * * find needed information'' (Document ID #0335). The International Brotherhood of Teamsters reported that the ''standardized, specific approach to labels and SDSs with a set format, content, and order will help with consistency and comprehensibility, and improve the SDSs ability to communicate hazard info to workers'' (Document ID #0357). The American Industrial Hygiene Association felt that ''standardized label elements will make hazard identification easier'' (Document ID #0365). The American Petroleum Institute commented that the revisions to the HCS would ''improve downstream hazard assessments'' (Document ID #0376). OSHA solicited comment on its estimated monetized benefits in the PEA arising from increased efficiency in handling hazardous materials. While a few stakeholders questioned OSHA's benefits estimates, they did not offer an alternative methodology for estimating potential time savings; nor did they offer quantitative alternatives for OSHA

[15] The formula for annualizing the benefits is equal to: $[(1.07)^{-4}]$ * $[(1—(1.07)^{-16})/0.07]$ * $[0.07/(1—(1.07)^{-20})]$,where the first term in brackets reflects the four year delay until annual benefits are realized; the second term in brackets reflects the present value of sixteen years of annual benefits (from years 5 through 20), and the third term in brackets annualizes the present value of benefits over a 20-year period.

to evaluate. As demonstrated throughout this preamble, stakeholders were largely supportive of OSHA's estimates.

For the benefits estimated in the PEA, PP&E worked closely with stakeholders, conducting multiple interviews and extensive research on the processes that companies use to classify chemical hazards, to develop SDSs and labels, and to handle, store, and use hazardous chemicals. Based on interviews with hazardous materials professionals in more than a dozen affected establishments, PP&E evaluated how these processes would be affected by the proposed revisions to the HCS and analyzed the potential savings that could reasonably be expected as a result of adopting these revisions.

For the PEA, OSHA used the PP&E 2009 report (Document ID #0273) to develop estimates of the cost reductions that the affected companies would expect to obtain as a result of the revisions to the OSHA HCS.[16] Among the various benefits expected to be realized as a result of the implementation of the revisions, as described in this section, OSHA quantified two general categories of cost savings in the PEA and has maintained the methodology employed to create those estimates [17] but used the most recent available economic data in arriving at the estimates of costs presented in this final analysis.

In the PEA (74 FR 50280, 50322, Sept. 30, 2009), OSHA estimated the number of hours that each industry would save by improving the efficiency and productivity of personnel who use SDSs in performing their job functions. OSHA estimated that the amount of time spent during affected activities in the manufacturing sector could be reduced by 3 percent for health and safety supervisors and by 15 percent for logistics personnel specializing in handling hazardous chemicals.[18] The Agency updated the number of health and safety supervisors and logistics personnel for this FEA to reflect the most recent data and estimated that the time reductions for handling hazardous chemicals, and the associated cost savings, would apply to about 7,000 health and safety supervisors and 49,000 logistics personnel in the manufacturing sector and would yield annualized benefits of approximately $475 million.[19] Similar potential time and cost savings as a result of the revisions to the OSHA HCS were not quantified for the non-manufacturing sectors.

As part of the PEA (*Id.* at 50322–23), OSHA also estimated that, for the manufacturing sectors, the costs associated with the creation and revision of SDSs in future years would be reduced as a result of the revisions to the HCS. The methodology for creating this estimate has been retained for the FEA but new economic data were incorporated where available. The creation and revision of individual SDSs will be less burdensome, and, in addition, fewer different versions of SDSs would need to be produced for affected chemicals and products. OSHA estimated that, depending on firm size, the combination of these two effects would result in annual savings equivalent to between 2.5 and 4 hours of a professional's time per existing SDS and a total annualized savings of $32 million.[20]

Combining the improved productivity of personnel who use SDSs and the improved efficiency of those who revise SDSs and labels, OSHA concluded that the annualized productivity savings for companies would be an estimated $507 million.

Another area in which the final rule is likely to provide cost savings to industry is in the provision of hazard communication training to new employees after the transition period. Both the current HCS and the revised HCS require employers to provide training on the safe handling of chemicals, on understanding SDSs and labels, and on being familiar with other information crucial to worker safety. Employers are permitted to offer training for categories of hazards (such as flammability or carcinogenicity) rather than training individually on each chemical. The primary sources of information for this training are the SDSs supplied by manufacturers, and the primary method for employees to determine the hazard associated with a specific chemical they are using is through the manufacturer's HCS-compliant label.

Under the revised HCS, SDSs and labels produced in the United States will all be formatted in the same way. As more countries and regions adopt the GHS, fewer variations of SDSs and labels will be seen in the workplace. Information will be located in the same place on every SDS and label an employee will encounter. Employers will no longer have to train on as many SDS formats; nor will they need to devote as many resources to gather information on work practices, PPE, etc. SDSs and labels will be required to provide complete hazard information, and the language that the hazard information is presented in will be uniform across labels and section 2 of the SDSs. The inclusion of the pictograms and standardized hazard statement removes or, at least reduces, training time spent on interpreting various—and in some cases ambiguous—hazard warnings that current SDSs and labels may bear. The standardized labels and elements based on the detailed criteria for each hazard also greatly simplify training by facilitating training on "categories of hazard" rather than having to cover every chemical individually where the hazard determination is based on broad definitions. All of these changes can be expected to reduce the costs of training employees to recognize chemical hazards in the workplace.

The rulemaking record included numerous descriptions of the difficulties for both employees and

[16] The full final report from PP&E detailing the extensive process by which these estimates were derived is available on the rulemaking docket. See Document ID #0550.

[17] There is no indication that two years would have been sufficient time to affect the processes involved with handling hazardous chemicals, and therefore OSHA did not feel it necessary to re-estimate the savings parameters established through PP&E's research.

[18] For example, as described by PP&E (2009, Document ID #0273), the job of a logistics person, depending on the company, consists of the following tasks: (1) Receive hazardous chemicals; (2) gather the associated SDSs—either those that are attached to the shipment or those that are attached to the invoice; (3) extract the relevant information from the SDSs and enter it in the plant's SDS management system; (4) insert paper copies of the SDSs into the (hard copy) SDS management folder; (5) if the information is not available (particularly in the older 9-section SDSs), then look for 12-section SDSs prepared by some other manufacturer; (6) prepare in-plant labels; (7) determine special storage and use requirements, make appropriate arrangements for short-term and long-term storage, and distribute information to different process lines or field offices; (9) participate in the training of line supervisors and production workers; (10) train new employees; and (11) carry out other logistics duties at the plant. The GHS standard, by making the structure and content of SDS uniform, would help to reduce the time it takes to perform each of the above tasks.

[19] These estimates assume 2,000 hours of work a year for 7,070 health and safety supervisors and 49,486 logistics personnel specializing in handling hazardous chemicals in the manufacturing sector; an hourly wage of $66.01 and $45.17, respectively; and a time savings of 3 percent and 15 percent, respectively, for health and safety supervisors and logistics personnel. The resulting annual savings of $699 million was multiplied by 0.6803 to annualize the savings over a twenty-year period with savings not accruing until four years after the effective date of the revisions (Document ID #0273).

[20] These estimates assume ⅓ of the estimated 1,414,636 SDSs are reviewed each year; savings per SDS is between 2 ½ and 4 hours, depending on firm size (with an average per SDS of about 3.2 hours); personnel reviewing the SDSs receive an hourly wage of $66; and existing compliance rates are between 1 percent and 75 percent, depending on firm size (with an average per SDS of about 53 percent). The resulting annual savings of $47 million was multiplied by 0.6803 to annualize the savings over a twenty-year period with savings not accruing until four years after the effective date of the revisions.

employers associated with training under the current HCS (see Document ID #0307, 0499 Tr. 92–3, 0499 Tr. 167–8, 0499 Tr. 175, 0527) and supported the idea that training would be easier—and therefore cheaper—under the revised HCS (see Document ID #0123, 0338, 0408, 0414, 0494 Tr. 74–5, 0495 Tr. 308–9, 0497 Tr. 95–6, 0499 Tr. 93, 0499 Tr. 96, 0499 Tr. 190–91). Nevertheless, given that the annualized benefits of the final rule already significantly exceed the costs, OSHA did not feel it was necessary to try to develop, from the limited data available, a quantified estimate of the monetized savings resulting from simplified training.[21]

An additional benefit of the adoption of GHS is that it would facilitate international trade, increasing 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. The Society for Chemical Manufacturers and Affiliates, for example, stated in their comment that while ''SOCMA member companies do not foresee significant savings from the change * * * for companies that do business globally there will be'' (Document ID #0402). While OSHA did not take quantitative benefits for these savings, the Agency believes that firms that operate globally may realize a cost savings as a result of the adoption of the GHS (Document ID #0336, 0339, 0361, and 0405). As a result of the direct savings resulting from the harmonization and the associated increase in international competition, prices for the affected chemicals and products, and the corresponding goods and services using them, should decline, although perhaps only by a small amount.

Finally, the GHS modifications to the OSHA HCS would meet the international goals for adoption and implementation of the GHS that have been supported by the U.S. government. Implementing GHS in U.S. federal laws and policies through appropriate legislative and regulatory action was anticipated by the U.S. support of 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.

A number of commenters suggested that the benefits OSHA estimated will result from this rule were incorrect or overstated. The National Association of Homebuilders expressed a belief that OSHA's ''assumption that the proposed revisions to the HCS [would] result in cost reductions * * * due to productivity gains is false'' (Document ID #0372), while the American Composites Manufacturers Association voiced concern that the benefits OSHA had estimated were speculative (Document ID #0407). Southern Company submitted that ''the benefits of adopting the GHS are minimal at best'' (Document ID #0378). Applied Safety and Ergonomics, Inc., urged OSHA to adopt a more conservative view of the expected benefits as they asserted that ''it is possible that many of the implied or expected benefits of the proposed changes to the HCS may not materialize'' (Document ID #0396). OSHA takes these comments seriously and evaluated all concerns raised by stakeholders on the estimated benefits of this standard. Unfortunately, most commenters did not include adequate detail or data that would allow the Agency to evaluate alternative benefits estimates. While future benefits (or costs) cannot be estimated with scientific precision, OSHA believes that the estimated benefits associated with this standard are based on sound data and that the resulting estimates are reasonable and have largely been supported by testimony and comment from stakeholders. It should be noted that many commenters who raised questions or concerns over OSHA's benefits estimates still largely supported the overall aim of the rulemaking and wished to see OSHA proceed with promulgation. The Agency addresses the inherent uncertainty in the economic analysis in Section VI.L Sensitivity Analysis in this preamble. In that section, various parameters are adjusted to evaluate the impact on the overall cost and benefits of the rule, and OSHA finds that even if estimated benefits were grossly overstated, this standard's benefits would still exceed costs.

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. OSHA has reviewed the requirements that would be imposed by the rule, and has assessed their technological feasibility. As a result of this review, OSHA has determined that compliance with the requirements of the rule is technologically feasible for all affected industries.

The revisions to OSHA's HCS would require employers that produce chemicals to reclassify chemicals in accordance with the new classification criteria and revise safety data sheets and labels associated with hazardous chemicals. Compliance with these requirements is not expected to involve any technological obstacles. A comment in the record indicated that ''[s]ome of the work [* * *] has already been done in order to comply with GHS implementation in Asian countries'' (Document ID #0405; see also Document ID #0352, 0377, and 0410). In addition to stakeholder comments, a January 4, 2011 press release from the European Chemicals Agency (ECHA) announced that the ECHA had received 3,114,835 notifications of 24,529 substances for the Classification and Labelling Inventory. Industry was required to notify the classification and labeling of all chemical substances that are hazardous or subject to registration under the Registration, Evaluation and Authorization of Chemicals (REACH) regulation and placed on the EU market in accordance with the GHS criteria. NIOSH is also currently working to update its International Chemical Safety Cards and Pocket Guide to incorporate the GHS classifications, which will further reduce the technological burdens of reclassification borne by manufacturers. (For a more detailed discussion of the EU implementation of the GHS and NIOSH's classification work, *see* Section XIII. Summary and Explanation of the Final Rule in this preamble.) This evidence lends support to OSHA's assertion that the requirements of the revisions to the HCS will not prove technologically infeasible. The rule would also require employers whose workplaces involve potential exposure to hazardous chemicals to train employees on the relevant aspects of the revised approach to hazard communication. Affected employees would need additional training to explain the new labels and safety data sheets. Compliance with these requirements is not expected to involve any technological obstacles.

The revisions to the HCS will require establishments that package or label hazardous chemicals to affix labels that include hazard warning pictograms enclosed in a red bordered diamond. While some establishments may not currently be printing labels in colors other than black and white, color printing technology is widely available

[21] However, in the sensitivity analysis presented in Section VI.L of this preamble, OSHA develops an estimate of monetized cost savings from simplified hazard communication training based on one commenter's estimate of the percentage reduction in training time resulting from the final rule.

and printing labels with a red bordered diamond or purchasing preprinted labels with a red bordered diamond is not expected to involve any technological obstacles. Research conducted by ERG (2010) under contract for OSHA found that printer technology is rapidly evolving—resulting in lower costs for printers and printing supplies and making better technology available to a wider range of buyers. Combined with currently available printing technology, this clearly demonstrates that printing product labels in color is technologically feasible.

Compliance with all of the requirements of the rule can be achieved with readily and widely available technologies. Businesses in the affected industries have long been required to be in compliance with the existing HCS, which includes similar requirements. The revised HCS would simply require modifying the labels and SDSs for hazardous chemicals, adding some training to ensure employees are familiar with these changes, and upgrading printing technology with widely available color printers or purchasing preprinted color labels. No new technologies are required for compliance with the modifications to the HCS. OSHA is aware that many U.S. businesses in the affected industries have already begun implementing many of the requirements of the GHS in order to meet the new foreign requirements for exported products. Therefore, OSHA believes that there are no technological constraints associated with compliance with any of the requirements of the revisions to the HCS.

F. Costs of Compliance

Introduction

This section presents the estimated costs of compliance for the revisions to the OSHA HCS. The estimated costs of compliance represent the additional costs necessary for employers to achieve full compliance with the new requirements of the final rule. They do not include costs associated with firms whose current practices are already in compliance with the new requirements.

The costs of compliance with the revisions to the HCS consist of four main categories: (1) The cost of reclassification and revision of SDSs and labels, (2) the cost of management familiarization and other management costs associated with the administration of hazard communication programs, (3) the cost of training employees, and (4) the cost of printing labels for hazardous chemicals in color. The first three categories are considered to be one-time transitional costs and were included in the PEA in support of the proposed rule. The fourth category is new and was developed in response to comments on the proposed rule. It includes both one-time transitional costs and costs that recur throughout the life of the rule.

The estimated compliance costs are based on a determination made by the Agency that the revisions would not significantly change the number of chemicals or products for which an SDS will be required. This also means that there will be no change in the number of establishments that are required to implement a hazard communication program. OSHA received no comments as part of the rulemaking record for this standard challenging this determination.

Other than the direct costs of reclassification and relabeling, the estimated compliance costs do not include any further 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 demand for products. Theoretically, such impacts, if any, with regard to possible changes in the uses and applications of affected chemicals, could be positive as well as negative. OSHA has determined that such effects, if any, will not be significant, and received no comment from stakeholders disputing this determination.

In addition to the revisions to the HCS, the rulemaking also includes related revisions to other OSHA standards. The revisions to the other standards generally ensure that all OSHA requirements related to hazard communication remain consistent with each other and become consistent with the revised HCS. OSHA has determined that the revisions to the other standards would not impose significant costs beyond those reflected in the compliance cost estimates for this rulemaking.

In order to have compliance costs presented on a consistent and comparable basis across various regulatory activities, the costs of compliance for this rule are expressed in annualized terms. Annualized costs represent the more appropriate measure for assessing the longer-term potential impacts of the rulemaking and for purposes of comparing compliance costs and cost-effectiveness across diverse regulations with a consistent metric. In addition, annualized costs are often used for accounting purposes to assess the cumulative costs of regulations on the economy or specific parts of the economy across different regulatory programs or across years. Annualized costs also permit costs and benefits to be presented in a comparable manner.

A seven percent discount rate was applied to costs incurred in future years to calculate the present value of these costs 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 20-year period, to calculate the annualized cost.[22]

Table VI–4 shows the estimated annualized compliance cost by cost category and by industry sector. All costs are reported in 2010 dollars. As shown in Table VI–4, the total annualized cost of compliance with the rulemaking is estimated to be about $201 million. Of this amount, the annualized cost of chemical hazard reclassification and revision of SDSs and labels is an estimated $22.5 million, the annualized cost of training employees is an estimated $95.4 million, the annualized cost of management familiarization and other management costs is an estimated $59.0 million, and the additional annualized label printing costs, incurred to comply with the requirement of a black pictogram surrounded by a red-bordered diamond, is an estimated $24.1 million.

As shown at the bottom of Table VI–4, most of the compliance cost associated with chemical hazard reclassification and revision of SDSs and labels would be borne by the chemical manufacturing industry (shown as the total for industries that produce SDSs and labels). Table VI–4 also shows that compliance costs are spread across all industries in the U.S. economy subject to OSHA jurisdiction, reflecting the fact that employee exposures to hazardous chemicals occur in almost every industry sector.

Other than the costs of printing labels in color, OSHA expects that all compliance costs would be incurred over a period of four years, as the rule would incorporate a four-year transition

[22] OSHA annualized costs for this rule over a 20-year period in accordance with Executive Order 13563, which directs agencies ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' In addition, OMB Circular A–4 states that analysis should include all future costs and benefits using a ''rule of reason'' to consider for how long it can reasonably predict the future and limit its analysis to this time period. Annualization should not be confused with depreciation or amortization for tax purposes. Annualization spreads costs out evenly over the time period (similar to the payments on a mortgage) to facilitate comparison of costs and benefits across different years. In this analysis, OSHA estimated a lifetime for hardware purchases (5 years for printers, for instance) which is unrelated to the annualization period. OSHA felt that an annualization period much shorter than 20 years (say, 10 years) would have been inappropriate for this rule because of the lagged phase-in of provisions (some of which will not take effect until five years after the final rule is published).

period into the compliance schedule for the standard. Specifically, for purposes of estimating the annualized compliance costs, OSHA assumed that the compliance costs associated with employee training and management familiarization would be incurred in the two-year period following the effective date of the final standard, and that other one-time compliance costs would be incurred in the four-year period following the effective date of the final standard. Initial printer costs to facilitate color printing would also be incurred during the four-year period following the effective date of the final standard, but all other color-printing costs would occur subsequent to the four-year transition period on a recurring annual basis.

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Table VI-4.
Annualized Costs of Compliance

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Management Familiarization and Other Costs	Cost of Training Employees	Additional Label Printing Costs	Total Annualized Costs
11	**Agriculture, Forestry, Fishing & Hunting**					
113	Forestry & Logging	$0	$93,551	$65,009	$0	$158,560
114	Fishing, Hunting and Trappinig	$0	$8,438	$6,320	$0	$14,758
115	Support Activities for Ag & Forestry	$0	$41,762	$35,066	$0	$76,828
211	**Oil and Gas Extraction**					
211111	Crude petroleum & natural gas extraction	$1,548,450	$309,208	$226,235	$254,118	$2,338,011
211112	Natural gas liquid extraction	$69,081	$7,743	$17,271	$1,127,047	$1,221,142
212	Mining (except Oil & Gas)	$0	$81,170	$261,843	$0	$343,013
213	Support Activities for Mining	$0	$96,086	$305,787	$0	$401,872
22	**Utilities**					
2211	Electric Power Gen, Trans & Distrib	$0	$374,809	$800,570	$0	$1,175,379
2212	Natural Gas Distribution	$0	$105,791	$85,604	$0	$191,395
2213	Water, Sewage, & Other Systems	$0	$197,830	$72,397	$0	$270,227
23	**Construction**					
236	Construction of Buildings	$0	$2,550,505	$2,801,770	$0	$5,352,275
237	Heavy Construction	$0	$450,057	$1,147,167	$0	$1,597,223
238	Special Trade Contractors	$0	$5,001,804	$6,819,043	$0	$11,820,847
31	**Manufacturing**					
311	Food Manufacturing	$0	$1,116,052	$2,733,685	$0	$3,849,737
312	Beverage &Tobacco Prod. Manuf.	$0	$168,097	$231,104	$0	$399,200
313	Textile Mills	$0	$136,365	$341,760	$0	$478,125
314	Textile Product Mills	$0	$305,029	$315,780	$0	$620,810
315	Apparel Manufacturing	$0	$493,665	$689,964	$0	$1,183,629
316	Leather & Allied Product Manufac.	$0	$63,087	$74,435	$0	$137,521
321	Wood Product Manufacturing	$0	$733,660	$1,080,826	$0	$1,814,486
322	Paper Manufacturing	$0	$198,334	$801,563	$0	$999,897
323	Printing and Related Support	$0	$1,493,924	$1,209,329	$0	$2,703,253
324	**Petroleum & Coal Prod. Manufac.**					
324110	Petroleum refineries	$315,750	$14,585	$94,309	$432,409	$857,053
324121	Asphalt paving mixture & block mfg	$1,559,277	$42,480	$29,818	$107,523	$1,739,097

Table VI-4.
Annualized Costs of Compliance (continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Management Familiarization and Other Costs	Cost of Training Employees	Additional Label Printing Costs	Total Annualized Costs
324	**Petroleum & Coal Prod. Manufac.**					
324122	Asphalt shingle & coating materials mfg	$234,057	$8,117	$20,954	$15,360	$278,488
324191	Petroleum lubricating oil & grease m	$8,744,161	$15,043	$14,167	$18,147	$8,791,518
324199	All other petroleum & coal products mfg	$83,129	$3,755	$5,960	$5,221	$98,065
325	**Chemical Manufacturing**					
325110	Petrochemical mfg	$46,818	$1,989	$9,922	$323,821	$382,550
325120	Industrial gas mfg	$44,487	$16,229	$687	$158,404	$219,808
325131	Inorganic dye & pigment mfg	$12,943	$4,566	$4,311	$64,207	$86,028
325132	Synthetic organic dye & pigment mfg	$42,591	$5,007	$7,137	$55,068	$109,803
325181	Alkalies & chlorine mfg	$5,851	$1,783	$0	$52,836	$60,470
325182	Carbon black mfg	$3,408	$1,118	$0	$19,910	$24,436
325188	All other basic inorganic chemical mfg	$219,073	$24,775	$63,624	$333,199	$640,670
325191	Gum & wood chemical mfg	$34,586	$2,942	$2,761	$133,833	$174,122
325192	Cyclic crude & intermediate mfg	$4,716	$1,628	$7,217	$8,615	$22,176
325193	Ethyl alcohol mfg	$68,273	$11,841	$11,163	$278,487	$369,765
325199	All other basic organic chemical mfg	$335,937	$30,244	$96,228	$793,726	$1,256,135
325211	Plastics material & resin mfg	$942,129	$34,079	$94,366	$143,198	$1,213,772
325212	Synthetic rubber mfg	$24,788	$7,315	$14,921	$18,210	$65,234
325221	Cellulosic organic fiber mfg	$561	$981	$4,501	$76,216	$82,260
325222	Noncellulosic organic fiber mfg	$0	$5,254	$33,643	$0	$38,897
325311	Nitrogenous fertilizer mfg	$4,990	$8,438	$2,241	$120,893	$136,562
325312	Phosphatic fertilizer mfg	$1,145	$1,907	$1,197	$64,639	$68,888
325314	Fertilizer (mixing only) mfg	$71,741	$24,733	$14,096	$155,412	$265,983
325320	Pesticide & other agricultural chemical mfg	$92,279	$10,648	$14,600	$191,933	$309,460
325411	Medicinal & botanical mfg	$84,575	$17,665	$28,525	$228,557	$359,322
325412	Pharmaceutical preparation mfg	$235,425	$45,461	$166,099	$1,167,008	$1,613,993
325413	In-vitro diagnostic substance mfg	$322,022	$11,191	$25,137	$158,958	$517,308
325414	Biological product (except diagnostic) mfg	$46,741	$12,875	$33,625	$153,268	$246,509
325510	Paint & coating mfg	$1,139,199	$66,247	$46,523	$2,792,967	$4,044,937
325520	Adhesive mfg	$414,507	$27,659	$33,387	$1,093,695	$1,569,248

Table VI-4.
Annualized Costs of Compliance (continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Management Familiarization and Other Costs	Cost of Training Employees	Additional Label Printing Costs	Total Annualized Costs
325	**Chemical Manufacturing**					
325611	Soap & other detergent mfg	$270,712	$37,500	$36,787	$398,890	$743,889
325612	Polish & other sanitation good mfg	$179,507	$30,676	$23,955	$1,339,816	$1,573,954
325613	Surface active agent mfg	$79,967	$7,056	$6,898	$733,406	$827,327
325620	Toilet preparation mfg	$313,087	$43,619	$91,329	$3,762,580	$4,210,615
325910	Printing ink mfg	$568,423	$20,951	$16,743	$619,764	$1,225,882
325920	Explosives mfg	$25,266	$2,989	$10,190	$138,747	$177,192
325991	Custom compounding of purchased resin	$84,781	$29,558	$34,340	$40,378	$189,058
325992	Photographic film, paper, plate, & chemical mfg	$66,738	$23,911	$11,429	$1,576,301	$1,678,379
325998	All other miscellaneous chemical product & preparation mfg	$778,192	$62,095	$53,931	$2,029,737	$2,923,955
326	Plastics and Rubber Products Man.	$792,799	$597,068	$1,646,370	$910,738	$3,946,975
327	Nonmetallic Mineral Prod. Manufac.	$899,675	$656,755	$939,905	$694,713	$3,191,048
331	Primary Metal Manufacturing	$286,757	$231,398	$837,022	$302,411	$1,657,589
332	Fabricated Metal Prod. Manufac.	$0	$2,695,084	$2,932,637	$0	$5,627,722
333	Machinery Manufacturing	$0	$1,159,329	$1,761,288	$0	$2,920,617
334	Computer & Electronic Prod Man.	$0	$634,246	$1,156,476	$0	$1,790,722
335	Electric Equipment, Appliance Man.	$0	$266,332	$718,571	$0	$984,903
336	Transportation Equip. Manufacturing	$0	$607,390	$2,733,887	$0	$3,341,277
337	Furniture & Related Product Man.	$0	$992,072	$1,036,890	$0	$2,028,962
339	Miscellaneous Manufacturing	$1,368,364	$1,396,891	$1,136,333	$980,029	$4,881,617
42	**Wholesale Trade**					
423	Durable Goods	$0	$1,856,139	$1,774,386	$0	$3,630,525
424	Nondurable Goods	$0	$1,075,893	$1,135,948	$0	$2,211,842
42469	Other Chemicals & AlliedProducts	$0	$93,292	$67,218	$0	$160,510
4247	Petroleum & petroleum Products	$0	$87,299	$62,424	$0	$149,722
42495	Paint, Varnish, & Supplies	$0	$16,820	$12,344	$0	$29,164
44-45	**Retail Trade**					
441	Motor vehicle & parts dealers	$0	$1,305,535	$1,514,313	$0	$2,819,848
442	Furniture & home furnishings stores	$0	$359,469	$246,377	$0	$605,846

Table VI-4.
Annualized Costs of Compliance (continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Management Familiarization and Other Costs	Cost of Training Employees	Additional Label Printing Costs	Total Annualized Costs
44-45	**Retail Trade**					
443	Electronics & appliance stores	$0	$126,537	$87,754	$0	$214,291
444	Building material & garden equipment & supplies dealers	$0	$594,405	$449,187	$0	$1,043,592
445	Food & beverage stores	$0	$757,094	$628,686	$0	$1,385,780
446	Health & personal care stores	$0	$930,261	$1,176,208	$0	$2,106,469
447	Gasoline stations	$0	$571,479	$377,463	$0	$948,943
448	Clothing & clothing accessories stores	$0	$107,070	$73,802	$0	$180,872
451	Sporting goods, hobby, book, & music stores	$0	$147,142	$98,228	$0	$245,370
452	General merchandise stores	$0	$457,639	$388,312	$0	$845,951
453	Miscellaneous store retailers	$0	$289,925	$191,356	$0	$481,281
454	Nonstore retailers	$0	$234,565	$189,046	$0	$423,611
48-49	**Transportation & Warehousing**					
481	Air transportation	$0	$43,925	$113,775	$0	$157,700
483	Water transportation	$0	$20,684	$59,553	$0	$80,237
484	Truck transportation	$0	$861,427	$1,381,115	$0	$2,242,542
485	Transit & ground passenger transportation	$0	$92,278	$93,882	$0	$186,160
486	Pipeline transportation	$0	$30,080	$28,818	$0	$58,898
487	Scenic & sightseeing transportation	$0	$11,480	$9,626	$0	$21,106
488	Support activities for transportation	$0	$295,873	$434,291	$0	$730,164
492	Couriers & messengers	$0	$102,552	$375,406	$0	$477,958
493	Warehousing & storage	$0	$85,947	$624,857	$0	$710,804
51	**Information**					
511	Publishing industries	$0	$211,932	$276,389	$0	$488,321
512	Motion picture & sound recording industries	$0	$43,869	$30,110	$0	$73,979
515	Broadcasting (except Internet)	$0	$413,612	$218,390	$0	$632,002
516	Internet Publishing and Broadcasting	$0	$413,612	$254,170	$0	$667,782
517	Telecommunications	$0	$72,968	$37,505	$0	$110,474
518	Internet Service Providers, Web Search Portals, and Data Processing Services	$0	$72,968	$46,267	$0	$119,235
519	Other Information Services	$0	$72,968	$37,681	$0	$110,649

Table VI-4.
Annualized Costs of Compliance (continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Management Familiarization and Other Costs	Cost of Training Employees	Additional Label Printing Costs	Total Annualized Costs
52	**Finance & Insurance**					
521	Monetary authorities - central bank	$0	$687	$598	$0	$1,285
522	Credit intermediation & related activities	$0	$68,113	$45,885	$0	$113,998
523	Securities intermediation & related activities	$0	$25,202	$16,408	$0	$41,610
524	Insurance carriers & related activities	$0	$479,517	$316,850	$0	$796,367
525	Funds, trusts, & other financial vehicles	$0	$8,404	$5,527	$0	$13,931
53	**Real Estate & Rental and Leasing**					
531	Real estate	$0	$1,217,020	$943,304	$0	$2,160,324
532	Rental & leasing services	$0	$535,012	$392,423	$0	$927,435
533	Lessors of intangible assets, except copyrighted works	$0	$7,289	$5,308	$0	$12,597
54	**Professional, Technical & Technical**					
5411	Legal services	$0	$15,907	$10,682	$0	$26,589
5412	Accounting, tax return prep, bookkeeping, & payroll services	$0	$161,382	$109,248	$0	$270,631
5413	Architectural, engineering, & related services	$0	$289,947	$206,120	$0	$496,068
5414	Specialized design services	$0	$69,938	$49,915	$0	$119,853
5415	Computer systems design & related services	$0	$57,365	$39,741	$0	$97,106
5416	Management, scientific, & technical consulting services	$0	$223,220	$174,797	$0	$398,017
5417	Scientific R&D Serv.	$0	$73,126	$106,703	$0	$179,829
5418	Advertising & related services	$0	$125,140	$96,521	$0	$221,661
5419	Other professional, scientific, & technical services	$0	$814,550	$816,229	$0	$1,630,779
55	**Management of Companies**					
551111	Offices of bank holding companies	$0	$11,502	$7,655	$0	$19,157
551112	Offices of other holding companies	$0	$59,551	$46,736	$0	$106,287
551114	Corporate, subsidiary, & regional managing offices	0	$389,323	$604,961	0	$994,284
56	**Adm and Support & Waste Managmt**					
561	Administrative and Support Serv.	$0	$3,106,810	$7,448,349	$0	$10,555,159
562	Wastemanagement & Remediation Serv.	$0	$199,382	$386,503	$0	$585,885
61	**Educational Services**					
6111	Elementary & secondary schools	$0	$180,241	$170,120	$0	$350,361
6112	Junior colleges	$0	$8,033	$9,681	$0	$17,713

Table VI-4.
Annualized Costs of Compliance (continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Management Familiarization and Other Costs	Cost of Training Employees	Additional Label Printing Costs	Total Annualized Costs
61	**Educational Services**					
6113	Colleges, universities, & profesional schools	$0	$31,127	$348,409	$0	$379,536
6114	Business schools, & computer & management training	$0	$3,211	$2,192	$0	$5,402
6115	Technical & trade schools	$0	$21,833	$16,341	$0	$38,174
6116	Other schools & instruction	$0	$24,312	$17,659	$0	$41,970
6117	Educational support services	$0	$11,255	$8,182	$0	$19,436
62	**Healthcare and Social Assistance**					
621	Ambulatory health care services	$0	$5,494,851	$9,889,378	$0	$15,384,229
622	Hospitals	$0	$85,271	$8,922,206	$0	$9,007,477
623	Nursing & residential care facilities	$0	$764,947	$4,571,756	$0	$5,336,703
624	Social assistance	$0	$1,149,425	$1,035,487	$0	$2,184,913
71	**Arts, Entertainment & Recreation**					
711	Performing arts, spectator sports, & related industries	$0	$90,960	$104,494	$0	$195,454
712	Museums, historical sites, & similar institutions	$0	$28,502	$29,422	$0	$57,925
713	Amusement, gambling, & recreation industries	$0	$399,676	$490,827	$0	$890,503
72	**Accommodation & Food Services**					
721	Accommodation	$0	$650,644	$1,255,780	$0	$1,906,424
722	Foodservices & drinking places	$0	$479,719	$329,616	$0	$809,336
81	**Other Services (except Public Adm.)**					
811	Repair & maintenance	$0	$2,627,056	$2,490,259	$0	$5,117,315
811121	Automotive body, paint, & interior repair & maintenance	$0	$186,989	$284,066	$0	$471,055
812	Personal & laundry services	$0	$1,554,430	$1,167,679	$0	$2,722,109
812320	Drycleaning & laundry services (except coin-operated)	$0	$231,568	$159,733	$0	$391,302
812921	Photofinishing laboratories (except one-hour)	$0	$28,333	$11,585	$0	$39,919
813	Religious/grantmaking/civic/professional & similar org	$0	$924,155	$663,723	$0	$1,587,877
99	**State and Local Government**					
9992	State Government	$0	$143,639	$484,520	$0	$628,158
9993	Local Government	$0	$120,037	$2,444,561	$0	$2,564,598
	Total	**$22,466,962**	**$59,017,784**	**$95,421,653**	**$24,074,395**	**$200,980,794**
	Total for firms producing SDSs	**$22,466,962**	**$3,912,723**	**$5,936,215**	**$24,074,395**	**$56,390,294**
	Total for firms not producing SDSs	**$0**	**$55,105,062**	**$89,485,438**	**$0**	**$144,590,500**

Note: Costs are expressed in 2010 dollars

Source: Office of Regulatory Analysis, OSHA based on PP&E (2009) and ERG (2012)

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In the appendix to this cost section, Table VI–8 shows, by industry and by cost element, total non-annualized (non-discounted) compliance costs of about $2.1 billion estimated to be incurred during the four-year phase-in of the revisions to the HCS.

OSHA received numerous comments on additional costs that had not been considered as part of the PEA. OSHA has carefully evaluated those comments on costs and prepared the following responses.

Stakeholders were concerned about the costs associated with relabeling current inventory. Procter & Gamble reported that they felt ‘‘the largest economic impact of GHS compliance to our business will be in the area of re-labeling’’ (Document ID #0381) and numerous other commenters echoed those concerns (Document ID #0386, 0392, 0393, 0400, and 0402). OSHA anticipates that the four-year phase-in for the revisions to the OSHA HCS (increased from three years in the proposed rule) will provide adequate time for companies to deplete inventory and replace in-house containers that are labeled in accordance with the original OSHA HCS and therefore will mitigate any costs associated with relabeling in-house containers or products in inventory.

The Society of Chemical Manufacturers and Affiliates was concerned that OSHA had not considered the costs associated with mailing revised labels, stating that ‘‘a large portion of label revisions will go via the mail service. If a chemical manufacturer produces 75 chemicals and has 50 customers at 70 cents a mailing, it could cost the company as much as $2625.00’’ (Document ID #0402). The revisions to the HCS do not require that establishments mail revised labels to customers. Manufacturers are only required to provide products labeled in accordance with the GHS criteria by the effective date. OSHA did consider the costs associated with mailing updated SDSs and determined that manufacturers are currently providing updated paper or electronic SDSs to customers as they are revised and would not incur additional costs associated with this standard.

Some comments felt that OSHA had overlooked the time and costs associated with relabeling in-house containers with GHS compliant labels (Document ID #0378 and 0386). The phase-in period for the revisions to the HCS provides adequate time for firms to deplete products in inventory that are not labeled with GHS-compliant labels and to replace workplace containers or signs/permanent labels (such as regulated area signs) in the course of the normal cycle for wear-and-tear replacement. OSHA believes that any costs incurred that are outside the costs that would normally be incurred to replace in-house containers would be negligible and has not estimated a cost for this activity.

Some stakeholders anticipated costs associated with translating labels and SDSs into Spanish (Document ID #0381 and 0393). While some companies may find it necessary, based on customer demand, to provide products with labels and SDSs printed in Spanish, the revisions to the OSHA HCS do not contain any requirement for translating labels or SDSs into Spanish. OSHA has not taken costs related to translating labels and SDSs as part of this FEA.

OSHA received comment that firms will incur costs associated with managing multiple SDSs during the transition period. For example, the Society of Plastics Industry, Inc., reported that ‘‘multiple suppliers of the same chemical [may] switch over to the GHS on different schedules’’ and that ‘‘additional time will be required for personnel to sort out and implement appropriate measures for managing this situation’’ (Document ID #0392, 0402, 0415, and 0452). OSHA appreciates that there may be some time during the transition period where some SDSs are GHS-compliant while others are not. However, given the non-uniformity of SDSs currently circulating to firms, the Agency feels that users will already have a system in place for managing multiple SDSs for identical products and that no additional costs will be incurred as a result of the transition to new SDSs.

The U.S. Chamber of Commerce expressed concern that ‘‘employers will also incur legal costs for counsel to review and analyze the revised SDSs to make sure the SDSs provide appropriate explanations and protection from liability’’ (Document ID #0397). However, the final rule primarily changes the format of SDSs, and generally does not make substantial changes to the categories of information that must be included in the SDS. OSHA does not see why a new legal review to protect against tort liability would be necessary in such circumstances. In addition, the Agency believes that such legal costs would be relatively rare and not representative of the vast majority of employers. Furthermore, such legal costs as occur may simply be an alternative to other in-house professional review services that OSHA has already included in the costs. Finally, employers incurring such legal costs for SDS review arguably have been regularly incurring these costs under the existing HCS as part of periodic SDS changes; in that case, they are costs not attributable to this final rule.

The Society of Chemical Manufacturers and Affiliates felt that costs would be incurred because ‘‘someone will have to inventory all of the MSDSs, make the required changes and then communicate those changes to customers and other affected personnel’’ (Document ID #0402). The revisions to the OSHA HCS do not require manufacturers to provide new SDSs to customers who have purchased a product and received an SDS in the past. This final rule also includes a four-year phase-in period for firms to update their SDSs and requires only that those updated, GHS-compliant SDSs be provided to users who purchase a company's product after the effective date. OSHA realizes that some firms may choose to provide updated SDSs to past purchasers of their products, but the updates to the OSHA HCS do not require that they do so. Subsequently, OSHA has not taken any costs related to this activity.

Ferro Corporation's comment in the rulemaking record expressed concern that OSHA did not take into account conversion costs for ‘‘MSDSs and labels for experimental products that are being resampled’’ (Document ID #0363). OSHA's analysis does not make a distinction between commercial and experimental products, but it does not exclude costs associated with experimental products. The Agency feels that this economic analysis captures those costs as well as the transitional costs for products that are sold commercially.

The Society of Plastics Industry, Inc. expressed concern that the revisions to the OSHA HCS would require employers ‘‘to perform new personal protective equipment (PPE) hazard assessments, select new PPE or select PPE for workers who did not previously use it’’ or ‘‘to add or modify ventilation systems or to have their employees use respiratory protection to address newly discovered hazards, and to implement respiratory protection programs’’ (Document ID #0392). The scope of hazards covered by the GHS is very similar to what is covered by the current HCS as discussed in Section XIII Summary and Explanation. While the revisions to the OSHA HCS could, theoretically, result in some chemicals that were not considered hazardous being classified as such now, OSHA does not expect any significant change in chemicals covered under this final rule and did not receive any specific examples from stakeholders, despite repeated requests for them. For this reason, OSHA has concluded that there will be no additional costs related to PPE for this standard.

Multiple stakeholders questioned whether OSHA had taken into account the cost to update workplace signs to come into compliance with the revised OSHA HCS. Southern Company reported that the cost to purchase signs for their 29 affected plants would be $58,000 plus the cost of employee time to install the signs (Document ID #0378), and API reported that one of its member companies recently updated the signs at its small refinery at a cost of $200,000 (Document ID #0376). OSHA feels that the four-year phase-in time for these revisions to the HCS, combined with the limited number of affected workplace signs, will minimize any cost that firms may incur. The phase-in period will allow firms to update their signs during the normal replacement lifecycle of three to five years for those signs and will result in minimal costs.

Commenters felt that ''costs for re-classification and modification of SDS and labels would need to include substantial consulting fees'' (Document ID #0392). OSHA maintains that any firm preparing labels and SDSs under the current OSHA HCS will not find it significantly burdensome to prepare labels and SDSs under the revised HCS. On the contrary, OSHA expects that the revisions to the HCS would be able to prepare SDSs and labels at lower cost in the future (for which the Agency earlier, in Section VI.D: Benefits, estimated productivity savings). In addition, much reclassification work has already been done by firms that sell to the EU or to Asian markets.

Estimation of Compliance Costs

The remainder of this section explains how the compliance costs arising from the final rule were calculated by describing the data and methodology used to estimate each of the major cost elements. A more complete and detailed description of the estimation of compliance costs can be found in the revised final version of the PP&E 2009 report (Document ID #0273), the ERG (2010, 2011) reports focusing on the costs of printing labels in color, and the updated cost estimates for the final rule in ERG (2012).

The major elements of the revisions to the HCS that involve compliance costs include (1) the classification of chemicals in accordance with the GHS criteria, and the revisions to the safety data sheets and labels corresponding to the affected hazardous chemicals; (2) even though it is not directly a result of any specific requirement included in the revisions to the HCS, the cost for managers and administrators of hazard communication programs to become familiar with the revisions to the standard and to manage, update, and revise their programs as may be necessary to ensure compliance with the revised standard; (3) incremental training for employees already trained under the existing OSHA hazard communication programs to ensure their familiarization with the new formats, information, and symbols that would be introduced into the workplace as a result of the revisions to the HCS; and (4) costs to upgrade label printing technology or purchase labels preprinted in multiple colors in order to comply with the requirement that the pictogram on the label be enclosed in a red-bordered diamond.

The estimated compliance costs presented in this analysis of the revisions to the HCS are largely based on research conducted by PP&E (2009), which was expanded and updated for the FEA by ERG (2010, 2011, and 2012). Both PP&E and ERG performed this research under contract to the Department of Labor specifically for the purpose of developing estimates of compliance costs for, and assessing the potential impacts that may be associated with, revisions to the OSHA HCS in order to implement the GHS.

The estimated costs of compliance with many of the 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.

Costs Associated With Chemical Classifications and Revisions to Safety Data Sheets and Labels

The revisions to the OSHA HCS continue to require firms that sell hazardous chemicals to employers to provide information about the associated hazards. Information is required to be presented in a safety data sheet (SDS) in the format specified in the revised standard, and some information is also required to be presented on product labels.

The existing OSHA HCS already requires information about hazardous chemicals to be provided in SDSs and on labels. In addition, under the existing standard, SDSs are to be revised within three months after a manufacturer or employer becomes aware of any significant new information about a chemical hazard.

The final rule requires chemicals to be classified into the appropriate hazard classes and categories based on the information about the chemicals that the manufacturers currently have. This information would have been assembled for purposes of conducting a hazard determination under the current HCS. In addition, the current HCS requires chemical manufacturers and importers to remain aware of developments regarding the hazards of the chemicals they produce or import in order to update the labels and SDSs for the chemicals in a timely manner. The classification of the chemicals into the hazard classes and categories under the revised provisions does not require any additional testing, studies, or research to be conducted. Manufacturers would be able to rely on the information they already have in determining how to properly classify their chemicals.

Generally, chemical manufacturers and importers periodically review, revise, and update SDSs and labels. Changes are made as necessary as information regarding specific hazards develops, new information about protective measures is ascertained, or changes are made to product information and marketing materials. Labels and SDSs must also be produced or modified when products are introduced or changed. Therefore, there is a regular cycle of change for these documents for a variety of reasons. The final rule may require more extensive change than would normally occur, but the phase-in period is such that the chemical manufacturers and importers can take advantage of the normal cycle of change to phase in the revisions for all their products over a reasonable time period. This should have less impact on normal operations than a short time period that would require all SDSs and labels to be revised at the same time.

The transition period that would be allowed by the delayed effective date for the requirement to adopt the new format should help ensure that the transition can be completed in conjunction with revisions and updates that would normally be expected to occur even without the implementation of the final rule. In addition, the format for SDSs required by the final rule is consistent with the format adopted by the American National Standards Institute (ANSI) and therefore has already been implemented by many of the affected businesses.

Based on ERG (2012), OSHA developed estimates of the costs that would be associated with the classification of chemicals in accordance with the final rule and with the revisions to the corresponding SDSs and labels for those chemicals. The estimated compliance costs represent the incremental costs that would be incurred to achieve compliance with the final rule. These estimated costs would be in addition to the costs that would already be incurred to continue to remain in compliance with applicable requirements of the existing HCS.

The revisions to the HCS would allow for a transition period of four years following the publication of a final rule. During this period, even in the absence of any pertinent OSHA rulemaking, producers of affected chemicals would presumably be ensuring that the information provided in their SDSs and labels remains accurate and current. Producers of hazardous chemicals are generally expected to regularly review the available information regarding any hazards that may be associated with their products and to revise SDSs and labels accordingly.

In addition, 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, the chemical producer would be required under existing OSHA and other applicable standards to review the available hazard information, to classify the chemical in accordance with applicable hazard criteria, and to develop corresponding SDSs and labels.

The estimated costs of compliance with the final rule do not include the costs associated with activities such as those described in the above paragraphs, but rather reflect only the additional costs that chemical producers would not already be expected to incur.

The estimated compliance costs associated with the reclassification of hazards and changes to SDSs and labels are directly related to the numbers of SDSs affected. Based on ERG (2012), OSHA developed estimates of the number of potentially affected SDSs by industry, for each of the industries producing the corresponding chemicals and products (as shown in Table VI–3). Downstream users, distributors, and wholesalers are generally expected to continue to rely on SDSs provided by manufacturers to fulfill their obligations under the OSHA standard, as has been the practice for decades.

The costs of compliance associated with the classification of chemicals in accordance with the criteria specified in the final rule and with the revisions to the corresponding SDSs and labels for those chemicals were based on PP&E industry interviews and, as described below, are based on the same time and software estimates as those presented in the proposed rule.

Generally, for smaller establishments with relatively few chemicals affected, OSHA estimated the incremental compliance costs to be the equivalent of the cost of seven hours of time of a professional with the requisite expertise for each affected chemical, on average. Based on ERG's (2012) updates to the PP&E 2009 report (Document ID #0273), OSHA estimated the cost of hourly compensation for a professional for this purpose to be $66. As a result, a small establishment (with fewer than 100 employees) with 20 SDSs for 20 chemicals, for example, would have estimated incremental compliance costs of $9,240 (7 hours times 20 SDSs times $66).

In larger establishments with more affected chemicals, the incremental compliance costs were estimated to consist of two parts. First, labor costs were estimated according to the size of the establishment. OSHA, based on PP&E interviews with stakeholders, estimated that entities with 100 to 499 employees would incur, on average, the equivalent of five hours of time of a professional with the requisite expertise for each affected chemical, and that entities with 500 or more employees would incur the equivalent of three hours of professional time per chemical. Again, OSHA estimated the hourly compensation for a professional for this purpose to be $66.

The rulemaking record presented a wide range of estimates for the time required to update SDSs with a low estimate of four hours per SDS (Document ID #0119 and 0123), a few estimates in the range of 25–30 hours per SDS (Document ID #0134 and 0402), and upper bound estimates as high as 150 hours per SDS (Document ID #0341). OSHA evaluated these estimates and felt that the upper estimates are not defensible for the following reasons: (1) Firms will not be required to gather or evaluate additional data; (2) firms currently must update their SDSs periodically, and there was no evidence presented in the record that suggested that updates under the current HCS take anywhere near 150 hours per SDS; and (3) the Agency does not feel that it is clear that these estimates account for only the incremental time needed to prepare an updated SDS, taking into account any time that would be spent updating SDSs during the transition period in the absence of any revisions to the OSHA HCS. The Agency acknowledges that some SDS updates may take longer than the average listed above, but also feels that many chemicals—especially pure substances which will likely already have been classified according to the GHS for the EU or Asian markets—will take less than the estimated time used in the economic analysis. Therefore, OSHA feels that the estimated time to update SDSs used in this analysis represents a reasonable average for most chemicals.

The labor cost per SDS was estimated to be lower for larger companies based on the determination that larger companies produce more SDSs, and would therefore experience efficiencies associated with producing them. These efficiencies include economies of scale, the use of software specifically designed to classify hazards and produce SDSs, and the generally lower cost per SDS associated with many mixtures.

In addition to labor costs, many of these larger establishments may incur additional expenditures to purchase or modify software that can be used to classify chemicals and to produce corresponding SDSs and labels. Such software is available from a variety of vendors; the software can be purchased or used on a subscription basis. Publicly available information about the products and services being offered and sold to businesses for purposes of complying with hazard communication requirements indicates that most of the relevant vendors are aware of and prepared for an upcoming alignment with the GHS. Therefore, their products and services are or will be adapted to enable compliance with the revisions to the HCS. In addition, some firms may purchase custom or proprietary software from private vendors to achieve compliance with existing requirements or future revisions to hazard communication requirements or for other purposes.

Regardless of the particular approach individual companies may choose to most efficiently fulfill their obligations under the existing HCS, OSHA expects that a part of the costs associated with achieving compliance with the final rule would involve costs attributable to software modifications. Based on industry data obtained by PP&E, OSHA apportioned these costs on a per-SDS basis and estimated the cost per SDS to be $208, on average. Numerous stakeholders raised the issue of software updates and modifications in their comments submitted to the rulemaking record (Document ID #0018, 0105, 0114, 0363, 0371, and 0389). In response to the ANPR, the American Chemistry Council reported that their members estimated anticipated software update and conversion costs of up to $70,000. The ACC also reported that their members typically have hundreds, if not thousands, of SDSs (Document ID #0105). Using OSHA's per-SDS cost of $208, a firm that produced 336 SDSs (which would fall within the typical range for ACC members) could expect to incur costs of $70,000. This example suggests that OSHA's estimated cost-per-SDS is a reasonable one.

Based on ERG's (2012) updates to the PP&E 2009 report (Document ID #0273), OSHA estimated the numbers of SDSs produced in each industry that would potentially need to be revised under the final rule. As shown in Table VI–3, a total of about 1.4 million SDSs, one for each type of chemical produced by an individual manufacturer in the United States, were estimated to be in potential need of revision.

In developing estimates of the compliance costs associated with the rule, PP&E also considered the extent to which many firms have already performed the necessary reclassifications of chemical hazards and revisions to SDSs. Some chemical hazards have already been reclassified as would be required by the OSHA final rule because the U.S. Department of Transportation has required such classifications as part of their regulations for the transportation of hazardous chemicals (49 CFR Parts 171–180). The criteria for physical hazard classifications for purposes of transport have been internationally harmonized for some years, and these criteria formed the basis for the physical hazard criteria in the GHS. Therefore, many products intended for transport have already been classified under the new physical hazard criteria as well as the existing criteria in the HCS.

Many current SDSs are already produced to varying degrees in accordance with the requirements of the OSHA final rule because the widely followed ANSI industry consensus standard already reflects many of these requirements in its relevant criteria. In addition, many firms have implemented or are beginning to implement hazard reclassifications, SDS revisions, software modifications, and other changes in accordance with the requirements of the final 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. 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. Stakeholder comment in the docket suggested that some of the work related to reclassification has already been done (*e.g.,* Document ID #0352, 0377, 0405, and 0410), lending support to OSHA's baseline estimates of current compliance rates.

Research conducted by PP&E indicates that all of these factors contribute to a substantial degree of current compliance with the requirements of the final rule, even if the existing OSHA HCS standard remains unchanged.[23] Based on the ERG (2012) updates to the PP&E (2009) report (Document ID #0273), OSHA estimates that, on average, about 53 percent of the gross costs that would otherwise be associated with the revisions to the HCS have already been incurred by firms. However, this average is a result of very different levels of current compliance for different sizes of firms. PP&E estimated that the percentage of firms in current compliance with the final rule—with the exception of employee training—is 75 percent for firms with over 500 employees; 25 percent for firms with 100 to 500 employees; 5 percent for firms with 20 to 99 employees; and 1 percent for firms with fewer than 20 employees. OSHA used these percentages to reduce the number of affected firms reported in Table VI–3, for purposes of estimating the costs for affected firms to comply with the final rule (again, with the exception of employee training).

Based on the preceding analysis, OSHA estimates an annualized cost of approximately $22.5 million for the classification of chemicals in accordance with the criteria specified in the final rule and for revisions to the corresponding SDSs and labels for those chemicals.[24]

As discussed below, OSHA received some comments from the public regarding the estimated costs associated with chemical classifications and revisions to safety data sheets in response to the ANPR published by OSHA in the **Federal Register** on September 12, 2006 (71 FR 53617) and the Proposed Rulemaking published by OSHA in the **Federal Register** on September 30, 2009 (74 FR 50280). The comments received are publicly available as part of the rulemaking record, accessible through regulations.gov, in docket OSHA–H022K–2006–0062. Relevant information submitted by the public was incorporated into the development of the methodology and estimates presented in this economic analysis.

Some commenters provided examples of cost estimates that generally support the estimates of the preliminary economic analysis. Information from other commenters provided a wide range of cost estimates. The figures presented in some comments appeared to correspond to gross costs of creating SDSs, and in other cases it was not clear whether gross or incremental costs were being presented. In general, commenters did not provide the rationale underlying their cost estimates.

Comment from the Fragrance Materials Association of the United States (Document ID #0061) and the Flavor and Extract Manufacturers Association of the United States (Document ID #0062) stated that these Associations' best assessment is that it would take anywhere from two to eight hours to review information and prepare new labels and safety data sheets for each hazardous chemical

One company that produces and distributes about 4,000 different hazardous chemicals estimated that it will take four to six hours per product to prepare a GHS SDS. (Document ID #0026).

The National Paint and Coatings Association stated that it would take approximately five hours to research the information for a product SDS/label at a small company, at a cost of about $300 per product; it also estimated that, at a medium-sized company, this same task would take from 3–5 days to 3 weeks at a cost of approximately $1,000 to $1,800, and that at a larger company, the task would be even more expensive (Document ID #0050).

The National Association of Chemical Distributors estimated that converting an existing SDS to the new GHS format would require about 150 hours as

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[23] By current compliance, OSHA means firms that have already reclassified chemicals and prepared SDSs and labels in accordance with GHS requirements specified in the final rule and would therefore be ready to introduce these modifications at negligible additional cost when GHS becomes effective.

[24] This annualized estimate of $22.5 million reflects software costs of $55 million and labor costs of $226 million, both multiplied by 0.079932 to annualize these costs (incurred over the first four years) over a 20-year period. The $55 million in software costs is the result of about 264,000 modified SDSs [(929,000 SDSs for large establishments × 25% not in existing compliance × 95% requiring modification) + (233,000 SDSs for establishments with 100–500 employees × 75% not in existing compliance × 25% requiring modification)] at a cost of $208 per SDS. The $226 million in labor cost is the result of about 666,000 affected SDSs multiplied by an average of 5.14 hours of professional time per SDS (from 3 to 7 hours per SDS) multiplied by $66 per hour. The annualization factor, 0.079932, is equal to:

$$[(\tfrac{1}{4}) * [(1-(1.07)^{-4})/0.07] * [0.07/((1-(1.07)^{-20})],$$

where the first term in brackets reflects the fact that these costs are assumed to be spread equally over the first four years; the second term in brackets calculates the present value of the costs, and the third term in brackets annualizes the present value of the costs over a 20-year period.

compared to about 100 hours currently to revise an MSDS (Document ID #0060 and 0341).

Another commenter, Merck, which produces, imports, or distributes about 500 hazardous chemicals annually, estimated that, on average, it takes approximately 3 weeks to generate a single safety data sheet at an average cost of $1,500. Merck also stated that with a sufficient transition period of three to six years, the costs of moving to GHS would be minimal. Merck noted that the time and cost for additional changes to the GHS format should be minimal because it had already converted its SDSs to the 16-section ANSI/GHS format several years ago (Document ID #0072).

One trade association estimated that the costs associated with revising SDSs and labels for the 1,600 firms in the cleaning product formulator industry would total $575 million, not including the time needed to review changes to hazard classifications. The total numbers of SDSs per establishment are generally higher for the establishments represented by the trade association than the OSHA estimates for the industry category as a whole (Document ID #0032).

This trade association also provided some of the details underlying its cost estimates for individual companies. Cost estimates provided by the trade association for individual companies included costs per SDS as low as $30 and $80, and as high as $600 or more. One company (identified as Company #11) estimated the cost to revise the label and SDS would be $120 per product; another company (Company #2) estimated that this cost would be $2,600 per product. Some of the higher compliance cost estimates appear to be unrealistically high; for example, the estimated costs associated only with revising labels for company #3 appear to represent about 3 percent of total annual sales. While acknowledging that some firms may incur higher costs than others to revise SDSs and labels, these data generally appear to support that, at least for several firms in the industry, the costs minimally necessary to achieve compliance would be close to or less than the costs estimated by OSHA.

Ameren, an electric and gas services provider, estimated that all 9,000 of their employees would need one hour of training initially at a total cost of $450,000. The company estimated that it would take 100 hours to update their SDSs (fewer than 25) at a total cost of $6,500 and that updating the 25,000 SDSs in their database would take five minutes per SDS for a total cost of $102,700 (Document ID #0330).

The Independent Lubricant Manufacturers Association surveyed their members and reported that, with one SDS per product, their members could be expected to incur costs of $340,000 to $559,000 ($329 or $200 per SDS multiplied by 1700 SDSs per firm) to update SDSs. One member company estimated costs associated with update software at $200,000 in the first year and $1,000 per SDS in subsequent years to maintain the software and SDSs. Another company estimated that software would cost $50,000 and would include an additional $300,000 in staff time (Document ID #0371).

Another trade organization, The Society of Chemical Manufacturers and Affiliates, felt that it would take ten hours to revise a label or an SDS (Document ID #0402).

Several other commenters provided cost estimates related to the adoption of GHS requirements for chemical classifications and revisions to safety data sheets and labels. (*See,* for example, Document ID #0015, 0018, 0024, 0036, 0079, 0105, 0107, 0116, 0128, 0141, 0145, 0327, 0341, and 0377, among others.) Many estimates are broadly consistent with OSHA's estimates; in addition, some estimates appear to be similar to, but may actually be substantially lower than, OSHA's estimates to the extent they include costs attributable to the existing standard rather than just the incremental costs associated with the revisions to the HCS. Other estimates are substantially higher, but many of these also appear to represent gross costs associated with fulfilling hazard communication requirements without consideration of the incremental nature of the compliance costs for the revisions to the HCS, as discussed above.

Management Familiarization and Other Management-Related Costs

The implementation of GHS as part of the OSHA HCS would require that employees currently covered by the standard become familiar with the new system. The nature and extent of the familiarization required would vary depending on an employee's job and business. OSHA considered separately various training needs that may be imposed by the revisions.

Although it would not be explicitly required by the final rule, some establishments may choose to provide training to managers and other employees that are not directly covered by the training requirements of the HCS. Other management-related costs may include making revisions, if necessary, to existing hazard communication programs; promoting awareness of and providing information about the revisions to hazard communication programs; coordinating and integrating changes to hazard communication programs with other programs, processes, and functions; serving as an in-house resource for supporting the general adoption of the revised HCS; creating supplemental capacity for providing training and assistance to affected employees; and other ancillary costs for company-specific changes and general hazard communication program administration that may be incurred at some establishments.

These management costs could be considered discretionary since they are not explicitly required by the regulatory provisions. However, OSHA recognizes that these costs may be incurred in practice due to the manner in which some companies have implemented and integrated hazard communication programs in their facilities. These costs reflect the fact that hazard communications programs often are not implemented solely for purposes of complying with the OSHA standard, but may serve a variety of other purposes that are part of and that benefit the overall production process.

In some cases, health and safety supervisors, logistics personnel, and other personnel involved in administering, implementing, and ensuring compliance with the requirements of the HCS in affected establishments would be expected by company managers to become familiar with the revisions to the HCS. The responsibilities of these employees may include modifying written hazard communication programs as necessary, reviewing and preparing training materials, and training new and existing employees regarding the changes. A commenter asserted that OSHA had overlooked the cost to train the employees who would be providing training to production workers (Document ID #0392), and the American Chemistry Council also questioned whether OSHA had considered the necessary training for fire, EMS, or other emergency workers (Document ID #0393). The Agency has included these occupations in the cost estimates, allocating eight hours for training on the revised HCS elements, and included employees responsible for providing training as part of the management training and familiarization costs and has continued to include them in estimated the costs of the rule for this FEA.

In the PEA, OSHA estimated 8 hours of time, 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. Comments received on the topic of management familiarization yielded a wide range of time needed for this task. Some estimates were what OSHA considers to be unreasonably high (ranging from 16 to 56 hours (Document ID #0372)) and may not represent incremental costs only. OSHA did receive a comment that ''eight hours * * * [may be enough to gain] a basic understanding'' of the revisions to the OSHA HCS but went on to say that ''as much as a week * * * [may be needed to gain an] understanding of the details'' (Document ID #0392). OSHA believes that under the current HCS, managers spend some time each year reviewing and updating their hazard communication program. So, while a manager may spend more than 8 hours total reviewing and familiarizing themselves with the revised HCS, a portion of that time would not fall under new costs resulting from the promulgation of the rule. OSHA did not feel that commenters presented a strong case for changing the estimate of incremental time needed for familiarization with the revised HCS and has therefore maintained the estimate of 8 hours.

In many potentially affected establishments that do not produce SDSs, and that have few affected chemicals or few affected employees, a very basic hazard communication program may achieve compliance with the OSHA standard. For these establishments, outside of the manufacturing sector, that have a health and safety supervisor, the incremental management and administrative costs associated with the revisions to the OSHA standard were estimated to be two hours per establishment. For establishments outside of the manufacturing sector that do not have a health and safety supervisor, OSHA estimated that these costs would be negligible.

Based on the preceding analysis, OSHA estimates an annualized cost of approximately $59 million for management familiarization and other related management activities in response to GHS.[25]

Costs Associated With Training Employees

Production employees who are currently covered by and trained under the provisions of the existing HCS would need to receive some additional training to become familiar with the changes to SDSs and labels.

In many potentially affected establishments that do not produce SDSs, and that have few affected chemicals or few affected employees, a very basic hazard communication program may achieve compliance with the OSHA final rule. In these establishments, the incremental employee training costs associated with the revisions to the HCS may be relatively small. In other cases, employers may be able to integrate the necessary training into existing training programs and other methods of distributing safety and health information to employees, and thus may not incur much additional cost. Nevertheless, in general, employers will need to devote real time and resources to provide the necessary training in order to ensure that workers are familiar with the new hazard communication system.

In response to comments in the rulemaking record, the training time associated with the revisions to the OSHA HCS has been increased from those presented in the PEA. OSHA increased the estimated training time from 30 minutes to 60 minutes for most employees; from 15 minutes to 30 minutes for employees with minimal contact with hazardous chemicals; and from 5 to 10 minutes for employees in certain occupations in the transportation sector, where GHS pictograms are already in use. A complete occupation-by-occupation summary of OSHA's estimates is provided in the ERG (2012) revisions to the PP&E (2009) report.

The United Parcel Service, Inc. submitted comment supporting this increase, reporting that ''[i]nitial training takes about 15 minutes currently but will [* * *] double during the phase-in process'' and that ''training time (½ hr) will double to one hour [* * *] for employees who are 'users' '' (Document ID #0369). Other stakeholders also felt that training time was underestimated (Document ID #0330, 0345, 0347, 0363, 0392, 0397, 0400, 0402, 0404, and 0440), with the estimates of additional time needed over and above OSHA's estimates ranging from 15 minutes (Document ID #0330, 0369, and 0378) to 15 hours (Document ID #0400). OSHA's increase of training time by 100 percent over the estimated training time in the PEA represents a significant increase in response to comments, and the Agency believes that these estimates of training times are reasonable. The extra time OSHA has incorporated also addresses concerns of some stakeholders that firms will have to offer two iterations of training —one before the two-year familiarization deadline set forth in the regulatory text, and one closer to the effective date when all products have been converted to GHS-compliant SDSs and labels (Document ID #0339). However, for costing purposes, all training costs for workers to become familiar with GHS requirements were assumed to be incurred within the first two years after the effective date of the final rule. OSHA received comment that additional training time would be required to train employees responsible for reclassifying chemicals under the revised HCS (Document ID #0392). OSHA believes that the changes to the HCS are such that an employer who was capable of classifying chemical hazards under the current HCS would be able to become familiar with the GHS criteria in a relatively short period of time. The Agency has also allocated 3 to 7 hours per product to complete the reclassification and produce an updated SDS, which should allow for additional familiarization time if necessary. OSHA has not included additional training time for training on new hazards disclosed as a part of the transition. This concern was raised by a commenter (Document ID #0339), because it is theoretically possible that some chemicals could be classified with new hazards through the GHS classification schemes that were not previously presented in the workplace. However, the data used for classification is the same used for the current hazard determination, and OSHA believes that few new hazards would actually be introduced through this process. Compliance with the final rule is not expected to impose any additional training costs after the transition period.

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[25] This annualized estimate of $59 million reflects total costs of $692 million multiplied by 0.085332 to annualize these costs (incurred over the first two years) over a 20-year period. The $692 million is equal to $6 million for health and safety managers (7,070 affected managers × $1039 per manager (the estimated cost of one day training per manager) × 83% not currently in compliance) plus $15 million for logistics personnel in manufacturing (49,100 affected logistics persons × 8 hours × $66 per hour × 83% not currently in compliance) plus $163 million for health and safety supervisors in manufacturing (370,000 affected health and safety supervisors in manufacturing × 8 hours × $66 per hour × 83% not currently in compliance) plus $508 million for health and safety supervisors in non-manufacturing (3,848,000 affected H&S supervisors in non-manufacturing × 2 hours × $66 per hour × 100% not currently in compliance).

The annualization factor, 0.085332, is equal to:

$[(1/2) * [(1-(1.07)^{-2})/0.07] * [0.07/((1-(1.07)^{-20})]$,

where the first term in brackets reflects the fact that these costs are assumed to be spread equally over the first two years; the second term in brackets calculates the present value of the costs, and the third term in brackets annualizes the present value of the costs over a 20-year period.

Based on the preceding analysis, OSHA estimates that the annualized cost of training employees in response to GHS would be approximately $95.4 million.[26]

The revisions to the HCS may result in reductions in the costs associated with providing training for employees as required by the existing OSHA HCS. Affected companies could save considerable time and effort in training new employees in the future. The savings may be attributable in part to reducing or eliminating the need to explain the different types of formats used to convey hazard information and the different types of information included in the contents of SDSs and labels. OSHA did not quantify these potential savings in training costs as part of this FEA but, based on stakeholder comment and testimony in the rulemaking record, OSHA anticipates that companies will realize cost savings in future time periods from simplified hazard communication training facilitated by the final rule. A qualitative discussion of these cost savings was presented in Section VI.D: Benefits in this preamble and an estimate of the possible magnitude of these cost savings is presented in the sensitivity analysis in Section VI.L in this preamble.

Cost of Color Printing

The revisions to OSHA's HCS include a requirement that labels include a pictogram enclosed in a red-bordered diamond. The rulemaking record showed widespread (although not unanimous) support for requiring the red-bordered diamond. One commenter felt that ''the use of color to draw attention to a potential hazard is a useful tool and is likely to enhance the communication of safety information'' (Document ID #0327), another stated that ''the color red has been universally accepted as indicating a potential danger or hazard'' (Document ID #0339), and others showed general support for requiring red borders in order to achieve the highest level of harmonization (Document ID #0351 and 0383). Many stakeholders raised concerns that this requirement would result in additional costs to firms since many do not currently print labels in multiple colors or purchase pre-printed labels in multiple colors (Document ID #0120, 0327, 0328, 0344, 0363, 0383, 0389, and 0402). Requiring the red-bordered diamond on the label would mean that some firms would have to upgrade their printer technology or purchase more expensive pre-printed label stock that included the red-bordered diamond.

OSHA estimated the cost impacts of the rule's requirement that pictogram borders be printed in red based on a report on the subject prepared by ERG (2011). That report is based on data provided in an earlier report prepared by ERG (2010). The full ERG reports are available in the rulemaking docket on regulations.gov. To estimate costs for this provision, OSHA estimated the number of hazard labels printed per year, the number of establishments that would incur costs to upgrade their printing technology, and the cost to those establishments to upgrade their printing technology. OSHA estimates that approximately 949 million hazard labels are printed each year and the total incremental cost for establishments to comply with this provision of the OSHA standard is $24.1 million per year. The following section explains how OSHA, using ERG (2010 and 2011), developed estimates of the number of hazard labels printed per establishment, the number of establishments that would need to upgrade printer technology, and the cost to those establishments to comply with this provision of the final rule.

ERG (2011) used data on *Shipment Characteristics by Commodity by Shipment Weight* from the U.S. Census Bureau[27] and DOT's jointly produced Commodity Flow Survey (CFS) (U.S. Census Bureau, 2007).[28] Commodity shipments reported in this survey were classified using the Standard Classification of Transported Goods (SCTG) commodity codes,[29] which ERG mapped to the relevant NAICS industries.

For each of the SCTG commodity codes, the U.S. Census data present shipments of basic chemicals by shipment weight. In order to establish the types of shipments that might fall into each weight class, OSHA relied on preliminary research conducted by ERG (2010) on the weight and capacity of various shipping container units and the weight per gallon of various chemicals. Information was gathered on the types of containers typically used by specific industries and whether those containers would typically ship inside a labeled exterior container. OSHA calculated shipment weights for various chemicals shipped in various container types by multiplying the product weight per gallon by container capacity and adding the weight of the shipping container. As shown in Table VI–5, minimum, maximum, and simple average weights per full container were estimated for the different commodities evaluated in this test case using the Census-reported commodity shipments by shipment weight to establish some bounds on possible shipment types.

[26] This annualized estimate of $95.4 million reflects total costs of $1,118 million multiplied by 0.085332 to annualize these costs (for costing purposes, assumed to be entirely incurred over the first two years) over a 20-year period. The $1,118 million is equal to $785 million in employee hours to receive training (43.8 million affected employees × 0.84 hours × $21 per hour) plus $333 million in management hours to provide the training (6.0 million training sessions × 0.84 hours × $66 per hour). The 0.84 hours is the average estimated training time for all affected employees, with most receiving 60 minutes of training, some receiving 30 minutes of training, and a very few receiving 10 minutes of training. The total number of managers providing training (3.8 million) would, on average, be equal to approximately 8.7 percent of the number of employees receiving training in response to GHS.

[27] U.S. Census Bureau, 2007. Commodity Flow Survey: Shipment Characteristics by Commodity by Shipment Weight. Available at *http://www.bts.gov/publications/commodity_flow_survey/*.

[28] U.S. Census Bureau, 2007a. American Fact Finder: Commodity Flow Survey. Available at *http://www.census.gov/econ/census07/index.html*.

[29] The following 13 commodity codes were considered as those that would potentially contain hazardous chemicals: Alcoholic Beverages (Commodity code 8), Gasoline, including Aviation (Commodity code 17), Fuel Oils (Commodity code 18), Other Coal and Petroleum Products (Commodity code 19), Basic Chemicals (Commodity code 20), Pharmaceutical Products (Commodity code 21), Fertilizers (Commodity code 22), Other Chemical Products & Preparations (Commodity code 23), Plastics and rubber (Commodity code 24), Pulp, newsprint, paper, and paperboard (Commodity code 27), Nonmetallic mineral products (Commodity code 31), Base Metal in Primary or Semi-Finished Forms and in Finished Basic Shapes (Commodity code 32), and Miscellaneous Manufactured Products (Commodity code 40).

Table VI-5. Chemical Container Estimated Typical Shipment Weights

Container Type		Estimated Shipment Weight (lbs) Minimum	Typical	Maximum	Number of Labels per Container
250 milliliter jug		0.5	0.7	1.1	1.13[a]
500 milliliter jug		0.9	1.3	2.1	1.13[a]
1 liter jug		1.8	2.5	4.2	1.25[a]
2 liter jug		3.6	4.9	8.2	1.25[a]
1 gallon jug		7	9	16	1.25[a]
2.5 gallon jug		18	24	40	1.5[a]
5 gallon drum		34	48	80	1
30 gallon drum		200	280	470	1
55 gallon drum		360	510	860	1
275 gallon tote		1,800	2,500	4,200	1
330 gallon tote		2,200	3,000	5,100	1
Tank Truck	5,500 gal.	34,000	48,000	82,000	0
	7,000 gal.	43,000	61,000	105,000	0
	20,000 gal.	129,000	182,000	311,000	0
Rail Car	30,000 gal.	186,000	260,000	450,000	0
Barge		2,700,000	3,800,000	6,500,000	0

[a] Assumes 8 units per package for containers smaller than 1 liter, 4 units per package for containers from 1 liter to 1 gallon, and 2 units per package for 2.5 gallon containers.

Source: Office of Regulatory Analysis, OSHA based on ERG (2010)

Based on these calculations, OSHA was able to estimate the number of each type of container that would fall into each of the U.S. Census weight classes. The number of containers that would require a label under the OSHA HCS was refined by estimating the percentage of each commodity that was comprised of nonhazardous products and the percentage of the remaining products that would be sold to consumers. Neither of these types of products fall under the scope of OSHA's HCS and would not require a hazard warning label under the revised rule. For the remaining hazardous non-consumer shipments, assuming one label per container and one label on the outer packaging where applicable, ERG estimated that approximately 949 million hazard labels are applied annually to containers of all sizes.

In most cases one SCTG maps to multiple NAICS industries. In order to divide the number of labels for each SCTG among its constituent NAICS industries, OSHA used receipts data from the U.S. Census Bureau's Statistics of U.S. Businesses to calculate receipts for a particular NAICS industry as a percentage of receipts for all NAICS industries that map to one SCTG. This percentage was used to allocate the estimated number of labels printed for each SCTG among its constituent NAICS industries.

The labels printed per NAICS industry were then distributed among the various size classes based on each size class's share of receipts. In cases where receipts data were not available from the Statistics of U.S. Business (a situation found exclusively within the chemical manufacturing industry in the affected industries for this rule), OSHA calculated the average total receipts and average receipts for each establishment size class for six-digit NAICS in the 325 (Chemical Manufacturing) subsector and the ratio of average receipts for size class to total receipts for six-digit NAICS in 325. This ratio was multiplied by total receipts for the appropriate size class for each industry where receipts data were not available.

Having estimated the number of hazard labels used per year for each NAICS code, OSHA next estimated the costs associated with printing those labels with red pictogram borders. Affected establishments were assigned to one of four categories:

- Category 1: Companies printing only in black who don't own a color printer
- Category 2: Companies printing in black but who own a color printer
- Category 3: Companies using pre-printed stock or labels
- Category 4: Companies printing color labels

Establishments in Category 1 and Category 2 will have to buy new color printers (although Category 2 establishments will have to buy fewer new printers), as well as either color cartridges for laser printers or red ribbons for thermal transfer printers. Establishments in Category 3 will face higher costs for pre-printed stock or labels with red pictogram borders. Establishments in Category 4 will not face higher costs. Relying on conversations with companies and label printers/vendors, ERG allotted establishments into these four categories on the basis of establishment size (as shown in Table VI–6).

Table V1-6. Establishment Distribution

Establishment Size	Category 1	2	3	4	Total
Very Small	30%	10%	40%	20%	100%
Small	30%	10%	40%	20%	100%
Medium	30%	10%	40%	20%	100%
Large	5%	15%	50%	30%	100%
Total	26%	11%	42%	22%	100%

Source: Office of Regulatory Analysis, OSHA based on ERG (2011)

Using the estimates of the percentage of establishments per category by size and the data presented in the industry profile, OSHA was able to estimate the number of establishments per category by size. OSHA used the ratio of SDSs produced by size class to the ratio of total SDSs produced and used that ratio to estimate the number of labels produced per size class per NAICS industry. The results are shown in Table VI–7.

Table VI-7. Establishments and Labels by Category

Size Category	Establishments in Category	Number of Labels Per Year
Category 1: Companies Printing only B&W and no Color Printer		
Very Small	16,237	10,635,815
Small	4,475	18,958,765
Medium	2,267	28,721,211
Large	739	37,746,817
Category 2: Companies Printing B&W but Own Color Printer		
Very Small	5,412	3,545,272
Small	1,492	6,319,588
Medium	756	9,573,737
Large	2,216	113,240,450
Category 3: Companies Using Pre-Printed Stock/Labels		
Very Small	21,649	14,181,086
Small	5,966	25,278,353
Medium	3,022	38,294,949
Large	7,387	377,468,168
Category 4: Companies Printing Color Labels		
Very Small	10,824	7,090,543
Small	2,983	12,639,177
Medium	1,511	19,147,474
Large	4,432	226,480,901
Total, All Categories		
Very Small	54,122	35,452,716
Small	14,916	63,195,884
Medium	7,555	95,737,371
Large	14,774	754,936,337

Source: Office of Regulatory Analysis, OSHA based on ERG (2011)

The number of establishments per category per size class and the number of labels per establishment were then combined with the incremental costs to print in color as opposed to black only to arrive at an estimate of the cost of this provision.

The unit costs by category were estimated as follows.

A low-end laser printer was estimated to cost only a few hundred dollars while a higher-end laser printer can cost upwards of $1,000 to $5,000. OSHA estimates that on average, the incremental cost of buying a color printer instead of a black and white printer is $50 for a low-end laser printer, $100 for a high-end laser printer, $100 for a low-end thermal transfer printer, and $1,000 for a high-end thermal transfer printer. In this analysis, OSHA considers the cost of printers to be a one-time cost that establishments will incur during the four year transition period. The one-time, non-annualized cost to establishments to upgrade printer technology was estimated to be $11.8 million. Printer costs were annualized using a 7 percent interest rate over a five-year period.

The incremental cost of color cartridges for laser printers is a significant driver of costs under the rule. Black cartridges cost approximately $300, while printing in color requires buying four cartridges (cyan, magenta, yellow, and black) at an estimated cost of $1,200. Additionally, printers using black cartridges can print 20,000 labels, while color cartridges can print only 6,000 labels. This results in a per-label cost of $0.015 for black cartridges and $0.20 for color cartridges, for an incremental cost of $0.185.

For companies using thermal transfer printers, the cost of ribbons varies depending on the label material, but is approximately $30 per ribbon for black ribbons and $40 per ribbon for red ribbons. Since both black and red ribbons will be required to print labels under the final rule, the incremental cost of printing in color is the cost of the red ribbon or $40. Both types of ribbons will print approximately 1,000 labels, for a per-label cost of $0.034 for black ribbons and $0.04 for red ribbons, for an incremental cost of $0.01 per label.

For companies using pre-printed stock/labels, the cost of all black labels is estimated to be $0.10 per label while the cost of labels with red pictograms is estimated to be $0.15 per label. This results in an incremental cost of $0.05 per label.

For the purposes of this analysis, OSHA estimated that for those establishments in category 1 (those currently printing labels only with black ink who don't own a color printer) very small establishments will purchase one low-end laser printer, small establishments will purchase two high-end laser printers, medium establishments will purchase three low-end thermal transfer printers, and large establishments will purchase four high-end thermal transfer printers. For establishments in category 2 (those currently printing labels only in black ink but who own a color printer), OSHA estimated that very small establishments will purchase one low-end laser printer, small establishments will purchase one high-end laser printer, medium establishments will purchase two low-end thermal transfer printers, and large establishments will purchase three high-end thermal transfer printers. OSHA estimates that establishments in categories 3 and 4 (those purchasing preprinted black and white labels and those currently printing labels in color) will incur no costs to procure new printers.

Using the estimates described above, OSHA was able to determine the current costs of printing and the cost of printing labels with red-bordered pictograms.

For establishments in Category 1 (those printing black and white labels), the current average cost per label is $0.02 and the average cost per establishment is $132, and for establishments in Category 2 (those printing black and white labels but who own a color printer), the current average cost per label is $0.03 and the average cost per establishment is $344. Establishments in Category 1 and Category 2 will have to buy new color printers (although those in Category 2 will have to buy fewer printers). These establishments will also face higher costs for purchasing color cartridges and ribbons. For these establishments, the cost of purchasing a color printer becomes insignificant when annualized (at a 7 percent interest rate over five years) and when considered on a per-label basis. The main driver of overall costs is the incremental cost of purchasing color cartridges for those establishments using laser printers (establishments that OSHA estimates are small and very small). For very small and small establishments using a laser printer, the cost of cartridges goes from under $0.02 per label for a black cartridge to $0.20 per label for color cartridges. Cost increases are more modest for medium and large establishments using thermal transfer printers, with ribbon costs only increasing from $0.03 to $0.04 per label.

For establishments in Category 3 (those who use pre-printed stock or labels) the current average cost per label is $0.10 and the average cost to purchase labels per establishment is $1,148. Establishments in Category 3 will have to pay more for pre-printed stock or pre-printed labels with red pictograms than for their current hazard labels. OSHA estimates that costs will increase from $0.10 per label to $0.15 per label, increasing printing costs by 50 percent for all establishments in this category.

For establishments in Category 4 (those currently printing in color) the current average cost per label is $0.15 and the average cost per establishment is $1,880. Establishments in Category 4 will not have to pay any more to print red borders as they are already printing color labels.

The annualized cost of printers was calculated by finding the present value of the incremental printer cost incurred four years after the rule is published (to account for the compliance time for the labeling provisions of the rule). This present value was annualized over five years at a 7 percent interest rate to account for the life of the printer. In the cases of printing supplies (*i.e.,* cartridges, ribbons, or label stock), costs are calculated as though they would be incurred over a 20-year period, but would not begin to be incurred until four years after the rule is published. Detailed estimates are presented in Table VI–9 included in the appendix at the end of this section.

For all establishments in all categories, the total costs associated with the requirement to print red pictogram borders are approximately $24.1 million per year, which includes the annualized cost of new printers (approximately $2.4 million) and of 16 years' worth of annual printing supply costs. OSHA feels this estimate is in line with the comments received on the subject as part of the rulemaking record. Betco Corporation estimated that requiring color printing would increase printing costs by 25 percent (Document ID #0389), Dow Chemical estimated that black and white printing was 40 percent less expensive than color printing (Document ID #0353), and The National Paint & Coatings Association, Inc. estimated an increase of 15 percent to 47 percent to print in color depending on the size of the label (Document ID #0328). The Agency also feels that the four-year phase-in period allows adequate time for establishments to exhaust their current stock of labels, which will help ameliorate some cost concerns expressed by stakeholders.

Summary of Unit Cost Estimates

The following list provides a summary of the input estimates underlying the calculation of the compliance costs. It should be noted that these costs are intended to reflect only the incremental costs that would be incurred in addition to the associated costs that would be incurred in the absence of the revisions to the HCS. Except for employee training and color printing, these costs would apply only to those businesses not already in compliance with the revisions.

Reclassifying chemicals and modifying SDSs and labels:

- Large establishments (over 500 employees): an average of 3 hours per SDS; in addition, for 95 percent of establishments, an average of $208 per SDS for software modifications.
- Medium establishments (100–499 employees): an average of 5 hours per SDS; in addition, for 25 percent of establishments, an average of $208 per SDS for software modifications.
- Small establishments (1–99 employees): an average of 7 hours per SDS. Management familiarization and other costs:
- Eight hours for health and safety managers and logistics personnel in the manufacturing sector.
- Two hours for each hazard communication program manager not in the manufacturing sector.

Employee training:

- One hour per production employee in most industries;
- 30 minutes in occupations exposed to few hazardous chemicals and types of hazards;
- 10 minutes per employee in some occupations where GHS-type pictograms are already in use.

Color Printing

- Category 1 establishments (those currently printing only in black & white who do not own color printers): Large establishments $0.02 per label, medium establishments $0.01 per label, small establishments $0.13 per label, and very small establishments $0.14 per label.
- Category 2 establishments (those currently printing only in black & white but who own color printers): large establishments $0.02 per label, medium establishments $0.01 per label, small establishments $0.13 per label, and very small establishments $0.14 per label.
- Category 3 establishments (those currently purchasing pre-printed label stock): large establishments $0.03 per label, medium establishments $0.03 per label, small and very small establishments $0.03 per label.
- Category 4 establishments (those currently producing labels printed in multiple colors): No additional costs related to this provision.

Appendix to Section F: Total Non-Annualized Costs of Compliance

Table VI–8 shows the total non-annualized (non-discounted) compliance costs by industry and by cost element that are estimated to be incurred during the four-year phase-in of the revisions. Except for employee training and color printing, these estimates include no costs for businesses already in compliance with the revisions.

As shown in Table VI–8, the total cost of compliance with the rulemaking over the course of the transition period of four years is estimated to be about $2.1 billion. Of this amount, the cost of chemical hazard reclassification and revision of SDSs and labels is an estimated $281 million, the cost of training employees is an estimated $1,118 million, the cost of management familiarization and other costs such as updates to hazard communication programs is an estimated $692 million, and the one-time printer costs for companies needing to upgrade printing technology to print labels in color is an estimated $12 million.

Table VI–9 summarizes OSHA's estimates for printing costs. It shows annualized per-label costs by category and establishment size ranging from $0.01 to $0.14 and total annualized costs by category and establishment size. Total annualized costs include the cost of printers annualized over five years and the cost of printing supplies incurred over a 20-year period beginning four years after the rule is published.

BILLING CODE 4510–26–P

Table VI-8.
Total Costs of Compliance during Transition Period

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs & Labels	Cost of Training Employees	Management Familiarization & Other Costs	One-Time Printer Costs	Total Costs
11	**Agriculture, Forestry, Fishing & Hunting**					
113	Forestry & Logging	$0	$761,836	$1,096,318	$0	$1,858,153
114	Fishing, Hunting and Trappinig	$0	$74,061	$98,885	$0	$172,946
115	Support Activities for Ag & Forestry	$0	$410,931	$489,409	$0	$900,340
211	**Oil and Gas Extraction**					
211111	Crude petroleum & natural gas extraction	$19,372,038	$2,651,234	$3,623,590	$0	$25,646,863
211112	Natural gas liquid extraction	$864,246	$202,401	$90,742	$0	$1,157,389
212	Mining (except Oil & Gas)	$0	$3,068,524	$951,225	$0	$4,019,749
213	Support Activities for Mining	$0	$3,583,490	$1,126,023	$0	$4,709,513
22	**Utilities**					
2211	Electric Power Gen, Trans & Distrib	$0	$9,381,823	$4,392,355	$0	$13,774,178
2212	Natural Gas Distribution	$0	$1,003,184	$1,239,756	$0	$2,242,940
2213	Water, Sewage, & Other Systems	$0	$848,412	$2,318,357	$0	$3,166,769
23	**Construction**					
236	Construction of Buildings	$0	$32,833,731	$29,889,179	$0	$62,722,909
237	Heavy Construction	$0	$13,443,559	$5,274,180	$0	$18,717,739
238	Special Trade Contractors	$0	$79,911,845	$58,615,764	$0	$138,527,609
31	**Manufacturing**					
311	Food Manufacturing	$0	$32,035,849	$13,078,927	$0	$45,114,776
312	Beverage &Tobacco Prod. Manuf.	$0	$2,708,287	$1,969,911	$0	$4,678,197
313	Textile Mills	$0	$4,005,063	$1,598,052	$0	$5,603,115
314	Textile Product Mills	$0	$3,700,607	$3,574,615	$0	$7,275,222
315	Apparel Manufacturing	$0	$8,085,632	$5,785,224	$0	$13,870,855
316	Leather & Allied Product Manufac.	$0	$872,297	$739,306	$0	$1,611,604
321	Wood Product Manufacturing	$0	$12,666,117	$8,597,706	$0	$21,263,823
322	Paper Manufacturing	$0	$9,393,458	$2,324,258	$0	$11,717,716
323	Printing and Related Support	$0	$14,172,035	$17,507,178	$0	$31,679,213
324	**Petroleum & Coal Prod. Manufac.**					
324110	Petroleum refineries	$3,950,224	$1,105,201	$170,923	$104,110	$5,330,458
324121	Asphalt paving mixture & block mfg	$19,507,491	$349,431	$497,823	$499,510	$20,854,256

Table VI-8.
Total Costs of Compliance during Transition Period (continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs & Labels	Cost of Training Employees	Management Familiarization & Other Costs	One-Time Printer Costs	Total Costs
324	**Petroleum & Coal Prod. Manufac.**					
324122	Asphalt shingle & coating materials mfg	$2,928,198	$245,560	$95,128	$68,250	$3,337,136
324191	Petroleum lubricating oil & grease m	$109,394,737	$166,018	$176,282	$46,950	$109,783,987
324199	All other petroleum & coal products mfg	$1,039,991	$69,844	$44,007	$16,140	$1,169,982
325	**Chemical Manufacturing**					
325110	Petrochemical mfg	$585,728	$116,271	$23,307	$22,370	$747,676
325120	Industrial gas mfg	$556,565	$8,054	$190,183	$303,670	$1,058,472
325131	Inorganic dye & pigment mfg	$161,929	$50,521	$53,514	$20,960	$286,924
325132	Synthetic organic dye & pigment mfg	$532,839	$83,637	$58,677	$20,420	$695,573
325181	Alkalies & chlorine mfg	$73,203	$0	$20,893	$17,880	$111,976
325182	Carbon black mfg	$42,633	$0	$13,101	$9,540	$65,275
325188	All other basic inorganic chemical mfg	$2,740,735	$745,601	$290,336	$177,240	$3,953,912
325191	Gum & wood chemical mfg	$432,698	$32,356	$34,476	$9,430	$508,960
325192	Cyclic crude & intermediate mfg	$58,999	$84,571	$19,081	$9,550	$172,201
325193	Ethyl alcohol mfg	$854,141	$130,819	$138,768	$19,820	$1,143,549
325199	All other basic organic chemical mfg	$4,202,772	$1,127,684	$354,429	$188,220	$5,873,105
325211	Plastics material & resin mfg	$11,786,608	$1,105,863	$399,367	$210,110	$13,501,948
325212	Synthetic rubber mfg	$310,109	$174,855	$85,727	$30,190	$600,882
325221	Cellulosic organic fiber mfg	$7,021	$52,751	$11,495	$2,570	$73,837
325222	Noncellulosic organic fiber mfg	$0	$394,262	$61,566	$0	$455,828
325311	Nitrogenous fertilizer mfg	$62,429	$26,257	$98,880	$28,610	$216,177
325312	Phosphatic fertilizer mfg	$14,326	$14,025	$22,348	$13,440	$64,139
325314	Fertilizer (mixing only) mfg	$897,520	$165,196	$289,848	$68,670	$1,421,234
325320	Pesticide & other agricultural chemical mfg	$1,154,461	$171,100	$124,788	$54,030	$1,504,379
325411	Medicinal & botanical mfg	$1,058,085	$334,287	$207,015	$47,960	$1,647,347
325412	Pharmaceutical preparation mfg	$2,945,309	$1,946,506	$532,750	$218,940	$5,643,505
325413	In-vitro diagnostic substance mfg	$4,028,692	$294,582	$131,150	$48,440	$4,502,864
325414	Biological product (except diagnostic) mfg	$584,754	$394,047	$150,877	$85,610	$1,215,288
325510	Paint & coating mfg	$14,252,071	$545,201	$776,347	$181,900	$15,755,519
325520	Adhesive mfg	$5,185,730	$391,262	$324,138	$118,460	$6,019,591

Table VI-8.
Total Costs of Compliance during Transition Period (continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs & Labels	Cost of Training Employees	Management Familiarization & Other Costs	One-Time Printer Costs	Total Costs
325	**Chemical Manufacturing**					
325611	Soap & other detergent mfg	$3,386,775	$431,109	$439,460	$64,270	$4,321,613
325612	Polish & other sanitation good mfg	$2,245,744	$280,726	$359,492	$47,370	$2,933,332
325613	Surface active agent mfg	$1,000,438	$80,842	$82,686	$32,030	$1,195,995
325620	Toilet preparation mfg	$3,916,910	$1,070,277	$511,173	$93,070	$5,591,430
325910	Printing ink mfg	$7,111,319	$196,206	$245,528	$117,620	$7,670,673
325920	Explosives mfg	$316,089	$119,418	$35,022	$26,240	$496,770
325991	Custom compounding of purchased resin	$1,060,665	$402,427	$346,392	$93,080	$1,902,564
325992	Photographic film, paper, plate, & chemical mfg	$834,937	$133,931	$280,206	$33,750	$1,282,825
325998	All other miscellaneous chemical product & preparation mfg	$9,735,649	$632,012	$727,691	$171,790	$11,267,143
326	Plastics and Rubber Products Man.	$9,918,393	$19,293,692	$6,996,994	$2,393,990	$38,603,069
327	Nonmetallic Mineral Prod. Manufac.	$11,255,479	$11,014,675	$7,696,463	$3,466,920	$33,433,536
331	Primary Metal Manufacturing	$3,587,506	$9,809,003	$2,711,738	$895,140	$17,003,386
332	Fabricated Metal Prod. Manufac.	$0	$34,367,356	$31,583,489	$0	$65,950,844
333	Machinery Manufacturing	$0	$20,640,396	$13,586,090	$0	$34,226,486
334	Computer & Electronic Prod Man.	$0	$13,552,651	$7,432,685	$0	$20,985,336
335	Electric Equipment, Appliance Man.	$0	$8,420,877	$3,121,122	$0	$11,541,998
336	Transportation Equip. Manufacturing	$0	$32,038,215	$7,117,955	$0	$39,156,170
337	Furniture & Related Product Man.	$0	$12,151,235	$11,626,020	$0	$23,777,255
339	Miscellaneous Manufacturing	$17,119,063	$13,316,597	$16,370,063	$1,729,520	$48,535,243
42	**Wholesale Trade**					
423	Durable Goods	$0	$20,793,901	$21,751,951	$0	$42,545,852
424	Nondurable Goods	$0	$13,312,092	$12,608,313	$0	$25,920,406
42469	Other Chemicals & AlliedProducts	$0	$787,728	$1,093,281	$0	$1,881,009
4247	Petroleum & petroleum Products	$0	$731,540	$1,023,045	$0	$1,754,585
42495	Paint, Varnish, & Supplies	$0	$144,660	$197,110	$0	$341,770

Table VI-8.
Total Costs of Compliance during Transition Period (continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs & Labels	Cost of Training Employees	Management Familiarization & Other Costs	One-Time Printer Costs	Total Costs
44-45	**Retail Trade**					
441	Motor vehicle & parts dealers	$0	$17,746,120	$15,299,467	$0	$33,045,586
442	Furniture & home furnishings stores	$0	$2,887,276	$4,212,585	$0	$7,099,860
443	Electronics & appliance stores	$0	$1,028,381	$1,482,881	$0	$2,511,261
444	Building material & garden equipment & supplies dealers	$0	$5,263,984	$6,965,789	$0	$12,229,773
445	Food & beverage stores	$0	$7,367,518	$8,872,331	$0	$16,239,849
446	Health & personal care stores	$0	$13,783,895	$10,901,654	$0	$24,685,549
447	Gasoline stations	$0	$4,423,466	$6,697,123	$0	$11,120,588
448	Clothing & clothing accessories stores	$0	$864,884	$1,254,745	$0	$2,119,629
451	Sporting goods, hobby, book, & music stores	$0	$1,151,121	$1,724,350	$0	$2,875,471
452	General merchandise stores	$0	$4,550,599	$5,363,032	$0	$9,913,631
453	Miscellaneous store retailers	$0	$2,242,483	$3,397,608	$0	$5,640,091
454	Nonstore retailers	$0	$2,215,416	$2,748,848	$0	$4,964,263
48-49	**Transportation & Warehousing**					
481	Air transportation	$0	$1,333,320	$514,757	$0	$1,848,077
483	Water transportation	$0	$697,893	$242,394	$0	$940,287
484	Truck transportation	$0	$16,185,182	$10,094,994	$0	$26,280,177
485	Transit & ground passenger transportation	$0	$1,100,192	$1,081,399	$0	$2,181,591
486	Pipeline transportation	$0	$337,719	$352,501	$0	$690,220
487	Scenic & sightseeing transportation	$0	$112,806	$134,531	$0	$247,337
488	Support activities for transportation	$0	$5,089,423	$3,467,316	$0	$8,556,739
492	Couriers & messengers	$0	$4,399,349	$1,201,804	$0	$5,601,153
493	Warehousing & storage	$0	$7,322,655	$1,007,202	$0	$8,329,857
51	**Information**					
511	Publishing industries	$0	$3,238,982	$2,483,614	$0	$5,722,596
512	Motion picture & sound recording industries	$0	$352,855	$514,097	$0	$866,952
515	Broadcasting (except Internet)	$0	$2,559,300	$4,847,086	$0	$7,406,387
516	Internet Publishing and Broadcasting	$0	$2,978,602	$855,112	$0	$3,833,714
517	Telecommunications	$0	$439,520	$4,847,086	$0	$5,286,606
518	Internet Service Providers, Web Search Portals, and Data	$0	$542,194	$855,112	$0	$1,397,306
519	Other Information Services	$0	$441,581	$855,112	$0	$1,296,693

Table VI-8.
Total Costs of Compliance during Transition Period (continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs & Labels	Cost of Training Employees	Management Familiarization & Other Costs	One-Time Printer Costs	Total Costs
52	**Finance & Insurance**					
521	Monetary authorities - central bank	$0	$7,009	$8,053	$0	$15,062
522	Credit intermediation & related activities	$0	$537,720	$798,210	$0	$1,335,930
523	Securities intermediation & related activities	$0	$192,285	$295,335	$0	$487,620
524	Insurance carriers & related activities	$0	$3,713,142	$5,619,420	$0	$9,332,562
525	Funds, trusts, & other financial vehicles (part)	$0	$64,773	$98,489	$0	$163,262
53	**Real Estate & Rental and Leasing**					
531	Real estate	$0	$11,054,514	$14,262,163	$0	$25,316,677
532	Rental & leasing services	$0	$4,598,780	$6,269,765	$0	$10,868,545
533	Lessors of intangible assets, except copyrighted works	$0	$62,205	$85,419	$0	$147,624
54	**Professional, Technical & Technical**					
5411	Legal services	$0	$125,182	$186,416	$0	$311,598
5412	Accounting, tax return prep, bookkeeping, & payroll	$0	$1,280,274	$1,891,227	$0	$3,171,501
5413	Architectural, engineering, & related services	$0	$2,415,506	$3,397,872	$0	$5,813,378
5414	Specialized design services	$0	$584,946	$819,598	$0	$1,404,543
5415	Computer systems design & related services	$0	$465,723	$672,260	$0	$1,137,984
5416	Management, scientific, & technical consulting services	$0	$2,048,432	$2,615,901	$0	$4,664,332
5417	Scientific R&D Serv.	$0	$1,250,447	$856,960	$0	$2,107,407
5418	Advertising & related services	$0	$1,131,118	$1,466,510	$0	$2,597,627
5419	Other professional, scientific, & technical services	$0	$9,565,328	$9,545,647	$0	$19,110,976
55	**Management of Companies**					
551111	Offices of bank holding companies	$0	$89,710	$134,795	$0	$224,505
551112	Offices of other holding companies	$0	$547,700	$697,873	$0	$1,245,572
551114	Corporate, subsidiary, & regional managing offices	$0	$7,089,489	$4,562,445	$0	$11,651,934
56	**Adm and Support & Waste Managmt**					
561	Administrative and Support Serv.	$0	$87,286,642	$36,408,466	$0	$123,695,109
562	Wastemanagement & Remediation Serv.	$0	$4,529,397	$2,336,540	$0	$6,865,937

Table VI-8.
Total Costs of Compliance during Transition Period (continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs & Labels	Cost of Training Employees	Management Familiarization & Other Costs	One-Time Printer Costs	Total Costs
61	**Educational Services**					
6114	Business schools, & computer & management training	$0	$25,682	$37,627	$0	$63,309
6115	Technical & trade schools	$0	$191,500	$255,860	$0	$447,360
6116	Other schools & instruction	$0	$206,940	$284,905	$0	$491,845
6117	Educational support services	$0	$95,880	$131,891	$0	$227,770
62	**Healthcare and Social Assistance**					
621	Ambulatory health care services	$0	$115,892,872	$64,393,743	$0	$180,286,616
622	Hospitals	$0	$104,558,663	$999,281	$0	$105,557,944
623	Nursing & residential care facilities	$0	$53,576,064	$8,964,351	$0	$62,540,415
624	Social assistance	$0	$12,134,799	$13,470,026	$0	$25,604,825
71	**Arts, Entertainment & Recreation**					
711	Performing arts, spectator sports, & related industries	$0	$1,224,553	$1,065,952	$0	$2,290,505
712	Museums, historical sites, & similar institutions	$0	$344,797	$334,018	$0	$678,815
713	Amusement, gambling, & recreation industries	$0	$5,751,969	$4,683,774	$0	$10,435,743
72	**Accommodation & Food Services**					
721	Accommodation	$0	$14,716,394	$7,624,847	$0	$22,341,241
722	Foodservices & drinking places	$0	$3,862,750	$5,621,797	$0	$9,484,547
81	**Other Services (except Public Adm.)**					
811	Repair & maintenance	$0	$29,183,152	$30,786,274	$0	$59,969,426
811121	Automotive body, paint, & interior repair & maintenance	$0	$3,328,946	$2,191,315	$0	$5,520,261
812	Personal & laundry services	$0	$13,683,944	$18,216,247	$0	$31,900,191
812320	Drycleaning & laundry services (except coin-operated)	$0	$1,871,904	$2,713,729	$0	$4,585,634
812921	Photofinishing laboratories (except one-hour)	$0	$135,766	$332,037	$0	$467,803
813	Religious/grantmaking/civic/professional & similar org	$0	$7,778,119	$10,830,097	$0	$18,608,216
99	**State and Local Government**					
9992	State Government	$0	$5,678,048	$1,683,291	$0	$7,361,339
9993	Local Government	$0	$28,647,622	$1,406,703	$0	$30,054,326
	Total	**$281,075,248**	**$1,118,239,150**	**$691,624,961**	**$11,807,780**	**$2,102,747,140**
	Total for firms producing SDSs	**$281,075,248**	**$69,566,050**	**$45,852,902**	**$11,807,780**	**$408,301,980**
	Total for firms not producing SDSs	**$0**	**$1,048,673,100**	**$645,772,059**	**$0**	**$1,694,445,159**

Note: Costs are expressed in 2010 dollars
Source: Office of Regulatory Analysis, OSHA based on PP&E (2009) and ERG (2012)

Table VI-9. Summary of Color Printing Costs

Size Category	Annualized Printer Costs per Label[1]	Annualized Cartridge/Ribbon/Stock Costs per Label	Total Annualized Costs per Label	Total Annualized Costs per Establishment	Total Annualized Costs, All Establishments
Category 1: Companies Printing Only B&W and No Color Printer					
Very Small	$0.01	$0.13	$0.14	$91.74	$1,489,571
Small	$0.01	$0.13	$0.13	$570.41	$2,552,483
Medium	$0.00	$0.01	$0.01	$142.02	$321,896
Large	$0.01	$0.01	$0.02	$1,091.86	$806,560
Category 2: Companies Printing B&W but Own Color Printer					
Very Small	$0.01	$0.13	$0.14	$91.74	$496,524
Small	$0.00	$0.13	$0.13	$551.81	$823,074
Medium	$0.00	$0.01	$0.01	$123.42	$93,242
Large	$0.01	$0.01	$0.02	$905.80	$2,007,345
Category 3: Companies Using Pre-Printed Stock/Labels					
Very Small	$ -	$0.03	$0.03	$22.28	$482,349
Small	$ -	$0.03	$0.03	$144.11	$859,807
Medium	$ -	$0.03	$0.03	$431.02	$1,302,548
Large	$ -	$0.03	$0.03	$1,738.06	$12,839,037
Category 4: Companies Printing Color Labels					
Very Small	$ -	$ -	$ -	$ -	$ -
Small	$ -	$ -	$ -	$ -	$ -
Medium	$ -	$ -	$ -	$ -	$ -
Large	$ -	$ -	$ -	$ -	$ -
Total					$24,074,395

1 - Includes the cost of printers annualized over five years and the cost of printing supplies incurred over a 20-year period beginning four years after the rule is published

$ - entries indicated no costs, while $0.000 entries are non-zero fractions of a penny

Source: Office of Regulatory Analysis, OSHA based on ERG (2011)

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G. Net Benefits, Cost-Effectiveness, and Regulatory Alternatives

Table VI–1 provides a summary of the costs and benefits of the revisions to the OSHA HCS, and it shows the net benefits and cost-effectiveness of the revisions to the standard. Net monetized benefits are estimated to be $556 million annually, expressed in 2010 dollars and using a 7 percent discount rate. (Using a 3 percent discount rate instead would have the effect of lowering the costs to $161 million per year and increasing the gross benefits to $839 million per year. The result would be to increase net benefits from $556 million to $678 million per year.) The cost-effectiveness of the standard can be expressed as more than three dollars of benefits for every dollar of cost.

Some qualitative evidence of the cost-effectiveness of the standard was provided by comments submitted in response to the ANPR published by OSHA in the **Federal Register** on September 12, 2006 (71 FR 53617) and the Proposed Rule published by OSHA in the **Federal Register** on September 30, 2009 (74 FR 50280). There was widespread support among the commenters for the adoption of GHS in the United States (Document ID #0340, 0344, 0347, 0349, 0351, 0354, 0357, 0359, 0366, 0382, 0390, 0403, 0408, and 0414). Many stakeholders anticipate that the revisions to the HCS will ''achieve more effective hazard communication'' (Document ID #0344 and 0351), ''enhance the consistency and quality of hazard information for workers'' (Document ID #0347), and ''serve to further enhance worker protection'' (Document ID #0329). These sentiments were echoed in many of the comments submitted to the record and in much of the testimony delivered at the public hearings. This voicing of support included commenters who provided some of the largest estimates of the costs of the revisions (Document ID #0032, 0050, 0329, 0338, and 0341).

The available alternatives to the final rule are somewhat limited since this rule modifies the current HCS in order to align with the provisions of the UN's GHS. In Section III, the Agency qualitatively discussed the two major alternatives presented during this rulemaking process—(1) voluntary adoption of GHS within the existing HCS framework and (2) a limited adoption of specific GHS components and a variation on (1) that would require compliance with GHS but allow an exemption for small businesses to comply with either the current HCS or with the GHS-compliant HCS. All of these alternatives were soundly rejected by stakeholders. To allow certain parties to follow an alternative system or to allow voluntary adoption of the elements of a uniformity standard does nothing to reduce confusion, improve efficiency, or simplify processes. In order for those benefits to be realized, all elements must apply to all affected parties. OSHA has determined that both of the alternatives presented above would eliminate significant portions of the benefits of the rule.

OSHA did not attempt to evaluate the costs and benefits for the regulatory alternatives that involved partial or voluntary adoption of the GHS. The Agency did evaluate two alternatives where the effective dates were altered. For both alternatives, OSHA re-estimated the costs, benefits, and net benefits simply by adjusting the effective dates in its formulas. The results are summarized in Table VI–10.

In the first alternative considered, all elements of the revised HCS would be required to be implemented within two years. Under this alternative, all transitional costs would be incurred in two years and benefits would be realized beginning in the third year. OSHA estimated that annualized costs under this alternative would increase by $5 million, from $201 million to $206 million, while annualized benefits would increase by $166 million, from $757 million to $923 million. Estimated net benefits would therefore increase by $161 million, from $556 million to $717 million. However, OSHA believes that these estimates fail to capture the difficulty many firms would encounter in meeting these tighter enforcement dates. As a result, initial compliance rates would probably be lower and less effective, leading to reduced benefits. In addition, some compliance costs—such as for labels and signs—were viewed in this final rule as incremental, reflective of taking place within a normal replacement cycle of 3 to 5 years. With implementation required within two years, these costs could no longer be treated as incremental to existing HCS requirements, but would have to be recalculated as total replacement costs.

The second alternative that OSHA evaluated extended the timeline for training to be completed. For this alternative, all elements of the revised HCS (including training) would be required to be implemented by June 1, 2016. Under this alternative, training costs would not be realized for four and a half years (as opposed to the two-year requirement for training in the final version of this rule) while benefits would not be realized for five years (unchanged from the final rule). OSHA estimated that annualized costs under this second alternative would decrease by $12 million, from $201 million to $189 million, while annualized benefits would be unchanged. Estimated net benefits would therefore increase by $12 million, from $556 million to $568 million. However, these estimates fail to recognize that workers will be exposed to (some) GHS-compliant labels and SDS formats well before the 4½ year training date. The Agency would therefore expect an increase in injuries, illnesses, and fatalities as untrained workers are unable to effectively process and respond to the revised labels and SDS formats. As a result, benefits and net benefits would actually decline relative to those estimated for the final rule.

In summary, although both alternatives show greater net benefits, the Agency concludes that the timing of the final rule is preferable because of additional (but unquantified) compliance costs and reduced (but unquantified) benefits under the first alternative and because of reduced (but unquantified) worker health and safety benefits under the second alternative. In addition, OSHA expects that the final rule offers coordination benefits in that its requirements will fully take effect at the same time as the EU completes its transition.

Table VI-10
Regulatory Alternatives

	Years After Promulgation			Annualized Benefits	Annualized Costs	Annualized Net Benefits	Benefits Relative to Final Rule Implementation Timeline	Costs Relative to Final Rule Implementation Timeline	Net Benefits Relative to Final Rule Implementation Timeline
	To Complete Training	For Full Implementation	Until Benefits are Realized						
Alternative 1									
	2 years	2 years	3 years	$923 million	$206 million	$717 million	+ $166 million	+ $5 million	+ $161 million
Final Rule Implementation Timeline									
	2 years	4.5 years	5 years	$757 million	$201 million	$556 million	--	--	--
Alternative 2									
	4.5 years	4.5 years	5 years	$756 million	$189 million	$568 million	--	-$12 million	+ $12 million

Source: Office of Regulatory Analysis, OSHA

H. Economic Feasibility and Impacts

This section presents OSHA's analysis of the potential 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 the criteria established by the Small Business Administration) 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.

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) All costs are passed through to customers in the form of higher prices (consistent with a price elasticity of demand of zero), and (2) all costs are absorbed by the firm in the form of reduced profits (consistent with an infinite price elasticity of demand).

In the former case, the immediate impact of the rule would be observed in increased industry revenues. While there is no hard and fast rule, in the absence of evidence to the contrary, OSHA generally considers a standard to be economically feasible for an industry when the annualized costs of compliance are less than a threshold level of one percent of annual revenues. Common-sense considerations indicate that potential impacts of such a small magnitude are unlikely to eliminate an industry or significantly alter its competitive structure, particularly since most industries have at least some ability to raise prices to reflect increased costs and normal price variations for products typically exceed three percent a year (OSHA, 2011, Chapter VI). Of course, OSHA recognizes that even when costs are within this range, there could be unusual circumstances requiring further analysis.

In the latter case, 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. Again, while there is no hard and fast rule, in the absence of evidence to the contrary, OSHA generally considers a standard to be economically feasible for an industry when the annualized costs of compliance are less than a threshold level of ten percent of annual profits. This is a fairly modest threshold level, given that normal year-to-year variations in profit rates in an industry can exceed 40 percent or more (OSHA, 2011, Chapter VI).

For this final rule, all hazardous chemicals distributed in the United States have to be in compliance with the SDS and labeling revisions to the HCS, and chemical producers and users in most advanced economies will be under comparable GHS requirements (encompassing training, etc.) specific to their own country or economic union. For this reason, affected domestic establishments should not be susceptible to foreign competitors not bound by the requirements of the revisions to the HCS or similar GHS requirements. As a result, OSHA expects that the costs of this final rule will be passed on in higher prices rather than absorbed in lost profits, and therefore the Agency will tend to be primarily concerned with the ratio of industry costs to industry revenues rather than with the ratio of industry costs to industry profits.

In order to assess the nature and magnitude of the economic impacts associated with compliance with the final 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 of this preamble were compared with industry revenues and profits to provide a measure of potential economic impacts. Although Section VI.G also contains estimates of substantial productivity benefits arising from this final rule that more than offset the estimated costs, these cost savings have not been included in estimating the economic impacts of the final rule.

Table VI–11 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.

As is evident from the data and estimates presented in Table VI–6, the costs of compliance for the final rule are not large in relation to the corresponding revenues and profits in each of the industry sectors. The estimated costs of compliance represent about 0.001 percent of revenues and about 0.011 percent of profits on average across all entities; compliance costs represent less than 0.09 percent of revenues or, with the exception of three chemical manufacturing industries, less than 0.9 percent of profits in any individual industry sector. These three chemical manufacturing industries are NAICS 325181 Alkalies & chlorine manufacturing, NAICS 325191 Gum & wood chemical manufacturing, and NAICS 325992 Photographic film, paper, plate, & chemical manufacturing, and their compliance costs as a percentage of profits are 4.3 percent, 2.1 percent, and 2.4 percent, respectively. The cost of printing labels in color is the main cost driver for these industries.

Based on the Agency's two screening tests to determine if the economic impacts of the final rule exceed some minimum threshold level (*i.e.,* costs equal to one percent of revenue or ten percent of profits), OSHA concludes that the rule is economically feasible for the affected industries. In general, the courts have held that a standard is economically feasible if there is a reasonable likelihood that the estimated costs of compliance ''will not threaten the existence or competitive structure of an industry, even if it does portend disaster for some marginal firms'' (*United Steelworkers of America* v. *Marshall,* 647 F.2d 1189, 1272 (DC Cir. 1980)). The potential impacts of employer costs associated with achieving compliance with the final rule fall well within the bounds of economic feasibility in each industry sector. OSHA does not expect compliance with the requirements of the final rule to threaten the viability of employers or the competitive structure of any of the affected industry sectors.

The economic impact of the final rule is most likely to consist of a very small increase in prices for affected hazardous chemicals, of about 0.001 percent on average. Chemical manufacturing companies, all of whom must incur the costs of compliance unless they are already doing so, should be able to pass through costs to customers. The additional costs of a one-time revision to SDS and labeling criteria and one-time investments in printing technology are extremely small in relation to the value of the corresponding products, and there are generally no economic substitutes, or alternatives, that would not be subject to the same requirements. It is unlikely that a price increase of this magnitude would significantly alter the types or amounts of goods and services demanded by the public or any other affected customers or intermediaries. If the compliance costs of the final rule can be substantially recouped with a minimal increase in prices, there would be little or no effect on profits.

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Table VI-11.
Potential Economic Impacts

NAICS Code	Industry	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
11	**Agriculture, Forestry, Fishing & Hunting**					
113	Forestry & Logging	$158,560	$11,760,017	$464,427	0.0013%	0.0341%
114	Fishing, Hunting and Trappinig	$14,758	$2,409,281	$135,700	0.0006%	0.0109%
115	Support Activities for Ag & Forestry	$76,828	$14,115,139	$752,386	0.0005%	0.0102%
211	**Oil and Gas Extraction**					
211111	Crude petroleum & natural gas extraction	$2,338,011	$194,107,252	$27,427,230	0.0012%	0.0085%
211112	Natural gas liquid extraction	$1,221,142	$39,759,759	$4,240,675	0.0031%	0.0288%
212	Mining (except Oil & Gas)	$343,013	$85,057,794	$9,746,773	0.0004%	0.0035%
213	Support Activities for Mining	$401,872	$76,426,643	$8,757,729	0.0005%	0.0046%
22	**Utilities**					
2211	Electric Power Gen, Trans & Distrib	$1,175,379	$440,342,284	$19,549,326	0.0003%	0.0060%
2212	Natural Gas Distribution	$191,395	$123,708,390	$3,685,326	0.0002%	0.0052%
2213	Water, Sewage, & Other Systems	$270,227	$9,718,520	$686,142	0.0028%	0.0394%
23	**Construction**					
236	Construction of Buildings	$5,352,275	$752,446,316	$36,618,886	0.0007%	0.0146%
237	Heavy Construction	$1,597,223	$263,941,774	$14,141,733	0.0006%	0.0113%
238	Special Trade Contractors	$11,820,847	$694,885,238	$29,258,246	0.0017%	0.0404%
31	**Manufacturing**					
311	Food Manufacturing	$3,849,737	$590,833,582	$42,400,282	0.0007%	0.0091%
312	Beverage &Tobacco Prod. Manuf.	$399,200	$129,351,188	$9,392,713	0.0003%	0.0043%
313	Textile Mills	$478,125	$36,618,365	$2,209,564	0.0013%	0.0216%
314	Textile Product Mills	$620,810	$30,812,321	$1,950,283	0.0020%	0.0318%
315	Apparel Manufacturing	$1,183,629	$28,919,587	$1,576,569	0.0041%	0.0751%
316	Leather & Allied Product Manufac.	$137,521	$6,176,905	$408,409	0.0022%	0.0337%
321	Wood Product Manufacturing	$1,814,486	$100,862,580	$3,029,150	0.0018%	0.0599%
322	Paper Manufacturing	$999,897	$178,253,064	$13,644,088	0.0006%	0.0073%
323	Printing and Related Support	$2,703,253	$101,636,174	$4,395,616	0.0027%	0.0615%
324	**Petroleum & Coal Prod. Manufac.**					
324110	Petroleum refineries	$857,053	$561,943,070	$63,921,180	0.0002%	0.0013%
324121	Asphalt paving mixture & block mfg	$1,739,097	$11,626,178	$1,056,581	0.0150%	0.1646%

Table VI-11.
Potential Economic Impacts (contined)

NAICS Code	Industry	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
324	**Petroleum & Coal Prod. Manufac.**					
324122	Asphalt shingle & coating materials mfg	$278,488	$8,041,234	$817,009	0.0035%	0.0341%
324191	Petroleum lubricating oil & grease mfg	$8,791,518	$10,555,336	$1,012,789	0.0833%	0.8681%
324199	All other petroleum & coal products mfg	$98,065	$3,074,898	$261,714	0.0032%	0.0375%
325	**Chemical Manufacturing**					
325110	Petrochemical mfg	$382,550	$68,708,581	$3,958,311	0.0006%	0.0097%
325120	Industrial gas mfg	$219,808	$9,232,158	$529,438	0.0024%	0.0415%
325131	Inorganic dye & pigment mfg	$86,028	$1,321,184	$58,848	0.0065%	0.1462%
325132	Synthetic organic dye & pigment mfg	$109,803	$2,306,790	$124,761	0.0048%	0.0880%
325181	Alkalies & chlorine mfg	$60,470	$2,070,537	$1,397	0.0029%	4.3288%
325182	Carbon black mfg	$24,436	$1,015,512	$44,680	0.0024%	0.0547%
325188	All other basic inorganic chemical mfg	$640,670	$24,054,601	$1,314,697	0.0027%	0.0487%
325191	Gum & wood chemical mfg	$174,122	$1,003,423	$8,228	0.0174%	2.1161%
325192	Cyclic crude & intermediate mfg	$22,176	$4,833,694	$263,177	0.0005%	0.0084%
325193	Ethyl alcohol mfg	$369,765	$14,109,202	$629,938	0.0026%	0.0587%
325199	All other basic organic chemical mfg	$1,256,135	$81,302,259	$4,535,032	0.0015%	0.0277%
325211	Plastics material & resin mfg	$1,213,772	$87,266,908	$7,003,511	0.0014%	0.0173%
325212	Synthetic rubber mfg	$65,234	$7,072,263	$547,222	0.0009%	0.0119%
325221	Cellulosic organic fiber mfg	$82,260	$637,425	$82,266	0.0129%	0.1000%
325222	Noncellulosic organic fiber mfg	$38,897	$8,839,294	$112,622	0.0004%	0.0345%
325311	Nitrogenous fertilizer mfg	$136,562	$585,053	$44,549	0.0233%	0.3065%
325312	Phosphatic fertilizer mfg	$68,888	$561,376	$55,219	0.0123%	0.1248%
325314	Fertilizer (mixing only) mfg	$265,983	$4,275,079	$439,383	0.0062%	0.0605%
325320	Pesticide & other agricultural chemical mfg	$309,460	$11,569,635	$1,386,836	0.0027%	0.0223%
325411	Medicinal & botanical mfg	$359,322	$12,382,775	$2,190,199	0.0029%	0.0164%
325412	Pharmaceutical preparation mfg	$1,613,993	$140,546,097	$25,658,040	0.0011%	0.0063%
325413	In-vitro diagnostic substance mfg	$517,308	$12,672,955	$2,246,114	0.0041%	0.0230%
325414	Biological product (except diagnostic) mfg	$246,509	$15,530,258	$2,778,785	0.0016%	0.0089%
325510	Paint & coating mfg	$4,044,937	$23,373,658	$1,544,543	0.0173%	0.2619%

Table VI-11.
Potential Economic Impacts (contined)

NAICS Code	Industry	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
325	**Chemical Manufacturing**					
325520	Adhesive mfg	$1,569,248	$9,369,131	$598,100	0.0167%	0.2624%
325611	Soap & other detergent mfg	$743,889	$28,868,302	$3,234,866	0.0026%	0.0230%
325612	Polish & other sanitation good mfg	$1,573,954	$2,817,533	$251,107	0.0559%	0.6268%
325613	Surface active agent mfg	$827,327	$8,598,086	$982,496	0.0096%	0.0842%
325620	Toilet preparation mfg	$4,210,615	$47,135,570	$5,409,708	0.0089%	0.0778%
325910	Printing ink mfg	$1,225,882	$4,926,921	$248,371	0.0249%	0.4936%
325920	Explosives mfg	$177,192	$1,533,712	$81,027	0.0116%	0.2187%
325991	Custom compounding of purchased resin	$189,058	$9,842,609	$487,531	0.0019%	0.0388%
325992	Photographic film, paper, plate, & chemical mfg	$1,678,379	$1,680,687	$70,697	0.0999%	2.3740%
325998	All other miscellaneous chemical product & preparation mfg	$2,923,955	$17,432,274	$855,116	0.0168%	0.3419%
326	Plastics and Rubber Products Man.	$3,946,975	$211,794,903	$8,613,650	0.0019%	0.0458%
327	Nonmetallic Mineral Prod. Manufac.	$3,191,048	$127,080,322	$7,536,185	0.0025%	0.0423%
331	Primary Metal Manufacturing	$1,657,589	$256,127,735	$12,805,335	0.0006%	0.0129%
332	Fabricated Metal Prod. Manufac.	$5,627,722	$340,156,176	$22,909,813	0.0017%	0.0246%
333	Machinery Manufacturing	$2,920,617	$350,737,442	$18,293,730	0.0008%	0.0160%
334	Computer & Electronic Prod Man.	$1,790,722	$398,480,943	$35,239,356	0.0004%	0.0051%
335	Electric Equipment, Appliance Man.	$984,903	$131,026,369	$7,867,355	0.0008%	0.0125%
336	Transportation Equip. Manufacturing	$3,341,277	$729,869,304	$12,565,992	0.0005%	0.0266%
337	Furniture & Related Product Man.	$2,028,962	$85,030,749	$3,863,061	0.0024%	0.0525%
339	Miscellaneous Manufacturing	$4,881,617	$152,756,397	$12,480,274	0.0032%	0.0391%
42	**Wholesale Trade**					
423	Durable Goods	$3,630,525	$2,654,764,252	$80,481,465	0.0001%	0.0045%
424	Nondurable Goods	$2,211,842	$2,728,235,496	$90,983,434	0.0001%	0.0024%
42469	Other Chemicals & AlliedProducts	$160,510	$119,569,684	$4,399,084	0.0001%	0.0036%
4247	Petroleum & petroleum Products	$149,722	$632,241,487	$14,072,944	0.0000%	0.0011%
42495	Paint, Varnish, & Supplies	$29,164	$11,652,375	$417,801	0.0003%	0.0070%
44-45	**Retail Trade**					
441	Motor vehicle & parts dealers	$2,819,848	$896,297,538	$12,960,719	0.0003%	0.0218%
442	Furniture & home furnishings stores	$605,846	$112,218,395	$4,285,143	0.0005%	0.0141%

Table VI-11.
Potential Economic Impacts (contined)

NAICS Code	Industry	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
44-45	**Retail Trade**					
443	Electronics & appliance stores	$214,291	$116,040,434	$4,606,634	0.0002%	0.0047%
444	Building material & garden equipment & supplies dealers	$1,043,592	$332,908,952	$18,542,776	0.0003%	0.0056%
445	Food & beverage stores	$1,385,780	$552,381,358	$11,470,403	0.0003%	0.0121%
446	Health & personal care stores	$2,106,469	$259,106,568	$8,632,167	0.0008%	0.0244%
447	Gasoline stations	$948,943	$440,453,786	$4,754,655	0.0002%	0.0200%
448	Clothing & clothing accessories stores	$180,872	$218,738,679	$12,836,726	0.0001%	0.0014%
451	Sporting goods, hobby, book, & music stores	$245,370	$90,896,739	$2,725,660	0.0003%	0.0090%
452	General merchandise stores	$845,951	$593,383,265	$25,254,843	0.0001%	0.0033%
453	Miscellaneous store retailers	$481,281	$113,121,052	$4,227,386	0.0004%	0.0114%
454	Nonstore retailers	$423,611	$240,557,361	$10,409,634	0.0002%	0.0041%
48-49	**Transportation & Warehousing**					
481	Air transportation	$157,700	$141,849,515	$4,225,370	0.0001%	0.0037%
483	Water transportation	$80,237	$34,792,652	$2,289,955	0.0002%	0.0035%
484	Truck transportation	$2,242,542	$222,171,220	$6,377,563	0.0010%	0.0352%
485	Transit & ground passenger transportation	$186,160	$26,996,179	$719,894	0.0007%	0.0259%
486	Pipeline transportation	$58,898	$51,731,994	$9,006,192	0.0001%	0.0007%
487	Scenic & sightseeing transportation	$21,106	$2,079,372	$91,971	0.0010%	0.0229%
488	Support activities for transportation	$730,164	$94,811,422	$3,565,908	0.0008%	0.0205%
492	Couriers & messengers	$477,958	$79,205,101	$3,347,468	0.0006%	0.0143%
493	Warehousing & storage	$710,804	$39,951,180	$2,008,338	0.0018%	0.0354%
51	**Information**					
511	Publishing industries	$488,321	$272,103,899	$36,222,133	0.0002%	0.0013%
512	Motion picture & sound recording industries	$73,979	$92,572,421	$6,235,408	0.0001%	0.0012%
515	Broadcasting (except Internet)	$632,002	$97,003,312	$7,291,773	0.0007%	0.0087%
516	Internet Publishing and Broadcasting	$667,782	$476,693,650	$34,119,337	0.0001%	0.0020%
517	Telecommunications	$110,474	$11,856,575	$877,197	0.0009%	0.0126%
518	Internet Service Providers, Web Search Portals, and Data Processing Services	$119,235	$103,179,812	$7,682,215	0.0001%	0.0016%
519	Other Information Services	$110,649	$7,267,258	$649,722	0.0015%	0.0170%

Table VI-11.

Potential Economic Impacts (contined)

NAICS Code	Industry	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
52	**Finance & Insurance**					
521	Monetary authorities - central bank	$1,285	n.a	$28,820,277	0.0000%	0.0000%
522	Credit intermediation & related activities	$113,998	$1,342,773,502	$130,826,298	0.0000%	0.0001%
523	Securities intermediation & related activities	$41,610	$659,358,364	$72,290,929	0.0000%	0.0001%
524	Insurance carriers & related activities	$796,367	$1,629,364,475	$90,009,012	0.0000%	0.0009%
525	Funds, trusts, & other financial vehicles (part)	$13,931	$25,762,873	$18,111,414	0.0001%	0.0001%
53	**Real Estate & Rental and Leasing**					
531	Real estate	$2,160,324	$314,825,826	$41,055,039	0.0007%	0.0053%
532	Rental & leasing services	$927,435	$124,190,956	$5,355,074	0.0007%	0.0173%
533	Lessors of intangible assets, except copyrighted works	$12,597	$22,608,698	$8,399,407	0.0001%	0.0001%
54	**Professional, Technical & Technical**					
5411	Legal services	$26,589	$241,585,199	$20,428,332	0.0000%	0.0001%
5412	Accounting, tax return prep, bookkeeping, & payroll services	$270,631	$118,782,462	$11,402,885	0.0002%	0.0024%
5413	Architectural, engineering, & related services	$496,068	$255,969,849	$12,019,122	0.0002%	0.0041%
5414	Specialized design services	$119,853	$24,121,488	$1,545,094	0.0005%	0.0078%
5415	Computer systems design & related services	$97,106	$274,090,856	$17,426,282	0.0000%	0.0006%
5416	Management, scientific, & technical consulting services	$398,017	$193,880,951	$15,369,087	0.0002%	0.0026%
5417	Scientific R&D Serv.	$179,829	$113,331,959	$10,576,659	0.0002%	0.0017%
5418	Advertising & related services	$221,661	$83,216,540	$4,677,880	0.0003%	0.0047%
5419	Other professional, scientific, & technical services	$1,630,779	$64,824,047	$4,751,515	0.0025%	0.0343%
55	**Management of Companies**					
551111	Offices of bank holding companies	$19,157	$8,527,652	$1,201,436	0.0002%	0.0016%
551112	Offices of other holding companies	$106,287	$90,565,832	$61,020,373	0.0001%	0.0002%
551114	Corporate, subsidiary, & regional managing offices	$994,284	$408,918,738	$61,510,353	0.0002%	0.0016%
56	**Adm and Support & Waste Managmt**					
561	Administrative and Support Serv.	$10,555,159	$574,904,018	$27,403,980	0.0018%	0.0385%
562	Wastemanagement & Remediation Serv.	$585,885	$71,019,564	$3,495,353	0.0008%	0.0168%
61	**Educational Services**					
6111	Elementary & secondary schools	$350,361	$61,987,431	$5,020,872	0.0006%	0.0070%
6112	Junior colleges	$17,713	$6,981,654	$614,509	0.0003%	0.0029%

Table VI-11.
Potential Economic Impacts (contined)

NAICS Code	Industry	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
61	**Educational Services**					
6113	Colleges, universities, & profesional schools	$379,536	$165,761,113	$15,105,707	0.0002%	0.0025%
6114	Business schools, & computer & management training	$5,402	$9,493,068	$751,863	0.0001%	0.0007%
6115	Technical & trade schools	$38,174	$12,814,336	$1,068,596	0.0003%	0.0036%
6116	Other schools & instruction	$41,970	$16,556,465	$1,276,691	0.0003%	0.0033%
6117	Educational support services	$19,436	$10,672,499	$874,480	0.0002%	0.0022%
62	**Healthcare and Social Assistance**					
621	Ambulatory health care services	$15,384,229	$689,559,289	$36,230,870	0.0022%	0.0425%
622	Hospitals	$9,007,477	$695,851,749	$49,446,288	0.0013%	0.0182%
623	Nursing & residential care facilities	$5,336,703	$166,581,075	$10,579,315	0.0032%	0.0504%
624	Social assistance	$2,184,913	$127,324,825	$6,883,194	0.0017%	0.0317%
71	**Arts, Entertainment & Recreation**					
711	Performing arts, spectator sports, & related industries	$195,454	$78,496,916	$7,757,623	0.0002%	0.0025%
712	Museums, historical sites, & similar institutions	$57,925	$13,015,709	$1,046,388	0.0004%	0.0055%
713	Amusement, gambling, & recreation industries	$890,503	$104,539,320	$7,212,443	0.0009%	0.0123%
72	**Accommodation & Food Services**					
721	Accommodation	$1,906,424	$174,493,191	$11,640,221	0.0011%	0.0164%
722	Foodservices & drinking places	$809,336	$435,982,331	$21,820,336	0.0002%	0.0037%
81	**Other Services**					
811	Repair & maintenance	$5,117,315	$156,086,726	$6,134,849	0.0033%	0.0834%
811121	Automotive body, paint, & interior repair & maintenance	$471,055	$26,554,038	$868,428	0.0018%	0.0542%
812	Personal & laundry services	$2,722,109	$85,934,630	$4,719,981	0.0032%	0.0577%
812320	Drycleaning & laundry services (except coin-operated)	$391,302	$8,401,076	$432,114	0.0047%	0.0906%
812921	Photofinishing laboratories (except one-hour)	$39,919	$1,303,716	$71,376	0.0031%	0.0559%
813	Religious/grantmaking/civic/professional & similar org	$1,587,877	$335,201,310	$7,891,029	0.0005%	0.0201%
99	**State and Local Government**					
9992	State Government	$628,158	n.a.			
9993	Local Government	$2,564,598	n.a.			
	Total	**$200,980,794**	**$29,850,968,070**	**$1,792,406,985**		

Note: Costs are expressed in 2010 dollars
Source: Office of Regulatory Analysis, OSHA based on PP&E (2009) and ERG (2012)

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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 depend 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.

In the case of cost increases that may be incurred due to the requirements of the final rule, all businesses within each of the covered industry sectors would be subject to the same requirements. Thus, to the extent potential price increases correspond to costs associated with achieving compliance with the standards, the elasticity of demand for each entity will approach that faced by the industry as a whole.

Given the small increases in prices potentially resulting from compliance with the final rule 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.

OSHA expects the overall economic impact of the final rule to be both an increase in the efficiency of production of goods and services and an improvement in the welfare of society.

First, as demonstrated by the analysis of costs and benefits associated with compliance with the requirements of the final rule, OSHA expects that societal welfare will increase as a result of the revisions to the HCS, as the benefits far exceed compliance costs. The final rule is estimated to yield net annualized benefits of over $800 million.

Second, until now, many of the costs associated with the injuries, illnesses, and fatalities resulting from the risks addressed by the final rule have been externalized. For example, the costs incurred by society to supply certain products and services that are accompanied by injuries, illnesses, or fatalities from employee exposure to hazardous chemicals have not been fully reflected in the prices of those products and services. To the extent that fewer of these costs are externalized because of improved employer and employee information about hazardous chemicals in the workplace, the price mechanism will enable the market to produce a more efficient allocation of resources. However, reductions in externalities by themselves do not necessarily increase efficiency or social welfare unless the costs of achieving the reductions (including indirect and unintended consequences of regulatory approaches) are outweighed by the associated benefits, as they are in this instance.

In addition, based on an analysis of the costs and economic impacts associated with this rulemaking, OSHA concludes that the effects of the final rule on employment, wages, and economic growth for the United States would be negligible. This final rule is expected to result in increased import and export opportunities with U.S. trading partners due to the harmonization of the U.S. system with GHS. Hence, the primary effect on international trade, for businesses of all size, is likely to be favorable. This determination was supported by comment in the rulemaking record. For example, the Society of Chemical Manufacturers and Affiliates reported that companies that do business globally would see benefits related to the revisions to the OSHA HCS (Document ID #0402). Other stakeholders anticipate benefits related to global harmonization (Document ID #0382, 0388, 0393, and 0405) and mention that the standardization of the HCS will benefit those who are involved in international trade (Document ID #0410).

Statement of Energy Effects

As required by Executive Order 13211, and in accordance with the guidance for implementing Executive Order 13211 and with the definitions provided therein as prescribed by the Office of Management and Budget (OMB), OSHA has analyzed the standard with regard to its potential to have a significant adverse effect on the supply, distribution, or use of energy.

As a result of this analysis, OSHA has determined that this action is not a significant energy action as defined by the relevant OMB guidance.

I. Final Regulatory Flexibility Screening Analysis

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 description of the impact of the rule on small entities;
2. A statement of the need for, and objectives of, the rule;
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 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;
5. 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;
6. 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
7. 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 believes 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 this voluntary FRFA 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 FRFA will summarize the key aspects of OSHA's analysis as they affect small businesses.

1. A Description of the Impact of the Final Rule on Small Entities

The final regulation requires classification of chemicals, especially chemical mixtures, somewhat different from current hazard determination methods; a standardized format for the organization of MSDSs (now called SDSs); standardized labels and standardized pictograms; and training for affected employees on these changes. (Some commenters argued that GHS would also impose more stringent testing requirements, but as explained in Section III: Need and Support in this preamble, the HCS does not currently require testing of chemicals, and will not require testing with adoption of the GHS.[30])

For the purpose of its cost analysis, OSHA estimated four types of cost:

(1) Costs to chemical producers of classifying chemicals, reformatting SDSs, and developing new labels;

(2) Costs for safety and health managers and logistics personnel to familiarize themselves with the standard (although not required by the regulation, this is a necessary step in its implementation);

(3) Costs of training affected employees on how to find the information they need on SDSs and to comprehend pictograms and standard labels; and

(4) Costs to upgrade printing technology or purchase multi-colored labels to comply with the requirement that the pictograms be presented in a red-bordered diamond.

OSHA believes that, with the exception of the cost of color printing ink or printing cartridges or the cost of purchasing color pre-printed labels, these costs are a one-time cost that would be incurred during the four-year transition period after the final rule is published. OSHA anticipates that, once the final rule is implemented, the costs under the revised OSHA HCS will be only marginally higher than the costs under the existing HCS system and consist solely of the costs associated with color printing supplies. Once chemical producers, distributors, and users set up for and shift to the GHS system, OSHA expects there will be no additional costs arising from the final rule for classification, SDSs, and labeling.

OSHA also anticipates that, after the four-year transition period, the revisions to the HCS—resulting in more consistent chemical classifications and more uniform SDSs and labels—will yield production efficiencies for health and safety managers, logistics personnel, and others who handle hazardous chemicals. These cost savings (in addition to the health benefits for affected workers arising from this final rule) are considered in Section VI.D: Benefits in this preamble.

OSHA's criteria for determining whether there are significant economic impacts on a substantial number of small firms are that, for small entities in any given industry, the annualized costs exceed 1 percent of revenues or 5 percent of profits. All of OSHA's calculations of the economic impacts on small firms totally ignore any offsetting benefits of any kind, even though OSHA estimates that, for most small firms, the benefits of this rule will actually exceed the costs.

OSHA's industry-by-industry analysis, both for small firms (as defined by SBA) and for very small firms (defined by OSHA as those with fewer than 20 employees), shows that in no industry size class do the annualized costs exceed 0.28 percent of revenues or 3.3 percent of profits, and in almost all cases the annualized costs for small and very small firms are below 0.01 percent of revenues and 0.1 percent of profits. For affected small firms as defined by SBA, the average annualized cost per firm of the final rule would be $52 per year, which is equal to 0.001 percent of annual revenue and 0.03 percent of annual profit for the average firm. In terms of chemical-producing industries only, the average annualized cost per small firm as defined by SBA would be $544 per year, which is equal to 0.004 percent of annual revenue and 0.03 percent of annual profit for such a firm. For affected firms with fewer than 20 employees, the average annualized cost per firm of the final rule would be $35 per year (or 0.002 percent of annual revenue and 0.04 percent of annual profit), and the average annualized cost per firm that produces chemicals would be $255 per year (or 0.02 percent of annual revenue and 0.2 percent of annual profit).

Given these results, OSHA concludes that the final rule will not have a significant economic impact on a substantial number of small entities. Thus, a FRFA is not required for this rulemaking. However, recognizing the possible value that such an analysis may provide, OSHA has voluntarily included the elements of the FRFA as part of this Regulatory Flexibility Analysis (RFA) and has analyzed the potential impact of the revisions to OSHA's HCS on small entities. As described in Section VI.D Benefits in this preamble, the revisions to the HCS, on the whole, are expected to result in significant net benefits to employers, as the associated cost savings outweigh the corresponding compliance costs. This same conclusion generally applies to the small entities affected by the final rule.

In order to ensure that any potential significant adverse impact on a substantial number of small entities would be appropriately considered, OSHA also specifically evaluated the impact on small entities of the costs of compliance alone, without regard to the associated cost savings and health and safety benefits.

The total annualized cost of compliance with the final rule for small entities is estimated to be approximately $119 million, as shown by industry in Table VI–12.

To assess the potential economic impact of the final rule on small entities, OSHA calculated the ratios of compliance costs to profits and to revenues. These ratios are presented for each affected industry in Table VI–12. OSHA expects that among small entities potentially affected by the final rule, the average increase in prices necessary to completely offset the compliance costs would be 0.0013 percent. The average price increase necessary to completely offset compliance costs would not exceed 0.18 percent among small entities in any single affected industry sector.

In the event that no costs could be passed through, the compliance costs could be completely absorbed through an average reduction in profits of less than 0.03 percent for affected small entities. For small entities in most affected industries, the compliance costs could be completely absorbed through an average reduction in profits of less than 0.3 percent; the reduction in profits would be no more than 3.3 percent among small entities in any of the affected industries.

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[30] OSHA's estimation methodology assumes that firms will undertake the most cost effective method of complying with an OSHA requirement. Therefore, if firms choose to perform testing or to incur other costs not required by an OSHA rule they do so only because they feel there is some benefit to be gained.

Table VI-12.
Potential Impacts on Small Entities

NAICS Code	Industry	Number of Small Firms	Number of Affected Small Firms	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
11	**Agriculture, Forestry, Fishing & Hunting**							
113	Forestry & Logging	10,246	10,246	$152,247	$9,836,325	$368,480	0.0015%	0.0413%
114	Fishing, Hunting and Trappinig	2,330	809	$13,810	$1,274,953	$64,857	0.0011%	0.0213%
115	Support Activities for Ag & Forestry	10,056	4,197	$60,431	$8,440,938	$399,639	0.0007%	0.0151%
211	**Oil and Gas Extraction**							
211111	Crude petroleum & natural gas extraction	6,329	6,329	$1,921,467	$44,965,936	$6,353,658	0.0043%	0.0302%
211112	Natural gas liquid extraction	98	89	$63,723	$1,946,346	$233,417	0.0033%	0.0273%
212	Mining (except Oil & Gas)	4,296	4,296	$162,506	$20,126,179	$2,306,259	0.0008%	0.0070%
213	Support Activities for Mining	9,338	9,338	$180,086	$15,740,489	$1,803,703	0.0011%	0.0100%
22	**Utilities**							
2211	Electric Power Gen, Trans & Distrib	630	630	$32,858	$8,364,773	$371,360	0.0004%	0.0088%
2212	Natural Gas Distribution	433	433	$34,500	$21,621,345	$644,109	0.0002%	0.0054%
2213	Water, Sewage, & Other Systems	3,918	3,917	$215,732	$3,224,965	$227,687	0.0067%	0.0947%
23	**Construction**							
236	Construction of Buildings	240,886	240,886	$4,829,965	$455,390,191	$22,162,221	0.0011%	0.0218%
237	Heavy Construction	48,219	48,219	$1,142,904	$152,413,886	$8,166,182	0.0007%	0.0140%
238	Special Trade Contractors	505,012	505,012	$10,546,673	$521,088,838	$21,272,768	0.0020%	0.0496%
31	**Manufacturing**							
311	Food Manufacturing	21,036	21,036	$1,915,874	$134,452,295	$8,003,031	0.0014%	0.0239%
312	Beverage &Tobacco Prod. Manuf.	3,381	3,381	$230,228	$15,816,393	$979,511	0.0015%	0.0235%
313	Textile Mills	2,574	2,574	$273,603	$13,365,687	$604,503	0.0020%	0.0453%
314	Textile Product Mills	6,387	6,387	$488,724	$12,133,267	$477,482	0.0040%	0.1024%
315	Apparel Manufacturing	10,073	10,073	$987,297	$21,123,838	$1,006,901	0.0047%	0.0981%
316	Leather & Allied Product Manufac.	1,317	1,317	$105,795	$3,537,287	$224,500	0.0030%	0.0471%
321	Wood Product Manufacturing	14,365	14,365	$1,383,328	$54,672,850	$2,401,003	0.0025%	0.0576%
322	Paper Manufacturing	3,066	3,066	$423,100	$34,882,374	$1,638,919	0.0012%	0.0258%
323	Printing and Related Support	31,414	31,414	$2,309,226	$58,682,825	$2,628,148	0.0039%	0.0879%
324	**Petroleum & Coal Prod. Manufac.**							
324110	Petroleum refineries	241	241	$585,772	$343,480,378	$38,324,378	0.0002%	0.0015%
324121	Asphalt paving mixture & block mfg	430	430	$801,750	$4,836,036	$272,923	0.0166%	0.2938%

Table VI-12.
Potential Impacts on Small Entities (continued)

NAICS Code	Industry	Number of Small Firms	Number of Affected Small Firms	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
324	**Petroleum & Coal Prod. Manufac.**							
324122	Asphalt shingle & coating materials mfg	115	115	$179,338	$3,595,398	$303,910	0.0050%	0.0590%
324191	Petroleum lubricating oil & grease m	261	261	$5,967,934	$3,354,088	$181,685	0.1779%	3.2848%
324199	All other petroleum & coal products mfg	57	57	$69,289	$1,458,119	$75,120	0.0048%	0.0922%
325	**Chemical Manufacturing**							
325110	Petrochemical mfg	31	29	$181,400	$29,725,040	$1,708,872	0.0006%	0.0106%
325120	Industrial gas mfg	80	60	$118,752	$4,034,594	$229,527	0.0029%	0.0517%
325131	Inorganic dye & pigment mfg	64	59	$56,498	$1,321,184	$58,848	0.0043%	0.0960%
325132	Synthetic organic dye & pigment mfg	81	81	$78,237	$1,061,363	$52,897	0.0074%	0.1479%
325181	Alkalies & chlorine mfg	27	0	$44,964	$48,418	$1,397	0.0929%	3.2188%
325182	Carbon black mfg	7	0	$12,707	$710,858	$27,248	0.0018%	0.0466%
325188	All other basic inorganic chemical mfg	341	341	$425,853	$13,318,592	$695,205	0.0032%	0.0613%
325191	Gum & wood chemical mfg	36	36	$85,876	$200,485	$8,228	0.0428%	1.0437%
325192	Cyclic crude & intermediate mfg	20	20	$14,177	$1,416,764	$79,692	0.0010%	0.0178%
325193	Ethyl alcohol mfg	216	216	$337,532	$13,161,681	$575,264	0.0026%	0.0587%
325199	All other basic organic chemical mfg	478	478	$743,895	$41,617,066	$2,245,107	0.0018%	0.0331%
325211	Plastics material & resin mfg	500	500	$688,376	$33,067,342	$2,518,534	0.0021%	0.0273%
325212	Synthetic rubber mfg	114	114	$46,081	$4,221,987	$311,363	0.0011%	0.0148%
325221	Cellulosic organic fiber mfg	14	14	$76,023	$429,194	$43,195	0.0177%	0.1760%
325222	Noncellulosic organic fiber mfg	76	76	$23,084	$1,730,191	$112,622	0.0013%	0.0205%
325311	Nitrogenous fertilizer mfg	124	111	$88,829	$585,053	$44,549	0.0152%	0.1994%
325312	Phosphatic fertilizer mfg	22	9	$9,057	$561,376	$55,219	0.0016%	0.0164%
325314	Fertilizer (mixing only) mfg	325	325	$202,591	$2,703,733	$241,777	0.0075%	0.0838%
325320	Pesticide & other agricultural chemical mfg	160	160	$129,539	$2,278,731	$218,450	0.0057%	0.0593%
325411	Medicinal & botanical mfg	318	318	$217,086	$5,118,970	$843,230	0.0042%	0.0257%
325412	Pharmaceutical preparation mfg	719	719	$766,973	$47,353,816	$8,376,866	0.0016%	0.0092%
325413	In-vitro diagnostic substance mfg	174	174	$196,479	$2,338,572	$329,751	0.0084%	0.0596%
325414	Biological product (except diagnostic) mfg	186	186	$75,989	$1,981,852	$266,427	0.0038%	0.0285%
325510	Paint & coating mfg	1,033	1,033	$2,018,090	$5,715,541	$292,490	0.0353%	0.6900%

Table VI-12.
Potential Impacts on Small Entities (continued)

NAICS Code	Industry	Number of Small Firms	Number of Affected Small Firms	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
325	**Chemical Manufacturing**							
325520	Adhesive mfg	396	396	$934,519	$3,501,061	$182,023	0.0267%	0.5134%
325611	Soap & other detergent mfg	631	631	$518,718	$12,171,708	$1,234,837	0.0043%	0.0420%
325612	Polish & other sanitation good mfg	484	484	$754,448	$2,817,533	$251,107	0.0268%	0.3004%
325613	Surface active agent mfg	105	105	$322,753	$1,532,779	$136,166	0.0211%	0.2370%
325620	Toilet preparation mfg	716	716	$1,379,246	$7,105,015	$614,583	0.0194%	0.2244%
325910	Printing ink mfg	229	229	$640,692	$1,690,209	$69,214	0.0379%	0.9257%
325920	Explosives mfg	39	34	$100,467	$623,408	$30,640	0.0161%	0.3279%
325991	Custom compounding of purchased resin	437	437	$123,876	$4,008,676	$164,614	0.0031%	0.0753%
325992	Photographic film, paper, plate, & chemical mfg	368	368	$347,252	$1,680,687	$70,697	0.0207%	0.4912%
325998	All other miscellaneous chemical product &	1,002	1,002	$1,806,834	$7,182,713	$287,788	0.0252%	0.6278%
326	Plastics and Rubber Products Man.	10,576	10,576	$2,328,247	$72,020,363	$2,652,803	0.0032%	0.0878%
327	Nonmetallic Mineral Prod. Manufac.	11,059	11,059	$1,926,055	$45,869,413	$2,441,681	0.0042%	0.0789%
331	Primary Metal Manufacturing	4,070	4,070	$1,064,547	$110,979,728	$5,398,756	0.0010%	0.0197%
332	Fabricated Metal Prod. Manufac.	54,741	54,741	$4,676,924	$191,740,016	$8,416,483	0.0024%	0.0556%
333	Machinery Manufacturing	23,002	23,002	$2,017,492	$113,920,817	$5,370,764	0.0018%	0.0376%
334	Computer & Electronic Prod Man.	12,114	12,114	$1,053,509	$74,123,407	$4,884,417	0.0014%	0.0216%
335	Electric Equipment, Appliance Man.	5,074	5,074	$631,876	$61,849,868	$3,379,023	0.0010%	0.0187%
336	Transportation Equip. Manufacturing	10,295	10,295	$1,787,347	$266,882,922	$5,362,478	0.0007%	0.0333%
337	Furniture & Related Product Man.	20,762	20,762	$1,625,554	$41,713,192	$1,895,086	0.0039%	0.0858%
339	Miscellaneous Manufacturing	29,427	29,427	$4,045,036	$66,380,767	$5,423,342	0.0061%	0.0746%
42	**Wholesale Trade**							
423	Durable Goods	172,208	172,208	$2,157,709	$769,593,467	$24,381,098	0.0003%	0.0088%
424	Nondurable Goods	98,410	98,410	$1,309,223	$667,258,422	$19,185,635	0.0002%	0.0068%
42469	Other Chemicals & AlliedProducts	5,845	5,845	$80,895	$34,598,095	$1,075,989	0.0002%	0.0075%
4247	Petroleum & petroleum Products	4,387	4,387	$94,058	$174,676,116	$3,488,008	0.0001%	0.0027%
42495	Paint, Varnish, & Supplies	1,132	1,132	$18,385	$3,242,433	$100,826	0.0006%	0.0182%
44-45	**Retail Trade**							
441	Motor vehicle & parts dealers	79,058	79,058	$1,435,007	$208,068,124	$3,008,725	0.0007%	0.0477%
442	Furniture & home furnishings stores	45,956	45,179	$359,302	$54,830,969	$1,838,793	0.0007%	0.0195%

Table VI-12.
Potential Impacts on Small Entities (continued)

NAICS Code	Industry	Number of Small Firms	Number of Affected Small Firms	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
44-45	**Retail Trade**							
443	Electronics & appliance stores	30,345	12,027	$92,961	$33,194,347	$1,078,567	0.0003%	0.0086%
444	Building material & garden equipment &	59,222	59,222	$553,160	$107,347,788	$6,860,520	0.0005%	0.0081%
445	Food & beverage stores	114,512	65,895	$621,110	$127,787,344	$2,653,551	0.0005%	0.0234%
446	Health & personal care stores	43,238	43,238	$986,114	$74,326,476	$2,014,147	0.0013%	0.0490%
447	Gasoline stations	65,603	38,180	$516,264	$200,352,348	$1,872,251	0.0003%	0.0276%
448	Clothing & clothing accessories stores	66,367	6,087	$44,022	$50,650,932	$2,500,586	0.0001%	0.0018%
451	Sporting goods, hobby, book, & music stores	40,723	10,564	$100,751	$29,618,620	$888,154	0.0003%	0.0113%
452	General merchandise stores	10,285	2,988	$166,375	$6,961,451	$296,285	0.0024%	0.0562%
453	Miscellaneous store retailers	97,023	42,338	$321,289	$66,883,652	$2,220,417	0.0005%	0.0145%
454	Nonstore retailers	36,997	29,321	$205,662	$47,685,007	$1,768,922	0.0004%	0.0116%
48-49	**Transportation & Warehousing**							
481	Air transportation	2,852	1,698	$93,300	$74,988,885	$2,233,746	0.0001%	0.0042%
483	Water transportation	1,441	1,441	$62,171	$22,192,914	$1,460,675	0.0003%	0.0043%
484	Truck transportation	104,588	104,588	$1,387,829	$98,730,297	$2,229,347	0.0014%	0.0623%
485	Transit & ground passenger transportation	15,195	7,158	$123,189	$12,585,993	$284,243	0.0010%	0.0433%
486	Pipeline transportation	203	203	$31,176	$26,611,123	$4,571,907	0.0001%	0.0007%
487	Scenic & sightseeing transportation	2,641	1,922	$19,327	$1,817,370	$76,124	0.0011%	0.0254%
488	Support activities for transportation	29,382	29,382	$425,546	$37,836,198	$1,098,079	0.0011%	0.0388%
492	Couriers & messengers	8,025	8,025	$109,385	$7,908,051	$259,301	0.0014%	0.0422%
493	Warehousing & storage	7,650	7,650	$814,857	$44,887,109	$2,256,466	0.0018%	0.0361%
51	**Information**							
511	Publishing industries	22,414	16,449	$259,117	$60,181,512	$7,517,596	0.0004%	0.0034%
512	Motion picture & sound recording industries	20,942	3,249	$23,613	$20,440,179	$1,376,791	0.0001%	0.0017%
515	Broadcasting (except Internet)	5,188	2,179	$73,009	$8,205,091	$533,608	0.0009%	0.0137%
516	Internet Publishing and Broadcasting	8,649	1,812	$73,877	$25,767,514	$1,590,427	0.0003%	0.0046%
517	Telecommunications	2,262	288	$24,775	$2,979,262	$220,418	0.0008%	0.0112%
518	Internet Service Providers, Web Search Portals,	10,751	1,806	$26,351	$14,993,732	$1,116,353	0.0002%	0.0024%
519	Other Information Services	3,313	516	$24,998	$2,252,632	$201,394	0.0011%	0.0124%

Table VI-12.
Potential Impacts on Small Entities (continued)

NAICS Code	Industry	Number of Small Firms	Number of Affected Small Firms	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
52	**Finance & Insurance**							
521	Monetary authorities - central bank	0	0	$0	$0	$0	0.0000%	0.0000%
522	Credit intermediation & related activities	60,048	2,192	$16,041	$89,109,389	$6,952,079	0.0000%	0.0002%
523	Securities intermediation & related activities	54,907	849	$6,038	$65,856,935	$5,859,352	0.0000%	0.0001%
524	Insurance carriers & related activities	135,579	11,260	$174,227	$89,352,496	$4,156,905	0.0002%	0.0042%
525	Funds, trusts, & other financial vehicles (part)	1,974	150	$2,343	$4,664,777	$1,885,761	0.0001%	0.0001%
53	**Real Estate & Rental and Leasing**							
531	Real estate	267,658	215,505	$1,616,953	$187,937,841	$23,086,814	0.0009%	0.0070%
532	Rental & leasing services	27,586	27,586	$348,599	$30,435,251	$1,540,815	0.0011%	0.0226%
533	Lessors of intangible assets, except copyrighted	2,139	465	$4,659	$4,332,716	$808,598	0.0001%	0.0006%
54	**Professional, Technical & Technical**							
5411	Legal services	180,282	3,686	$18,327	$131,471,964	$5,815,833	0.0000%	0.0003%
5412	Accounting, tax return prep, bookkeeping, &	107,326	11,319	$115,574	$53,299,161	$2,963,976	0.0002%	0.0039%
5413	Architectural, engineering, & related services	98,949	24,341	$283,871	$102,067,890	$5,442,612	0.0003%	0.0052%
5414	Specialized design services	34,309	10,673	$113,201	$22,038,259	$1,411,654	0.0005%	0.0080%
5415	Computer systems design & related services	102,538	4,213	$38,852	$91,647,874	$4,371,825	0.0000%	0.0009%
5416	Management, scientific, & technical consulting	141,395	24,597	$258,781	$93,714,829	$7,937,161	0.0003%	0.0033%
5417	Scientific R&D Serv.	12,707	4,669	$68,909	$21,694,585	$1,644,682	0.0003%	0.0042%
5418	Advertising & related services	36,283	12,502	$146,165	$42,872,501	$2,621,856	0.0003%	0.0056%
5419	Other professional, scientific, & technical	64,194	64,194	$1,392,920	$45,338,083	$3,493,218	0.0031%	0.0399%
55	**Management of Companies**							
551111	Offices of bank holding companies	830	558	$8,962	$2,964,016	$379,227	0.0003%	0.0024%
551112	Offices of other holding companies	4,912	1,897	$30,901	$14,310,160	$8,492,350	0.0002%	0.0004%
551114	Corporate, subsidiary, & regional managing	14,364	13,507	$240,472	$58,659,988	$8,691,221	0.0004%	0.0028%
56	**Adm and Support & Waste Managmt**							
561	Administrative and Support Serv.	304,301	304,301	$5,370,593	$227,889,399	$9,566,172	0.0024%	0.0561%
562	Wastemanagement & Remediation Serv.	16,657	16,657	$342,365	$23,646,581	$1,025,723	0.0014%	0.0334%

Table VI-12.
Potential Impacts on Small Entities (continued)

NAICS Code	Industry	Number of Small Firms	Number of Affected Small Firms	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
61	**Educational Services**							
6111	Elementary & secondary schools	17,140	14,387	$271,863	$37,258,439	$2,956,637	0.0007%	0.0092%
6112	Junior colleges	316	231	$5,207	$970,101	$76,725	0.0005%	0.0068%
6113	Colleges, universities, & profesional schools	1,286	921	$20,190	$3,447,935	$270,829	0.0006%	0.0075%
6114	Business schools, & computer & management	6,839	494	$3,446	$5,885,007	$437,603	0.0001%	0.0008%
6115	Technical & trade schools	6,496	2,291	$25,476	$5,860,893	$441,780	0.0004%	0.0058%
6116	Other schools & instruction	35,900	4,486	$37,834	$13,872,429	$1,029,560	0.0003%	0.0037%
6117	Educational support services	5,921	823	$8,820	$4,622,266	$346,007	0.0002%	0.0025%
62	**Healthcare and Social Assistance**							
621	Ambulatory health care services	461,437	461,437	$11,286,651	$415,676,932	$17,219,892	0.0027%	0.0655%
622	Hospitals	961	961	$96,151	$4,659,947	$240,223	0.0021%	0.0400%
623	Nursing & residential care facilities	31,089	31,089	$1,274,167	$28,852,719	$1,335,763	0.0044%	0.0954%
624	Social assistance	110,507	86,080	$1,684,945	$87,629,512	$4,202,145	0.0019%	0.0401%
71	**Arts, Entertainment & Recreation**							
711	Performing arts, spectator sports, & related	42,712	14,018	$137,719	$35,801,342	$2,591,141	0.0004%	0.0053%
712	Museums, historical sites, & similar institutions	6,576	3,657	$40,810	$5,981,405	$389,268	0.0007%	0.0105%
713	Amusement, gambling, & recreation industries	65,299	53,347	$643,395	$49,529,622	$2,659,395	0.0013%	0.0242%
72	**Accommodation & Food Services**							
721	Accommodation	51,868	51,868	$1,103,859	$48,606,638	$2,289,522	0.0023%	0.0482%
722	Foodservices & drinking places	422,579	70,090	$518,022	$269,701,070	$12,083,561	0.0002%	0.0043%
81	**Other Services**							
811	Repair & maintenance	207,377	207,377	$4,629,491	$115,538,920	$4,197,153	0.0040%	0.1103%
811121	Automotive body, paint, & interior repair &	34,555	34,555	$444,618	$24,330,099	$774,830	0.0018%	0.0574%
812	Personal & laundry services	172,370	132,036	$2,162,047	$56,775,410	$2,829,275	0.0038%	0.0764%
812320	Drycleaning & laundry services (except coin-	23,148	20,821	$384,463	$8,081,256	$411,110	0.0048%	0.0935%
812921	Photofinishing laboratories (except one-hour)	1,027	913	$26,634	$917,908	$46,038	0.0029%	0.0579%
813	Religious/grantmaking/civic/professional &	293,086	122,396	$1,401,313	$240,527,375	$4,988,954	0.0006%	0.0281%
99	**State and Local Government**							
9992	State Government	n.a						
9993	Local Government	n.a						
	Total	**6,011,415**	**4,093,543**	**$119,242,319**	**$9,259,608,057**	**$461,323,810**		
	Total for firms producing SDSs	**72,142**	**72,040**	**$32,496,969**	**$954,172,574**	**$83,927,479**		
	Total for firms not producing SDSs	**5,939,273**	**4,021,503**	**$86,745,350**	**$8,305,435,483**	**$377,396,331**		

Note: Costs are expressed in 2010 dollars
Source: Office of Regulatory Analysis, OSHA based on ERG (2012)

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To further evaluate the potential for any adverse effects on small entities resulting from the final rule, OSHA assessed the short-term impacts that may be associated with the compliance costs during the transition period.

The total non-annualized compliance costs for small entities during the four-year transition period are estimated to be $1,330 million, or about $333 million per year for four years. Thus, the potential temporary impact would be about 0.004 percent of revenues or about 0.07 percent of profits, on average, per year for four years for affected small entities.

In order to further ensure that potential impacts on small entities were fully analyzed and considered, OSHA also separately examined the potential impacts of the final rule on very small entities, defined as those with fewer than 20 employees. As shown in Table VI–13, the total annualized costs for entities in this size class would be an estimated $67 million. The annualized costs represent about 0.002 percent of revenues and 0.04 percent of profits, on average, for affected very small entities. The annualized costs did not exceed 0.3 percent of revenues or 3.3 percent of profits for very small entities in any affected industry.

The total non-annualized compliance costs for very small entities during the four-year transition period are estimated to be $789 million, or about $197 million per year for four years. Thus, the potential temporary impact on very small entities would be about 0.005 percent of revenues or 0.1 percent of profits, on average, per year for four years.

In order to more carefully focus on the industry sectors most likely to have significant economic impacts, OSHA carefully examined those industries in the chemical manufacturing and petroleum and coal products manufacturing sectors (''chemical and petroleum producers'') that produce chemicals and SDSs. OSHA examined the extent to which these firms might have significant economic impacts if they produced an unusually high number of chemical products requiring SDSs.

To examine this issue, OSHA examined all small chemical and petroleum producers with respect to their costs as a percentage of revenues and profits. Using the same cost estimation methods as the base analysis, OSHA estimated how many separate chemical products a small firm would have to produce for its annualized costs of compliance with the final rule to exceed 5 percent of profits. OSHA found that the firm would have to produce 7,065 distinct chemical products, each requiring its own SDS. OSHA thinks it very unlikely that there are substantial numbers of small firms (with an average of 27 employees) that produce 7,065 or more distinct chemical products. Swedish data show that less than 0.1 percent of all firms (including large firms) in Sweden produce more than 500 distinct chemical products. (Swedish Chemical Agency, *http://www.kemi.se/templates/Page____2859.aspx*)

OSHA conducted a similar analysis for very small firms with fewer than twenty employees. This analysis found that such firms, with an average of 4.7 employees, would need to produce more than 310 distinct chemical products for costs to exceed 5 percent of profits. OSHA estimates that this would be a very rare situation.

Further, even if small firms could be found that produce more than 7,065 chemical products and very small firms that produce more than 310 chemical products, the costs would probably be much lower than OSHA estimates. First, firms producing this many distinct products probably would not produce SDSs and labels without the assistance of specialized computer software, which OSHA assumes most small firms do not use, but would instead invest in appropriate software to lower their costs, as most larger firms do. Second, firms producing large numbers of chemical products commonly do so because they sell a variety of different mixtures with similar ingredients. Once appropriate data for the ingredients of these mixtures had been developed, using the bridging principles outlined in Appendix A of this preamble, small firms developing SDSs and labels for each mixture would take far less than the 7 hours per chemical product that OSHA has estimated for small firms to convert to the GHS system.

OSHA therefore concludes that there are not a substantial number of small entities or very small entities that would have significant economic impacts from this rule as a result of producing a very large number of distinct chemical products.

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Table VI-13.
Potential Economic Impacts on Very Small Entitites

NAICS Code	Industry	Number of Small Firms	Number of Affected Small Firms	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
11	**Agriculture, Forestry, Fishing & Hunting**							
113	Forestry & Logging	9,762	9,762	$137,170	$7,083,785	$264,987	0.0019%	0.0518%
114	Fishing, Hunting and Trappinig	2,314	793	$11,990	$1,098,226	$55,867	0.0011%	0.0215%
115	Support Activities for Ag & Forestry	9,445	3,575	$42,788	$5,086,384	$237,153	0.0008%	0.0180%
211	**Oil and Gas Extraction**							
211111	Crude petroleum & natural gas extraction	5,799	5,799	$1,430,992	$12,488,688	$1,764,644	0.0115%	0.0811%
211112	Natural gas liquid extraction	77	77	$21,789	$209,640	$49,370	0.0104%	0.0441%
212	Mining (except Oil & Gas)	3,177	3,177	$69,027	$3,325,567	$381,077	0.0021%	0.0181%
213	Support Activities for Mining	7,928	7,928	$116,194	$6,182,889	$708,497	0.0019%	0.0164%
22	**Utilities**							
2211	Electric Power Gen, Trans & Distrib	687	687	$32,858	$8,364,773	$371,360	0.0004%	0.0088%
2212	Natural Gas Distribution	365	365	$19,030	$6,872,831	$204,745	0.0003%	0.0093%
2213	Water, Sewage, & Other Systems	3,787	3,787	$199,004	$2,032,054	$143,466	0.0098%	0.1387%
23	**Construction**							
236	Construction of Buildings	228,345	228,345	$4,098,063	$237,972,529	$11,581,277	0.0017%	0.0354%
237	Heavy Construction	40,670	40,670	$644,179	$46,766,241	$2,505,688	0.0014%	0.0257%
238	Special Trade Contractors	464,293	464,293	$8,027,825	$255,501,704	$10,430,522	0.0031%	0.0770%
31	**Manufacturing**							
311	Food Manufacturing	15,740	15,740	$909,705	$16,386,415	$617,518	0.0056%	0.1473%
312	Beverage &Tobacco Prod. Manuf.	2,767	2,767	$153,137	$3,071,858	$159,342	0.0050%	0.0961%
313	Textile Mills	1,820	1,820	$106,674	$1,883,037	$40,619	0.0057%	0.2626%
314	Textile Product Mills	5,361	5,361	$309,471	$3,003,179	$44,399	0.0103%	0.6970%
315	Apparel Manufacturing	8,183	8,183	$497,930	$5,242,059	$143,647	0.0095%	0.3466%
316	Leather & Allied Product Manufac.	1,074	1,074	$61,980	$630,150	$21,952	0.0098%	0.2823%
321	Wood Product Manufacturing	10,295	10,295	$620,859	$9,156,974	$622,642	0.0068%	0.0997%
322	Paper Manufacturing	1,525	1,525	$93,164	$2,621,087	$54,869	0.0036%	0.1698%
323	Printing and Related Support	26,437	26,437	$1,518,803	$15,154,719	$623,595	0.0100%	0.2436%
324	**Petroleum & Coal Prod. Manufac.**							
324110	Petroleum refineries	169	169	$75,267	$846,646	$70,857	0.0089%	0.1062%
324121	Asphalt paving mixture & block mfg	257	257	$113,535	$1,022,715	$84,309	0.0111%	0.1347%

Table VI-13.
Potential Economic Impacts on Very Small Entitites (continued)

NAICS Code	Industry	Number of Small Firms	Number of Affected Small Firms	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
324	**Petroleum & Coal Prod. Manufac.**							
324122	Asphalt shingle & coating materials mfg	64	64	$27,615	$191,591	$15,794	0.0144%	0.1748%
324191	Petroleum lubricating oil & grease m	176	176	$1,298,965	$478,715	$39,464	0.2713%	3.2916%
324199	All other petroleum & coal products mfg	38	38	$16,524	$90,947	$7,497	0.0182%	0.2204%
325	**Chemical Manufacturing**							
325110	Petrochemical mfg	19	19	$10,440	$122,412	$3,532	0.0085%	0.2956%
325120	Industrial gas mfg	60	60	$11,941	$113,624	$3,278	0.0105%	0.3643%
325131	Inorganic dye & pigment mfg	34	34	$7,228	$93,365	$2,694	0.0077%	0.2683%
325132	Synthetic organic dye & pigment mfg	51	51	$21,741	$80,292	$2,317	0.0271%	0.9385%
325181	Alkalies & chlorine mfg	15	0	$20,310	$48,418	$1,397	0.0419%	1.4539%
325182	Carbon black mfg	5	0	$5,763	$304,654	$8,790	0.0019%	0.0656%
325188	All other basic inorganic chemical mfg	168	168	$56,768	$408,393	$11,783	0.0139%	0.4818%
325191	Gum & wood chemical mfg	26	26	$26,086	$31,054	$896	0.0840%	2.9116%
325192	Cyclic crude & intermediate mfg	8	8	$3,193	$24,784	$715	0.0129%	0.4465%
325193	Ethyl alcohol mfg	123	123	$131,980	$1,283,404	$37,028	0.0103%	0.3564%
325199	All other basic organic chemical mfg	252	252	$101,014	$751,442	$21,680	0.0134%	0.4659%
325211	Plastics material & resin mfg	250	250	$64,501	$1,134,498	$46,939	0.0057%	0.1374%
325212	Synthetic rubber mfg	63	63	$9,107	$88,772	$3,673	0.0103%	0.2480%
325221	Cellulosic organic fiber mfg	8	8	$42,726	$185,094	$7,658	0.0231%	0.5579%
325222	Noncellulosic organic fiber mfg	36	36	$2,115	$57,718	$2,388	0.0037%	0.0886%
325311	Nitrogenous fertilizer mfg	94	94	$26,340	$338,169	$21,263	0.0078%	0.1239%
325312	Phosphatic fertilizer mfg	13	0	$1,722	$23,073	$1,451	0.0075%	0.1187%
325314	Fertilizer (mixing only) mfg	228	228	$58,951	$600,252	$37,743	0.0098%	0.1562%
325320	Pesticide & other agricultural chemical mfg	112	112	$51,087	$212,073	$13,335	0.0241%	0.3831%
325411	Medicinal & botanical mfg	210	210	$68,977	$356,186	$33,025	0.0194%	0.2089%
325412	Pharmaceutical preparation mfg	426	426	$136,912	$765,196	$70,947	0.0179%	0.1930%
325413	In-vitro diagnostic substance mfg	100	100	$45,644	$240,604	$22,308	0.0190%	0.2046%
325414	Biological product (except diagnostic) mfg	117	117	$27,538	$386,255	$35,813	0.0071%	0.0769%
325510	Paint & coating mfg	752	752	$568,789	$1,149,045	$40,737	0.0495%	1.3963%

Table VI-13.
Potential Economic Impacts on Very Small Entitites (continued)

NAICS Code	Industry	Number of Small Firms	Number of Affected Small Firms	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
325	**Chemical Manufacturing**							
325520	Adhesive mfg	260	260	$222,690	$565,487	$20,048	0.0394%	1.1108%
325611	Soap & other detergent mfg	493	493	$228,815	$2,370,087	$141,952	0.0097%	0.1612%
325612	Polish & other sanitation good mfg	372	372	$214,047	$396,210	$23,730	0.0540%	0.9020%
325613	Surface active agent mfg	75	75	$89,671	$227,968	$13,654	0.0393%	0.6567%
325620	Toilet preparation mfg	483	483	$306,787	$1,462,510	$87,595	0.0210%	0.3502%
325910	Printing ink mfg	160	160	$134,078	$237,906	$6,584	0.0564%	2.0364%
325920	Explosives mfg	17	17	$8,000	$27,807	$770	0.0288%	1.0396%
325991	Custom compounding of purchased resin	282	282	$41,174	$499,179	$13,815	0.0082%	0.2980%
325992	Photographic film, paper, plate, & chemical mfg	294	294	$119,425	$158,550	$4,388	0.0753%	2.7216%
325998	All other miscellaneous chemical product & preparation	725	725	$532,022	$1,346,709	$37,271	0.0395%	1.4274%
326	Plastics and Rubber Products Man.	6,146	6,146	$668,538	$7,396,665	$315,439	0.0090%	0.2119%
327	Nonmetallic Mineral Prod. Manufac.	7,988	7,988	$807,303	$8,597,728	$404,513	0.0094%	0.1996%
331	Primary Metal Manufacturing	2,397	2,397	$250,174	$5,830,566	$223,141	0.0043%	0.1121%
332	Fabricated Metal Prod. Manufac.	40,717	40,717	$2,413,283	$34,946,520	$1,706,322	0.0069%	0.1414%
333	Machinery Manufacturing	16,005	16,005	$939,380	$17,880,653	$731,804	0.0053%	0.1284%
334	Computer & Electronic Prod Man.	8,186	8,186	$463,555	$10,129,942	$568,805	0.0046%	0.0815%
335	Electric Equipment, Appliance Man.	3,326	3,326	$193,816	$3,979,298	$154,912	0.0049%	0.1251%
336	Transportation Equip. Manufacturing	6,686	6,686	$394,098	$8,047,938	$250,433	0.0049%	0.1574%
337	Furniture & Related Product Man.	17,105	17,105	$997,120	$9,753,841	$443,130	0.0102%	0.2250%
339	Miscellaneous Manufacturing	24,716	24,716	$2,544,473	$15,193,773	$1,241,339	0.0167%	0.2050%
42	**Wholesale Trade**							
423	Durable Goods	153,036	153,036	$1,405,401	$359,014,292	$11,373,749	0.0004%	0.0124%
424	Nondurable Goods	87,149	87,149	$889,501	$274,482,049	$7,892,163	0.0003%	0.0113%
42469	Other Chemicals & AlliedProducts	5,236	5,236	$55,192	$15,422,225	$479,626	0.0004%	0.0115%
4247	Petroleum & petroleum Products	3,447	3,447	$54,765	$45,454,555	$907,656	0.0001%	0.0060%
42495	Paint, Varnish, & Supplies	1,026	1,026	$11,692	$1,715,167	$53,335	0.0007%	0.0219%
44-45	**Retail Trade**							
441	Motor vehicle & parts dealers	76,594	76,594	$1,267,884	$125,419,149	$1,813,597	0.0010%	0.0699%
442	Furniture & home furnishings stores	44,370	42,150	$237,981	$35,302,841	$1,183,904	0.0007%	0.0201%

Table VI-13.
Potential Economic Impacts on Very Small Entitites (continued)

NAICS Code	Industry	Number of Small Firms	Number of Affected Small Firms	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
44-45	**Retail Trade**							
443	Electronics & appliance stores	29,916	10,386	$63,206	$21,198,389	$688,789	0.0003%	0.0092%
444	Building material & garden equipment & supplies	54,496	54,496	$356,277	$60,504,808	$3,866,819	0.0006%	0.0092%
445	Food & beverage stores	106,248	56,627	$383,032	$77,467,151	$1,608,634	0.0005%	0.0238%
446	Health & personal care stores	41,531	41,531	$816,673	$51,251,763	$1,388,853	0.0016%	0.0588%
447	Gasoline stations	62,530	33,521	$311,271	$136,136,010	$1,272,163	0.0002%	0.0245%
448	Clothing & clothing accessories stores	65,263	4,423	$31,634	$36,167,162	$1,779,208	0.0001%	0.0018%
451	Sporting goods, hobby, book, & music stores	39,460	8,319	$65,700	$19,884,637	$596,267	0.0003%	0.0110%
452	General merchandise stores	9,892	2,451	$153,225	$4,549,796	$193,643	0.0034%	0.0791%
453	Miscellaneous store retailers	94,696	37,897	$221,542	$47,600,822	$1,580,262	0.0005%	0.0140%
454	Nonstore retailers	36,473	28,430	$181,943	$37,826,412	$1,312,741	0.0005%	0.0139%
48-49	**Transportation & Warehousing**							
481	Air transportation	2,379	1,186	$11,294	$2,787,111	$83,022	0.0004%	0.0136%
483	Water transportation	1,102	1,102	$18,559	$1,658,779	$109,176	0.0011%	0.0170%
484	Truck transportation	96,981	96,981	$1,024,801	$53,129,572	$1,190,275	0.0019%	0.0861%
485	Transit & ground passenger transportation	12,623	4,566	$57,706	$4,110,799	$82,852	0.0014%	0.0696%
486	Pipeline transportation	129	129	$1,859	$453,117	$47,049	0.0004%	0.0040%
487	Scenic & sightseeing transportation	2,432	1,706	$13,771	$972,489	$39,216	0.0014%	0.0351%
488	Support activities for transportation	27,215	27,215	$316,950	$21,566,266	$622,749	0.0015%	0.0509%
492	Couriers & messengers	7,283	7,283	$63,738	$3,210,466	$92,706	0.0020%	0.0688%
493	Warehousing & storage	3,940	3,940	$74,120	$3,746,452	$188,333	0.0020%	0.0394%
51	**Information**							
511	Publishing industries	18,749	12,639	$122,029	$13,237,364	$1,536,839	0.0009%	0.0079%
512	Motion picture & sound recording industries	19,882	2,090	$13,281	$12,870,358	$866,910	0.0001%	0.0015%
515	Broadcasting (except Internet)	4,003	904	$24,190	$2,402,033	$156,213	0.0010%	0.0155%
516	Internet Publishing and Broadcasting	8,215	1,241	$24,532	$8,693,439	$536,578	0.0003%	0.0046%
517	Telecommunications	2,090	140	$11,435	$1,339,867	$99,129	0.0009%	0.0115%
518	Internet Service Providers, Web Search Portals, and Data	9,465	749	$12,071	$6,748,436	$502,452	0.0002%	0.0024%
519	Other Information Services	3,013	260	$11,560	$1,136,006	$101,564	0.0010%	0.0114%

Table VI-13.
Potential Economic Impacts on Very Small Entitites (continued)

NAICS Code	Industry	Number of Small Firms	Number of Affected Small Firms	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
52	**Finance & Insurance**							
521	Monetary authorities - central bank	39	6	$20	$63,481	$0	0.0000%	0.0000%
522	Credit intermediation & related activities	58,302	1,041	$0	$36,741,780	$2,866,497	0.0000%	0.0000%
523	Securities intermediation & related activities	54,840	728	$5,102	$51,977,778	$4,624,511	0.0000%	0.0001%
524	Insurance carriers & related activities	134,100	8,701	$133,466	$58,624,336	$2,727,353	0.0002%	0.0049%
525	Funds, trusts, & other financial vehicles (part)	1,978	141	$2,197	$4,149,107	$1,669,915	0.0001%	0.0001%
53	**Real Estate & Rental and Leasing**							
531	Real estate	262,422	206,955	$0	$137,996,566	$16,534,927	0.0000%	0.0000%
532	Rental & leasing services	25,843	25,843	$236,889	$15,896,665	$808,404	0.0015%	0.0293%
533	Lessors of intangible assets, except copyrighted works	2,057	377	$3,143	$3,197,850	$596,803	0.0001%	0.0005%
54	**Professional, Technical & Technical**							
5411	Legal services	174,289	2,513	$12,279	$86,321,366	$3,818,405	0.0000%	0.0003%
5412	Accounting, tax return prep, bookkeeping, & payroll	102,379	7,108	$69,157	$31,004,051	$1,426,974	0.0002%	0.0048%
5413	Architectural, engineering, & related services	90,882	15,816	$148,349	$49,779,421	$2,658,956	0.0003%	0.0056%
5414	Specialized design services	33,538	9,844	$94,996	$16,869,744	$1,080,586	0.0006%	0.0088%
5415	Computer systems design & related services	96,915	2,208	$20,296	$47,470,852	$2,264,474	0.0000%	0.0009%
5416	Management, scientific, & technical consulting services	136,770	19,483	$161,366	$62,747,767	$5,320,724	0.0003%	0.0030%
5417	Scientific R&D Serv.	11,083	2,936	$32,012	$8,652,898	$655,982	0.0004%	0.0049%
5418	Advertising & related services	33,960	10,014	$89,819	$25,585,465	$1,564,672	0.0004%	0.0057%
5419	Other professional, scientific, & technical services	59,820	59,820	$1,172,569	$28,685,212	$2,222,800	0.0041%	0.0528%
55	**Management of Companies**							
551111	Offices of bank holding companies	302	73	$1,115	$401,910	$46,789	0.0003%	0.0024%
551112	Offices of other holding companies	4,071	1,031	$12,205	$8,669,791	$4,714,950	0.0001%	0.0003%
551114	Corporate, subsidiary, & regional managing offices	1,415	524	$5,840	$897,050	$106,581	0.0007%	0.0055%
56	Adm and Support & Waste Managmt	0	0	0	0	0	0.0000%	0.0000%
561	Administrative and Support Serv.	273,987	273,987	$3,634,708	$104,303,502	$4,378,375	0.0035%	0.0830%
562	Wastemanagement & Remediation Serv.	14,617	14,617	$245,885	$10,742,530	$465,981	0.0023%	0.0528%

Table VI-13.
Potential Economic Impacts on Very Small Entitites (continued)

NAICS Code	Industry	Number of Small Firms	Number of Affected Small Firms	Total Annualized Costs	Revenues ($1,000)	Profits ($1,000)	Costs as a Percent of Revenues	Costs as a Percent of Profits
61	**Educational Services**							
6111	Elementary & secondary schools	8,138	5,363	$62,351	$3,918,185	$270,574	0.0016%	0.0230%
6112	Junior colleges	176	54	$724	$124,349	$8,587	0.0006%	0.0084%
6113	Colleges, universities, & profesional schools	868	503	$6,832	$604,290	$41,730	0.0011%	0.0164%
6114	Business schools, & computer & management training	6,405	257	$1,747	$3,173,380	$219,140	0.0001%	0.0008%
6115	Technical & trade schools	5,744	1,466	$11,805	$2,641,692	$182,424	0.0004%	0.0065%
6116	Other schools & instruction	33,022	2,466	$19,157	$7,652,439	$528,446	0.0003%	0.0036%
6117	Educational support services	5,542	441	$4,626	$2,292,614	$158,318	0.0002%	0.0029%
62	**Healthcare and Social Assistance**							
621	Ambulatory health care services	433,397	433,397	$8,823,627	$259,677,755	$9,455,515	0.0034%	0.0933%
622	Hospitals	504	504	$13,219	$587,182	$21,065	0.0023%	0.0628%
623	Nursing & residential care facilities	18,280	18,280	$401,057	$6,068,649	$217,711	0.0066%	0.1842%
624	Social assistance	89,268	64,212	$831,622	$25,670,497	$920,922	0.0032%	0.0903%
71	**Arts, Entertainment & Recreation**							
711	Performing arts, spectator sports, & related industries	40,669	11,900	$92,728	$24,982,338	$1,625,229	0.0004%	0.0057%
712	Museums, historical sites, & similar institutions	5,747	2,793	$20,149	$2,170,237	$111,949	0.0009%	0.0180%
713	**Amusement, gambling, & recreation industries**							
72	Accommodation & Food Services	382526	67413.91073	864432.113	122534789	4355186.6	0.0037%	0.0979%
721	Accommodation	42,530	42,530	$707,086	$20,102,488	$756,368	0.0035%	0.0935%
722	Foodservices & drinking places	339,996	24,884	$157,346	$102,432,301	$3,598,819	0.0002%	0.0044%
81	**Other Services**							
811	Repair & maintenance	200,415	200,415	$4,075,592	$83,539,569	$2,994,138	0.0049%	0.1361%
811121	Automotive body, paint, & interior repair &	32,865	32,865	$350,734	$17,431,293	$550,217	0.0020%	0.0637%
812	Personal & laundry services	166,031	123,170	$1,758,251	$37,427,321	$1,820,112	0.0047%	0.0966%
812320	Drycleaning & laundry services (except coin-operated)	21,723	19,022	$288,538	$5,077,872	$250,119	0.0057%	0.1154%
812921	Photofinishing laboratories (except one-hour)	911	786	$20,103	$366,845	$18,070	0.0055%	0.1113%
813	Religious/grantmaking/civic/professional & similar org	268,457	97,196	$859,850	$127,185,009	$2,599,099	0.0007%	0.0331%
99	**State and Local Government**							
9992	State Government	n.a						
9993	Local Government	n.a						
	Total	5,797,845	3,605,268	$67,485,667	$3,924,513,515	$173,571,057		
	Total for firms producing SDSs	54,122	54,089	$10,650,638	$68,381,146	$4,995,173		
	Total for firms not producing SDSs	5,743,723	3,551,179	$56,835,029	$3,856,132,369	$168,575,884		

Note: Costs are expressed in 2010 dollars
Source: Office of Regulatory Analysis, OSHA based on ERG (2012)

BILLING CODE 4510–26–C

2. A Statement of the Need for, and Objectives of, the Rule

OSHA's HCS was first adopted in 1983 for manufacturing (48 FR 53280, Nov. 25, 1983). Later the Agency expanded the scope of coverage to include all industries where employees are potentially exposed to hazardous chemicals (52 FR 31852, Aug. 24, 1987).

The HCS requires chemical manufacturers and importers to evaluate the hazards of the chemicals they produce or import. The current rule provides definitions of health and physical hazards to use as the criteria for determining hazards in the evaluation process. Information about chemical hazards and appropriate protective measures is then required to be conveyed to downstream employers and employees by putting labels on containers and preparing and distributing safety data sheets. All employers with hazardous chemicals in their workplaces are required to have a hazard communication program, including container labels, safety data sheets, and employee training.

Ensuring that this information is available in workplaces helps employers design and implement appropriate controls for chemical exposures, provides employees the knowledge of the hazards and identities of the chemicals, and gives employees the opportunity to participate actively in the successful control of exposures. Together employers and employees can use this information to reduce the potential for adverse effects to occur. The information transmitted under the HCS requirements provides the foundation upon which a workplace chemical safety and health program is built. Without this information, appropriate controls could not be identified and implemented.

OSHA's HCS is designed to disseminate information on chemicals, which will precipitate changes in handling methods and thus protect those potentially exposed to the chemical from experiencing adverse effects. To protect employees and members of the public who are potentially exposed to chemicals during their production, transportation, use, and disposal, a number of countries have developed laws that require information about those chemicals to be prepared and transmitted to affected parties. These laws vary with regard to the scope of chemicals covered, definitions of hazards, the specificity of requirements (*e.g.,* specification of a format for safety data sheets), and the use of symbols and pictograms. The inconsistencies between the various laws are substantial enough that different labels and safety data sheets must often be used for the same product when it is marketed in different nations. For example, Canada has established requirements for labels under its Workplace Hazardous Materials Information System (WHMIS). WHMIS requires that labels include specified symbols within a defined circle. U.S. chemical manufacturers must label their chemicals accordingly for marketing in Canada.

Development of multiple sets of labels and safety data sheets for each product shipped to different countries is a major compliance burden for chemical manufacturers, distributors, and transporters involved in international trade. Small businesses may have particular difficulty in coping with the complexities and costs involved, and it has been argued that these differing requirements may be a technical (non-tariff) barrier to trade.

These concerns led, in June 1992, to a mandate from the United Nations Conference on Environment and Development (UNCED)(Chapter 19 of Agenda 21), supported by the U.S., calling for development of a globally harmonized chemical classification and labeling system. The negotiations were extensive and spanned a number of years. The product resulting from this effort, the Globally Harmonized System of Classification and Labeling of Chemicals, was formally adopted by the new United Nations Committee of Experts on the Transport of Dangerous Goods and the Globally Harmonized System of Classification and Labelling of Chemicals in December 2002.

The final rule incorporates the GHS's requirements into the HCS. They require chemical manufacturers to apply new hazard classification criteria to their chemicals and to prepare and distribute new labels and safety data sheets. Further, these SDSs and labels will be standardized in a way that they are not under the existing HCS. OSHA's current performance-based approach to SDSs and labeling can create confusion among those who seek to use hazard information effectively. For example, labels and safety data sheets may include symbols and hazard statements that are unfamiliar to readers or not well understood. This lack of standardization and the absence of pictograms are particularly a problem for U.S. workers not literate in English. Containers may be labeled with such a large volume of information that important statements are not easily recognized.

OSHA believes that adoption of these new requirements will benefit employers and enhance employee safety. Employers who use chemicals and employees exposed to those chemicals will benefit from receiving the revised labels and safety data sheets prepared in a consistent format. OSHA believes that the information will be easier to comprehend and access in the new approach, allowing it to be used more effectively for the protection of employees. The primary effect in workplaces where chemicals are used but not produced will be to integrate the new approach into the workplace hazard communication program, including ensuring that both employers and employees understand the pictograms and other information provided on the chemicals' labels and SDSs.

OSHA believes that adoption of the GHS will improve labels and SDS comprehensibility through implementation of a uniform approach. The current regulatory system includes a performance-oriented approach to labels and SDSs, allowing the producers to use whatever language or format they choose to provide the necessary information. This result in a lack of consistency makes it difficult for users of chemicals to properly identify their hazards and recommended protective measures, particularly when purchasing the same product from multiple suppliers. Having the information provided in the same words and pictograms on labels, as well as having a standardized order of information on SDSs, will help all users, including employers, employees, and emergency responders, to more easily identify the critical information necessary to protect employees.

In addition, OSHA believes that American employees and employers will receive benefits from the international adoption of GHS. Development of the GHS system required extensive work by a great number of people and resources from many countries and organizations. The reason it received such support is the belief that there are significant benefits associated with implementation of a globally harmonized approach to hazard communication. Countries, international organizations, chemical producers, users of chemicals, and employees working with chemicals would all benefit. There are at least four reasons to expect that GHS will be adopted globally.

First and foremost, the GHS modifications of the HCS will enhance protection of workers and the environment. Occupationally related injuries, illnesses, and fatalities remain a serious problem in the U.S. For example, although likely to contain very significant underreporting, data from the Bureau of Labor Statistics indicate that, in 2007, employees suffered an estimated 55,400 illnesses attributable to chemical exposures (BLS, 2008), and that some 17,340 chemical-source injuries and illnesses involved days away from work (BLS, 2009). As shown in this FEA, the adoption of the revisions to OSHA's HCS is expected to result in a significant reduction in injuries, illnesses, and fatalities among U.S. employees exposed to hazardous chemicals. In addition, while some countries, such as ours, already have the benefits of protection under existing systems, many do not have such comprehensive approaches. Thus, implementation of the GHS would provide these countries with the important protections that result from dissemination of information about chemical hazards and protective measures. The U.S. expects to improve and build on worker protections it already has.

Second, OSHA believes that the final rule will facilitate international trade in chemicals. It will reduce the burdens caused by having to comply with differing requirements for the same product and facilitate small business participation in international trade.

Third, one of the initial reasons this system was pursued internationally involved concerns about animal welfare and the proliferation of requirements for animal testing and evaluation. Existing systems with different definitions of hazards often result in duplicative testing to produce data related to the varying cut-offs in the different systems. Having one agreed definition will reduce the need for this duplicative testing. It should be noted, however, that OSHA's HCS has never had testing requirements. The HCS is based on collecting and evaluating the best available existing evidence on the hazards of each chemical.

Fourth, information transmittal systems provide the underlying infrastructure for the sound management of chemicals in a country. Those countries that do not have the resources to develop and maintain such a system can use the GHS to build their chemical safety and health programs. Since it has been developed, and will be maintained, through an international approach, national resources used to achieve chemical safety and health can be streamlined. Unlike some other issues, a country's approach to the sound management of chemicals definitely affects others countries. In some cases, bordering countries may experience their neighbors' pollution and other effects of uncontrolled chemical exposures. In all countries, there is a need to acquire sufficient information to properly handle chemicals when they are imported from other countries. Thus having a coordinated and harmonized approach to the development and dissemination of information about chemicals would be mutually beneficial to importing and exporting countries.

In the U.S., there are four primary regulatory agencies that exercise jurisdiction over chemical hazard communication: OSHA; the Department of Transportation, which regulates chemicals in transport; the Consumer Product Safety Commission, which regulates consumer products; and the Environmental Protection Agency, which regulates pesticides and has other labeling authority under the Toxic Substances Control Act. These agencies are not domestically harmonized in terms of definitions of hazards and other requirements. If all four agencies adopt the GHS, the U.S. will have the additional benefit of harmonizing the overall U.S. approach to classification and labeling. Since most chemicals are produced in a workplace and shipped elsewhere, many employers deal with at least two sets of federal requirements. Thus these employers would be likely to obtain some benefits from domestic harmonization.

OSHA has made a determination that the revisions to the HCS will improve the quality and consistency of information provided to employers and employees regarding chemical hazards and associated protective measures. The Agency anticipates this improved information will enhance the effectiveness of the HCS in ensuring that employees are apprised of the chemical hazards to which they are exposed, and in reducing the incidence of chemical-related occupational illnesses and injuries. OSHA estimates that (1) savings in benefits from improved employee health and safety exceed the costs of the final rule, and (2) cost savings to chemical users exceed the costs of the final rule.

An additional and more complete discussion of the reasons why this standard is being promulgated by the Agency is provided in other sections of this preamble.

The primary objective of aligning the HCS with the GHS is to achieve the benefits of the OSHA HCS in a more comprehensive, efficient, and effective manner. The revisions are expected to provide an increased degree of occupational safety and health for employees potentially exposed to hazardous chemicals in the workplace and to provide updated, clear, and comprehensive standards regarding the classification of chemical hazards and the manner in which relevant information about chemical hazards is disseminated to affected employees.

The intent of the HCS is to ensure that all chemical hazards are properly evaluated and that information concerning chemical hazards and associated protective measures is transmitted to employers and employees. The standard achieves this goal by requiring chemical manufacturers and importers to review available scientific evidence concerning the physical and health effects of the chemicals they produce or import to determine if they are hazardous.

For every chemical found to be hazardous, the chemical manufacturer or importer must develop a container label and an SDS and provide both to downstream users of the chemical. All employers with employees exposed to hazardous chemicals must develop a hazard communication program and ensure that exposed employees are provided with labels, access to SDSs, and training on the hazardous chemicals in their workplace.

The three information components in this system—labels, SDSs, and employee training—are all essential to the effective functioning of the program. Labels provide a brief, conspicuous summary of hazard information at the site where the chemical is used. SDSs provide detailed technical information and serve as a reference source for exposed employees, industrial hygienists, safety professionals, emergency responders, health care professionals, and other interested parties. Training is designed to ensure that employees understand the chemical hazards in their workplace and are aware of recommended protective measures. Labels, SDSs, and training are complementary parts of a comprehensive hazard communication program—each element reinforces the knowledge necessary for effective protection of employees.

Information provided in accordance with the HCS serves to reduce the incidence of chemical-related illnesses and injuries in the workplace. This is accomplished by modifying the behavior of both employers and employees. For example, the information contained in the HCS enables employers to implement protective measures in the workplace. Employers will also have information to choose less hazardous alternatives or select appropriate engineering controls, work practices, and personal protective equipment. Improved understanding of chemical hazards by supervisory personnel results in safer handling of hazardous substances, as well as proper storage and housekeeping measures.

Employees provided with information and training on chemical hazards are able to fully participate in the protective measures instituted in their workplaces. Knowledgeable employees can take the steps required to work safely with chemicals in their workplace and are able to determine what actions are necessary if an emergency occurs. Information on chronic effects of exposure to hazardous chemicals helps employees recognize signs and symptoms of chronic disease and seek early treatment. Information provided under the HCS also enables health and safety professionals to provide better services to exposed employees. Medical surveillance, exposure monitoring, and other services are enhanced by the ready availability of health and safety information.

OSHA believes that the comprehensive approach adopted in the HCS, which includes requiring evaluation of chemicals and the transmittal of information through labels, SDSs, and training, is sound. This final rule does not alter that approach. Rather, the final rule is intended to improve the effectiveness of the HCS by enhancing the quality and consistency of the information provided to employers and employees. OSHA believes this can be accomplished by revising the requirements of the standard to conform to the more specific and detailed provisions of the GHS for classification, labeling, and SDSs.

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.

The Office of Advocacy in the SBA did not submit any comments to OSHA in response to the proposed rule.

4. 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.

OSHA received numerous comments in the record about the impact of this rulemaking on small entities. There were concerns about OSHA's preliminary cost estimates and concerns that this rule would have a substantial impact on small manufacturers. OSHA carefully evaluated these concerns and has addressed them below as well as in Section VI.F: Costs of Compliance in this preamble.

Some stakeholders felt that OSHA should convene a Small Business Regulatory Enforcement Fairness Act (SBREFA) panel for this rulemaking (Document ID #0361, 0372, 0397, 0407, and 0411). OSHA evaluated this rule under the provisions of the Regulatory Flexibility Act, which requires that OSHA hold a SBREFA (or SBAR—Small Business Advocacy Review) panel when a rule is expected to have a significant impact on a substantial number of small entities. The modifications to the hazard communication standard do affect a substantial number of small entities, but the costs per firm do not rise to the level where they would impose a significant economic impact on a substantial number of small entities. OSHA defines a significant economic impact on small entities as costs that exceed one percent of revenues or five percent of profits for small entities in any affected industry. The Regulatory Flexibility Act does not define the term ''significant economic impact.'' Instead, as noted in the RFA's legislative history, Congress suggested that agencies refer to SBA guidelines for measuring the impact of rules on small businesses. *See* 126 Cong. Rec. S10,942 (Aug. 6, 1980). In relevant guidance, the SBA's Office of Advocacy states that the impact of a regulation ''could be significant if the cost of the proposed regulation (a) eliminates more than 10 percent of the businesses' profits; (b) exceeds 1 percent of the gross revenues of the entities in a particular sector or (c) exceeds 5 percent of the labor costs of the entities in the sector.'' *See* ''A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act'' (*http://archive.sba.gov/advo/laws/rfaguide.pdf*). Notably, OSHA's threshold of 5 percent of profits is significantly more protective of small businesses than the Office of Advocacy's suggested threshold of 10 percent.

OSHA's two thresholds have long been a part of the Agency's published SBREFA procedures (*See http://www.dol.gov/dol/regs/appendix.htm,* prepared pursuant to Section 212 of the SBREFA) and were originally developed in close cooperation with the Office of Advocacy (*See* SBA Office of Advocacy, 2003, p. 18).

Furthermore, in employing a dual threshold, based on either revenue or profit impacts, OSHA has taken special pains to identify potentially significant impacts on small entities.[31]

While this rule will be costly in the aggregate, it is not aggregate costs but the significance of impacts on small entities that triggers the need for a SBREFA panel. No panel was or is needed for this rulemaking because costs per small entity do not meet the threshold that OSHA uses to define a significant economic impact on a substantial number of small entities.

Stakeholders also expressed concerns that costs were underestimated and that costs to small entities would be considerable. The U.S. Chamber of Commerce asserted that ''the imposition of a completely new system of classification of chemicals represents huge burdens on small employers with significant costs'' (Document ID #0397). OSHA acknowledges that there will be transitional costs for small businesses but feels that the additional transition time OSHA has incorporated into the final rule and discussed in more detail elsewhere in the FEA, combined with OSHA compliance assistance and the fact that many firms have already made the transition to GHS, should allow small employers to adopt the GHS criteria without overwhelming challenges. The U.S. Chamber of Commerce did not provide additional details, which were solicited as part of both the ANPR and the NPRM, on what types of costs small businesses would incur or the possible magnitude of those costs. Without detailed estimates, OSHA cannot fully evaluate alternative costs for small businesses; nor can OSHA adopt alternative cost estimates without persuasive evidence in the record.

Wacker Chemical Company felt that the changes to the HCS would have a large impact on small businesses ''result[ing] from the lack of personnel and financial resources to implement changes of this magnitude which may involve reclassification of the companies' products, reauthoring SDSs

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[31] By comparison, many other agencies, such as EPA and the Department of Homeland Security, rely only on revenue impacts. See also *Aeronautical Repair Station Ass'n, Inc.* v. *F.A.A.*, 494 F.3d 161, 175 (D.C. Cir. 2007). (Federal Aviation Administration made determination that proposed regulation would not have significant economic impact on substantial number of small entities based on its calculation of annualized costs of less than 1 percent of annual median revenue); *Washington* v. *Daley*, 173 F.3d 1158, 1171 (9th Cir. 1999) (parties agreed that economic impact of Department of Commerce regulation would be considered significant if regulation resulted in more than 5 percent reduction in annual gross revenues). It should also be noted that, in OSHA's experience, the 5-percent profitability threshold is much more likely than the 1-percent revenue threshold to trigger a significant impact on a substantial number of small entities. This is supported by the fact that, with profit rates in the United States equal to approximately 6 percent of revenues (as it is, on average, for all firms affected by this final rule), for a firm with profits of 6 percent of revenues, 5 percent of profits will be approximately equivalent to 0.3 percent of revenues.

and labels, and training personnel'' (Document ID #0335), and IBM Corporation expressed concern that small businesses ''may not have the technical resources and skill to generate safety data sheets for [* * *] mixtures'' (Document ID #0334). The Agency believes that small firms have the expertise to make the hazard determinations and meet the other transitional requirements of the revised HCS and, other than comments on the possibility of technical expertise being an issue for small firms asserted by a few firms who do not qualify as small, OSHA did not receive solid evidence that a lack of technical expertise among small firms would actually be a significant issue. Chemical manufacturers and users have been able to comply with the current HCS, and manufacturers have been able to make the classification determinations and label their products in the appropriate manner. In addition, some small firms are likely already complying with the requirements of GHS in order to facilitate international trade. The revised HCS will not be considerably more technical or require considerably more expertise in order to comply than the current HCS. There is also no evidence, from the experiences of firms in the EU or in Asian markets where the GHS criteria for classification of chemicals, label elements, and SDS formats have already been adopted into practice, that small firms are not able to comply due to either overwhelming costs or to a lack of technical expertise required to make the changes.

Many comments expressed general concern that OSHA underestimated the compliance burden on small businesses (Document ID #0336, 0372, 0397, and 0407), and OSHA has increased some costs (for instance, doubling the time required for training) in response to these comments. The comments, while appreciated and insightful, did not contain the level of detail that OSHA would need in order to make a case for changing many of the estimates in the PEA. For the most part, comments received on the issue of costs to and impacts on small businesses simply stated that (in general) costs to small businesses were understated in the PEA or asserted that impacts would be significant without providing data to support alternative estimates. In order to assess the impacts on the cost effectiveness of this standard of possible underestimation of cost parameters, the Agency has included a sensitivity analysis in Section VI.L: Sensitivity Analysis in this preamble. Additional concerns about costs that are not specific to small businesses are addressed further in Section VI.F: Costs of Compliance in this preamble.

Many commenters, including some who voiced concerns about costs, did not support a voluntary adoption approach or any other exemption or modified system for small businesses (Document ID #0324, 0327, 0328, 0329, 0335, 0338, 0351, 0352, 0370, 0376, 0377, 0381, 0382, 0393, and 0410). DuPont felt that dual systems would ''undermine the goal of harmonization [* * * and] be very confusing for employees'' (Document ID #0329). Ferro Corporation expressed the view that ''failure to implement [the requirements of the rule] across-the-board will cause confusion; negate main benefits; and potentially be less protective'' (Document ID #0363).

Many of the commenters who addressed small business issues felt that the benefits to small businesses would be negligible (Document ID #0372, 0378, 0385, 0396, 0397, 0400, 0402, and 0407). Commenters who viewed the primary benefits of adopting the GHS as facilitating international trade were likely to favor an alternative of less than full compliance with GHS. As has been addressed throughout the FEA, however, OSHA's estimates of the benefits of this final rule reflect fewer worker injuries and illnesses, efficiency improvements in the safe handling of hazardous chemicals, and less costly and more effective hazard communication training of new workers. While OSHA recognizes the significant potential trade benefits of this final rule, the Agency did not quantify or monetize these benefits.

In response to numerous comments received in the record, OSHA has extended the phase-in period for this rulemaking and aligned the phase-in of this rule to correspond to the EU's deadline for classification of mixtures. Some of these comments asserted that more time would be especially beneficial to small businesses, reducing the compliance burden significantly (Document ID #0399, 0405, and 0408). For example, the National Association of Chemical Distributors suggested a timeline of 3 years plus 18 months for distributors and downstream users (Document ID #0341). The effective dates in the final rule take these (and other suggestions) into account and provide substantial additional time for implementation. Where the proposal required all labels and SDSs to be in compliance with the new requirements in three years after publication (or August 2014), the final rule requires manufacturers and importers to modify labels and SDSs by June 1, 2015. The final rule also gives distributors an additional six months, until December 1, 2015, to sell stock labeled under the current standard. In addition, employers are given another six months, until June 1, 2016, to update their training and their hazard communication program with any new hazard information received because of the final rule. Finally, the proposal required that exposed employees receive initial training two years after adoption (or August 2013), whereas the final rule gives employers until December 1, 2013 to complete this training.

5. Description of and estimate of the number of small entities to which the rule will apply.

OSHA has completed an analysis of the economic impacts associated with this final rule, including an analysis of the type and number of small entities to which the final rule applies. In order to determine the number of small entities potentially affected by this rulemaking, OSHA used the definitions of small entities developed by the Small Business Administration (SBA) for each industry.

The final standard impacts firms that are the primary producers or distributors of hazardous chemicals, and firms whose employees are exposed to hazardous chemicals. Based on the definitions of small entities developed by SBA for each industry, the final rule is estimated to potentially affect a total of 4,093,543 small entities, as shown in Table VI–12. The rule has its greatest impacts on the 72,040 small firms that produce chemicals that require SDSs and labels.

6. Description of the projected reporting, recordkeeping, and other compliance requirements of the rule.

The final standard includes revised criteria for classification of chemical hazards; revised labeling provisions that include requirements for use of standardized signal words, pictograms, and hazard statements; a specified format for safety data sheets; and related revisions to definitions of terms used in the standard, employee information and training requirements, and other sections of HCS. The final rule also modifies other OSHA standards that contain hazard communication requirements to harmonize them with the requirements of GHS. In addition, certain OSHA standards use HCS terms, and OSHA is making changes to ensure that the scope of those standards is not changed by the GHS revisions.

The preamble to the final standard provides a comprehensive description of, and further detail regarding, the compliance requirements of the rulemaking. A description of the types of entities which would be 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 and the corresponding supporting research, and is summarized below with a summary of unit costs. Except for employee training and color printing, these costs would apply only to those small businesses not already in compliance with the revisions.

Reclassifying chemicals and modifying SDSs and labels:

• Medium establishments (100–499 employees): An average of 5 hours per SDS; in addition, for 25 percent of establishments, an average of $208 per SDS for software modifications.

• Small establishments (1–99 employees): An average of 7 hours per SDS. Management familiarization and other costs:

• Eight hours for health and safety managers and logistics personnel in the manufacturing sector;

• Two hours for each hazard communication program manager not in the manufacturing sector.

Employee training:

• One hour per production employee in most industries;

• Thirty minutes in occupations exposed to few hazardous chemicals and types of hazards;

• Ten minutes per employee in some occupations where GHS-type pictograms are already in use.

Color Printing

• Category 1 establishments (those currently printing only in black & white who do not own color printers): Medium establishments $0.01 per label, small establishments $0.13 per label, and very small establishments $0.14 per label.

• Category 2 establishments (those currently printing only in black & white but who own color printers): Medium establishments $0.01 per label, small establishments $0.13 per label, and very small establishments $0.14 per label.

• Category 3 establishments (those currently purchasing pre-printed label stock): Medium establishments $0.03 per label, small and very small establishments $0.03 per label.

• Category 4 establishments (those currently producing labels printed in multiple colors): No additional costs related to this provision.

7. A description of the steps the Agency has taken to minimize the significant economic impact on small entities.

OSHA has extended the phase-in period for this rulemaking in response to stakeholder concern. The Agency believes that the additional time granted to manufacturers, distributors, and users of chemicals will serve to reduce the transitional costs associated with this rule. Chemical manufacturers currently revise SDSs and labels periodically to include new or updated hazard information, and the extended time frame will allow firms to adopt the GHS criteria into their hazard communication program and to modify SDSs, warning labels, and workplace signs within the normal flow of their operations.

OSHA will be offering guidance materials such as quick cards and fact sheets to aid firms in developing and implementing the training requirements of this rule. OSHA will also be releasing a small business compliance guide to provide additional guidance to small businesses, which will ease the economic impact and compliance burden. The Agency solicited comment from stakeholders as part of the ANPR and NPRM on what compliance assistance tools would be most helpful and has incorporated the suggestions received in the record in the development of guidance materials.

J. Environmental Impacts

OSHA has reviewed the provisions of this final rule in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), the Council on Environmental Quality (CEQ) NEPA regulations (40 CFR Parts 1500–1508), and the Department of Labor's NEPA Procedures (29 CFR Part 11). As a result of this review, OSHA has determined that the final rule will have no significant adverse effect on air, water, or soil quality, plant or animal life, use of land, or other aspects of the environment. OSHA anticipates that the more complete and easier-to-understand SDSs resulting from this rule will, in addition to increasing employee health and safety, have positive effects on the environment.

K. Unfunded Mandates Reform Act Analysis

Section 3 of the Occupational Safety and Health Act makes clear that OSHA cannot enforce compliance with its regulations or standards on the U.S. government ''or any State or political subdivision of a State.'' Under voluntary agreement with OSHA, some States enforce compliance with their State standards on public sector entities, and these agreements specify that these State standards must be equivalent to OSHA standards. Thus, although OSHA may include compliance costs for affected public sector entities in its analysis of the expected impacts associated with the final HCS rule, the rule does not involve any unfunded mandates being imposed on any State or local government entity.

Based on the analysis presented in this economic analysis, OSHA concludes that the final rule would impose a Federal mandate on the private sector in excess of $100 million in expenditures in any one year. Accordingly, this economic analysis of the final rule, concerning revisions to the HCS, constitutes the written statement containing a qualitative and quantitative assessment of the anticipated costs and benefits of the Federal mandate, as required under Section 202(a) of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532(a)).

L. Sensitivity Analysis

In this section, OSHA provides a sensitivity analysis of the major assumptions underlying the Agency's estimates of the annualized costs and annualized benefits of the final rule. The purpose is to determine whether OSHA's conclusion that the final rule yields net benefits is vulnerable to a reasonable change in any one of these assumptions. OSHA's choice of how much to increase unit cost parameters in the sensitivity analysis was intended to reflect an upper bounds (or more) of reasonableness, based on comments, as well as on professional experience and common sense. (As a result, there are almost no estimates provided by commenters of higher unit costs than we used in the sensitivity analysis, and we rejected those few outliers as being unrealistically large and certainly not representative of the average establishment covered by this rule.) OSHA's choice of how much to decrease unit benefit parameters was more subjective and reflected the fact that few commenters provided alternative quantitative estimates. Broadly, the Agency cut unit benefit parameters by at least half in all cases for the sensitivity analysis, which OSHA believes is consistent with the spirit of comments that either supported OSHA's estimates of benefits or thought benefits were somewhat overestimated—the exception being those few commenters who disputed the existence of health and safety benefits or productivity benefits arising from the proposed rule. However, it should be carefully noted that any given benefit category could be reduced to zero and the net benefits would still be positive. This can be seen in Table VI–1, which shows that the estimated net positive annualized benefits of the final rule ($556 million) significantly exceed the estimated annualized benefits for any individual category of benefits—Reduction in Safety and Health Risks ($250 million); Productivity Improvements for Health and Safety Managers and Logistics Personnel ($475 million); and Savings during Periodic Updating of SDSs and Labels ($32 million).

The sensitivity analysis below shows that OSHA's conclusion that the final rule produces net benefits is not dependent on any particular assumption. In fact, the estimated annualized health and safety benefits of the rule alone, independent of any productivity benefits, exceed the estimated annualized cost of the rule. Further, the broad support from industry for this rule, even from those commenters critical of some of OSHA's estimates of costs and benefits, suggests that industry believes the productivity benefits of the rule exceed the costs.

The methodology and calculations underlying the estimation of the compliance costs, benefits, and economic impacts 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 variations in the relevant input parameters.

For example, if the estimated time that companies need to reclassify chemical hazards and revise SDSs and labels were doubled, the corresponding labor costs (but not software costs) of reclassification and revision of SDSs and labels would double as well.

OSHA evaluated a series of such changes in input parameters to test whether and to what extent the general conclusions of the economic analysis held up. On the whole, OSHA found that the conclusions of the analysis are reasonably robust, as changes in any of the input parameters tend not to produce disproportionately large changes in the results. The results also show significant net annualized benefits for the rule regardless of the individual revisions to costs, benefits, or discount rate. The results of the individual sensitivity tests are summarized in Table VI–14 and are described in more detail below.

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Table VI-14
Sensitivity Tests

Impact Variable	OSHA's Best Estimate	Sensitivity Test	Impact on Annualized Costs or Benefits	Percentage Impact on Costs or Benefits	Adjusted Annualized Costs or Benefits	Adjusted Annualized Net Benefit
Cost				**Percentage Cost Impact**	**Adjusted Costs**	
OSHA's Best Estimate of Annualized Total Cost and Annualized Net Benefits					*$201 million*	*$556 million*
Time to Reclassify Chemicals; Revise SDSs and Labels	5.1 hours	100% increase	$18 million	9%	$219 million	$538 million
Number of SDSs	1,414,636	100% increase	$23 million	11%	$223 million	$533 million
Number of Employees Requiring Training	43.7 million	50% increase	$48 million	24%	$248 million	$508 million
Training Time Per Employee	0.84 hours	100% increase	$96 million	48%	$297 million	$460 million
Cost of Color Printing	$24 million	100% increase	$24 million	12%	$225 million	$532 million
Benefit				**Percentage Benefit Impact**	**Adjusted Benefits**	
OSHA's Best Estimate of Annualized Total and Net Benefits					*$757 million*	*$556 million*
Reduced Injuries, Illnesses, and Fatalities Relative to HCS Estimate	1%	0.5%	$ -125 million	-17%	$632 million	$431 million
	1%	5%	$1,000 million	132%	$1,757 million	$1,556 million
Savings due to Improved Efficiency in Creating and Revising SDSs	3.2 hours	50% decrease	$-17 million	-2%	$740 million	$539 million
Savings due to Improved Efficiency of S&H Managers and Logistics Personnel	3%, 15%	67% decrease	$-315 million	-42%	$442 million	$241 million
Savings due to Simplified Hazard Communication Training of All Affected New Employees in Future Periods	Unquantified	0.5 hours/worker	$285 million	38%	$1,042 million	$841 million
Discount Rate	7%	3%				$678 million

Source: U. S. Department of Labor, OSHA, Directorate of Evaluation and Analysis, Office of Regulatory Analysis.

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In the sensitivity test on costs where OSHA doubled the estimated time that companies need to reclassify chemical hazards and revise SDSs and labels, and estimates of other input parameters remained unchanged, as shown in Table VI–14, the estimated total costs of compliance would increase by $18 million annually, or by about 9 percent, while net benefits would also decline by $18 million, from $556 million to $538 million annually.

In a second sensitivity test, OSHA doubled the estimated total number of affected SDSs addressed by this rulemaking, which increased the estimated total cost of reclassification and revision of SDSs and labels. As shown in Table VI–14, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $23 million annually, or by about 11 percent, while net benefits would also decline by $23 million annually, from $556 million to $533 million annually.[32]

In a third sensitivity test, when OSHA increased by 50 percent the estimated number of employees required to be covered by hazard communication programs and to be trained on GHS, the corresponding estimate of the total costs associated with training employees increased by 50 percent. As shown in Table VI–14, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $48 million annually, or by about 24 percent, while net benefits would also decline by $48 million annually, from $556 million to $508 million annually.

In a fourth sensitivity test, when OSHA doubled the estimated incremental amount of time necessary for training employees on GHS, the corresponding estimate of the total costs associated with training employees also doubled. As shown in Table VI–14, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $96 million annually, or by about 48 percent, while net benefits would also decline by $96 million annually, from $556 million to $460 million annually.

OSHA performed a fifth sensitivity test where the estimated incremental per-label cost of printing labels in color was doubled. As shown in Table VI–14, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $24 million annually, or by about 12 percent, while net benefits would also decline by $24 million annually, from $556 million to $532 million annually

OSHA also performed sensitivity tests on several input parameters used to estimate the benefits of the final rule. In one sensitivity test on benefits, OSHA reduced its estimate of health and safety benefits of the final rule from 1 percent to 0.5 percent of the benefits estimated for the existing HCS. As shown in Table VI–14, if OSHA's estimates of other input parameters remained unchanged, the total estimated benefits of the final rule would decline by $125 million annually, or by about 17 percent, while net benefits would also decline by $125 million annually, from $556 million to $431 million annually.

In a second, parallel sensitivity test on benefits, OSHA increased its estimate of health and safety benefits of the final rule from 1 percent to 5 percent of the benefits estimated for the existing HCS. As shown in Table VI–14, if OSHA's estimates of other input parameters remained unchanged, the total estimated benefits of the final rule would increase by $1,000 million annually, or by about 132 percent, while net benefits would also increase by $1,000 million annually, from $556 million to $1,556 million annually.

In a third sensitivity test on benefits, OSHA reduced its estimate of savings due to the improved efficiency in creating and revising SDSs under GHS by 50 percent. As shown in Table VI–14, if OSHA's estimates of other input parameters remained unchanged, the total estimated benefits of the final rule would decline by $17 million annually, or by about 2 percent, while net benefits would also decrease by $17 million annually, from $556 million to $539 million annually.

In a fourth sensitivity test on benefits, OSHA reduced its estimate of savings due to the improved efficiency of safety and health managers and logistics personnel by 67 percent. As shown in Table VI–14, if OSHA's estimates of other input parameters remained unchanged, the total estimated benefits of the final rule would decline by $315 million annually, or by about 42 percent, while net benefits would also decrease by $315 million annually, from $556 million to $241 million annually.

And finally, in the fifth sensitivity test on benefits, OSHA tested the effect of including cost savings from simplified hazard communication training in future periods made possible by the final rule.[33] For this sensitivity test, OSHA added a cost savings of a half hour, on average, in training time per new employee once the transition period ends and the final rule is fully implemented. OSHA chose a half-hour time savings based on the testimony of the one commenter who provided an estimate of the time savings from simplified hazard communication training.[34] As shown in Table VI–14, as a result of adding the half-hour savings in training time, assuming OSHA's estimates of other parameters remain unchanged, the total benefits of the final rule would increase by $285 million annually,[35] or by about 38 percent, while net benefits would also increase by $285 million annually, from $556 million to $841 million annually.

OSHA also examined the effect of a change in the discount rate on the annualized costs and benefits. Changing the discount rate from 7 percent, used in the base case, to 3 percent would have the effect of lowering the costs to $161 million per year and increasing the gross benefits to $839 million per year. The result, as shown in Table VI–14, would be to increase net benefits by

[32] For this sensitivity analysis, OSHA calculated only the impact on costs of an increase in the number of SDSs. However, in principle, each additional SDS would yield future benefits due to improved efficiencies in creating and revising SDSs under GHS. Although not shown in Table VI–8, this effect would increase benefits by $32 million annually, more than offsetting the $23 million annual cost increase.

[33] As noted in the earlier discussion on benefit, in Section VI.D of this preamble, comments on the proposed rule contained extensive qualitative support for the proposition that the revisions to the HCS rule will make training easier and therefore less time-consuming and less costly.

[34] Printing Industries of America testified at the OSHA public hearing held in Pittsburgh that training for an employee who would be responsible for working with hazardous materials is ''approximately an hour to an hour and a half'' and that training would be less time-consuming under the revised HCS and might be reduced ''possibly by a third simply because [the revised HCS will] be removing a number of types [of MSDS and labeling systems]'' (Document ID #0499, Tr. 96–7). This estimate would be consistent with a saving in training time of one-third to one-half of an hour relative to current training time of one to one and a half hours. OSHA chose the one-half-hour estimate because a representative training time for all the commenters would be at least an hour and a half (and arguably more like 3 hours). Furthermore, in its final economic analysis for the original hazard communication rule, OSHA estimated that the rule would require an average of 3 hours of training per employee (48 FR 53280, Nov. 25, 1983).

[35] This estimate uses the BLS turnover rate to arrive at the number of new employees per year per establishment and assumes from one to ten employees per training session, depending on establishment size. The cost savings due to simplified training take into account one half hour of managerial time to deliver the training plus one half hour of time for each of 17.5 million new employees a year to receive the training. The annualized cost savings of $285 million is equal to annual cost savings of $465.5 million multiplied by an annualization factor of 0.6130 to reflect the fact that these cost savings would not begin to be realized until five years after the effective date of the final rule.

$122 million per year, from $556 million to $678 million per year.

OSHA also considered the sensitivity of its findings that the final rule is economically feasible and does not have a significant economic impact on a substantial number of small entities. For example, even if all of the estimated annualized costs of compliance were to increase by 50 percent, these costs would still represent less than 0.005 percent of annual revenues and less than 0.1 percent of annual profit for the average establishment, small entity, or very small entity, and no small entity or very small entity would have costs in excess of 1 percent of revenues or 5 percent of profits.

In conclusion, the sensitivity analysis demonstrates that even with relatively large variations in the input parameters, there would not be any disproportionately large changes in the estimates of compliance cost or benefits. Further, even if there were a 50 percent increase in all of the compliance cost estimates, there would still be a relatively high confidence in OSHA's finding concerning economic feasibility, the certification that the standard will not have significant economic impacts on a substantial number of small entities, and the conclusion that the benefits of the final rule exceed the costs.

VII. OMB Review Under the Paperwork Reduction Act of 1995

The final rule revises existing Hazard Communication collection of information (paperwork) requirements that are currently approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA–95), 44 U.S.C. 3501 *et seq.,* and OMB's regulations at 5 CFR part 1320. On October 30, 2009, the Department of Labor submitted Hazard Communication collection of information requirements identified in the NPRM to OMB for review in accordance with 44 U.S.C. 3507(d). In accordance with 44 U.S.C. 3506(c)(2), the proposed regulation solicited public comments on the revision of the Hazard Communication Standard's (HCS) Information Collection Request (ICR) (paperwork burden hour and cost analysis) for the proposal. OSHA received no public comments on the Hazard Communication Standard's ICR. On November 18, 2009, OMB filed a comment on the Hazard Communication Standard NPRM ICR in accordance with 44 U.S.C. 3507(d). OMB stated, ''This OMB action is not an approval to conduct or sponsor an information collection request under the Paperwork Reduction Act of 1995.'' The final Standard modifies existing information collection requirements that are currently approved under OMB Control Number 1218–0072. This ICR has been revised and submitted to OMB. OSHA will publish a separate notice in the **Federal Register** that will announce the result of OMB's reviews. The Department of Labor notes that a Federal agency cannot conduct or sponsor a collection of information unless OMB approves it under the PRA–95, and the agency displays a currently valid OMB control number. 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.

The final rule standardizes the hazard communication requirements for hazardous chemical products used in U.S. workplaces, and thus provides employees with consistent hazard communication information. Hazard communication is currently addressed by many different international, national, and State authorities. These existing requirements are not always consistent and often contain different definitions of hazards and varying provisions for what information is required on labels and safety data sheets (SDSs). The final standard harmonizes the U.S. system with international norms and as a result would enhance worker safety and facilitate international trade. The final rule's modifications to the Hazard Communication Standard's collection of information requirements include: (1) Revised criteria for classification of chemical hazards; (2) revised labeling provisions that include requirements for use of standardized signal words, pictograms, hazard statements, and precautionary statements; (3) a specified format for SDSs; and (4) related revisions to definitions of terms used in the Standard and to requirements for employee training on labels and SDSs.

Paragraph (d), ''hazard classification,'' requires chemical manufacturers and importers to evaluate chemicals produced in their workplaces or imported by them to classify the chemicals' health and physical hazards in accordance with the Standard. For each chemical, the chemical manufacturer or importer must determine the hazard classes, and the category of each hazard 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. Chemical manufacturers, importers or employers classifying chemicals must identify and consider the full range of available scientific literature and other evidence concerning the potential hazards. There is no requirement to test the chemical to determine how to classify its hazards. Mandatory Appendix A to § 1910.1200 shall be consulted for classification of health hazards, and Mandatory Appendix B to § 1910.1200 shall be consulted for the classification of physical hazards.

For mixtures, chemical manufacturers, importers, or employers evaluating chemicals also must follow the procedures described in Appendixes A and B to § 1910.1200 to classify the hazards of the chemicals, including determinations regarding when mixtures of the classified chemicals are covered by the Standard. When classifying mixtures they produce or import, chemical manufacturers and importers of mixtures may rely on the information provided on current SDSs of the individual ingredients except where the chemical manufacturer or importer knows, or in the exercise of reasonable diligence should know, that the SDS misstates or omits information required by the provisions in the final HCS.

Pursuant to paragraph (e), employers are required to develop, implement, and maintain at each workplace a written hazard communication program which at least describes how the criteria specified in paragraphs (f), (g), and (h) of the standard on labels and other forms of warning, SDSs, and employee information and training will be met, and which also includes the following: (i) a list of the hazardous chemicals known to be present using a product identifier that is referenced on the appropriate SDS (the list may be compiled for the workplace as a whole or for individual work areas); and (ii) the methods the employer will use to inform employees of the hazards of non-routine tasks (for example, the cleaning of reactor vessels) and the hazards associated with chemicals contained in unlabeled pipes in their work areas. The final rule makes no changes to this requirement.

Paragraph (f) modifies existing label requirements by requiring more specific information. Paragraph (f)(1) requires chemical manufacturers, importers, or distributors to ensure that each shipped container of classified hazardous chemicals leaving the workplace is labeled, tagged, or marked with the following information:

(i) Product identifier;

(ii) Signal word;
(iii) Hazard statement(s);
(iv) Pictogram(s);
(v) Precautionary statement(s); and
(vi) Name, address, and telephone number of the chemical manufacturer,
importer, or other responsible party.

The chemical manufacturer, importer, or distributor must ensure that the information provided under (i) through (v) above must be in accordance with the mandatory Appendix C, *Allocation of Label Elements,* for each hazard class and associated hazard category for the hazardous chemical; prominently displayed; and in English (other languages may also be included if appropriate). In addition, the information in (ii) through (iv) must be located together on the label, tag, or mark.

For labels in the workplace, except as provided in paragraphs (f)(7) and (f)(8) of the Standard, employers must ensure that each container of hazardous chemicals in the workplace is labeled, tagged, or marked with either (i) the information specified under (f)(1)(i) through (v) for labels on shipped containers; or (ii) product identifier and words, pictures, symbols, or combination thereof, which provide at least general information regarding the hazards of the chemicals, and which, in conjunction with the other information immediately available to employees under the hazard communication program, will provide employees with the specific information regarding the physical and health hazards of the hazardous chemical.

OSHA has also updated the language for workplace signs and labels to incorporate the GHS hazard statement and the applicable precautionary statement(s), where required. Most OSHA substance-specific heath standards require hazard warning signs, usually for regulated areas, and the language required on the signs varies. With the GHS revision, these standards retain the requirements for specific warning language for specific signs; however, OSHA has modified the language to be compatible with GHS and consistent throughout the OSHA standards. The GHS classification process for a specific substance dictates the hazard warnings and the precautionary statements that will be required on the new GHS-compliant product labels. OSHA believes that having signs and labels in the same formats and containing identical warnings for the same health effects will make it far easier for employers and employees to quickly recognize the hazard and the degree of danger of a hazard, thus enhancing communication.

The final rule modifies the language requirements for signs and labels found in the Agency's health standards listed below in Table VII–1. Since the final rule provides specific language for signs and for labels on containers of contaminated clothing, waste and debris, the Agency is exempted from taking burden hours and costs for these provisions. (*See* 5 CFR 1320.2(c)(2) (''Controlling paperwork burden on the public'')). The Agency is taking burden hours and costs for employers to label, tag, or mark each container of hazardous chemicals with either (i) the information specified under (f)(1)(i) through (v) for labels on shipped containers; or (ii) the product identifier and words, pictures, symbols, or combination thereof, which provide at least general information regarding the hazards of the chemicals.

BILLING CODE 4510–26–P

Table VII–1

General Industry	
Standard	**OMB Control Number**
Welding, Cutting, and Brazing 1910.252	1218-0207
Asbestos 1910.1001	1218-0133
13 Carcinogens 1910.1003	1218-0085
Vinyl Chloride 1910.1017	1218-0010
Inorganic Arsenic 1910.1018	1218-0104
Lead 1910.1025	1218-0092
Chromium (VI) 1910.1026	1218-0252
Cadmium 1910.1027	1218-0185
Benzene 1910.1028	1218-0129
Coke Oven Emissions 1910.1029	1218-0128
Cotton Dust 1910.1043	1218-0061
1,2-dibromo-3-chloropropane 1910.1044	1218-0101
Acrylonitrile 1910.1045	1218-0126
Ethylene Oxide 1910.1047	1218-0108
Formaldehyde 1910.1048	1218-0145
Methylenedianiline 1910.1050	1218-0184
1,3-Butadiene 1910.1051	1218-0170
Methylene Chloride 1910.1052	1218-0179
Hazard Communication 1910.1200	1218-0072

Construction Industry	
Standard	**OMB Control Number**
Methylenedianiline 1926.60	1218-0183
Lead 1926.62	1218-0189
Asbestos 1926.1101	1218-0134
Chromium 1926.1126	1218-0252
Cadmiun 1926.1127	1218-0186
Maritime	
Standard	**OMB Control Number**
Asbestos 1915.1001	1218-0195
Chromium (VI) 1915.1026	1218-0252

BILLING CODE 4510–26–C

Pursuant to paragraph (f)(11), chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within six months of becoming aware of the new information, and shall ensure that labels on containers of hazardous chemicals shipped after that time contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.

Paragraph (g)(2) requires the chemical manufacturer or importer preparing the SDS to ensure that it is in English (although the employer may maintain copies in other languages as well), and include the following section numbers and headings, and associated information under each heading, in the order listed (*See* Appendix D to § 1910.1200—Safety Data Sheets, for the specific content of each section of the safety data sheet).

Section 1, Identification;
Section 2, Hazard(s) identification;
Section 3, Composition/information on ingredients;
Section 4, First-aid measures;
Section 5, Fire-fighting measures;
Section 6, Accidental release measures;
Section 7, Handling and storage;
Section 8, Exposure controls/personal protection;
Section 9, Physical and chemical properties;
Section 10, Stability and reactivity;
Section 11, Toxicological information; and
Section 16, Other information, including date of preparation or last revision.

Although not required by the final rule, an employer may include the following sections to be consistent with the GHS:

Section 12, Ecological information;
Section 13, Disposal considerations;
Section 14, Transport information; and
Section 15, Regulatory information.

Paragraph (g)(5) requires the chemical manufacturer, importer or employer preparing the SDS to ensure that the information provided accurately reflects the scientific evidence used in making the hazard classification. If the chemical manufacturer, importer or employer preparing the SDS becomes newly aware of any significant information regarding the hazards of a chemical, or ways to protect against the hazards, this new information must be added to the SDS within three months. If the chemical is not currently being produced or imported, the chemical manufacturer or importer must add the information to the SDS before the chemical is introduced into the workplace again.

Paragraph (g)(11) requires that employers ensure the SDSs are readily available, upon request, to designated representatives, the Assistant Secretary, and the Director, in accordance with the requirements of 29 CFR 1910.1020(e).

OMB Control Number: 1218–0072.
Affected Public: Business or other for-profit.
Number of Respondents: 5,514,697.
Frequency: On Occasion.
Average Time per Response: The average time per response ranges from twelve seconds for employers to label portable in-plant containers to seven hours for employers to reclassify chemicals and revise SDSs and labels.
Estimated Total Burden Hours: 11.3 million hours.
Estimated Cost: $34.7 million.

VIII. Federalism and Consultation and Coordination With Indian Tribal Governments

The Agency reviewed this final rule according to the most recent Executive Order (''E.O.'') on Federalism (E.O. 13132, 64 FR 43255, August 10, 1999). This E.O. requires that Federal agencies, to the extent possible, refrain from limiting State policy or local policymaking discretion, consult with States and local officials prior to taking any actions that restrict their policy options, and take such actions only where there is constitutional and statutory authority to do so and the problem is of national significance. The E.O. generally allows Federal agencies to preempt State law only where there is clear evidence of Congressional intent to allow it, or where the exercise of State authority would conflict with the exercise of Federal authority under a statute; in such cases, Federal agencies must limit preemption of State law to the extent possible.

In Section 18 of the Occupational Safety and Health Act (the OSH Act), Congress expressly provides that States may adopt, with Federal OSHA approval, a plan for the development and enforcement of occupational safety and health standards. States that obtain Federal approval for such plans are referred to as ''State Plan States'' (29 U.S.C. 667). Occupational safety and health standards developed by such State Plan States, among other things, must be at least as effective in providing safe and healthful employment and places of employment as Federal OSHA standards.

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).

This final rule complies with E.O. 13132. In States that do not have OSHA-approved State Plans, this rule limits State policy options in the same manner as all OSHA standards.

OSHA also reviewed this final rule in accordance with E.O. 13,175 on Consultation and Coordination with Indian Tribal Governments (65 FR 67,249 (Nov. 9, 2000)), and determined that it does not have ''tribal implications'' as defined in that order. The final rule does 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.

IX. State Plans

When federal OSHA promulgates a new standard or more stringent amendment to an existing standard, the 27 States or U.S. territories with their own OSHA-approved occupational safety and health plans must revise their standards to reflect the new standard or amendment, or show OSHA why there is no need for action, e.g., because an existing state standard covering this area is already ''at least as effective'' as the new federal standard or amendment. 29 CFR 1953.5(a). The state standard must be at least as effective as the final federal rule, must be applicable to both the private and public (state and local government employees) sectors, and must be completed within six months of the publication date of the final federal rule. When OSHA promulgates a new standard or a standards amendment which does not impose additional or more stringent requirements than an existing standard, states are not required to revise their standards, although OSHA may encourage them to do so.

The 27 States and U.S. territories with OSHA-approved occupational safety and health plans 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. Connecticut, Illinois, New Jersey, New York and the Virgin Islands have OSHA approved State Plans that apply to public-sector employees only.

This final rule modifies OSHA's hazard communication standard to conform to the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS). It requires chemical manufacturers to use revised criteria for classification of chemical hazards, revised labeling provisions, and a specified format for safety data sheets. There are also revised requirements for employers to train their employees regarding labels and safety data sheets for hazardous chemicals. This GHS rule will also increase worker protection by improving the quality and consistency of information provided to employers and employees regarding chemical hazards and protective measures. Therefore, State Plan States must adopt comparable provisions within six months of publication of the final rule. Each State's existing requirements will continue to be in effect until it adopts the required revisions.

X. Unfunded Mandates

OSHA reviewed this final rule according to the Unfunded Mandates Reform Act of 1995 (''UMRA''; 2 U.S.C. 1501 *et seq.*) and Executive Order (''E.O.'') 12875 (58 FR 58093, Oct. 28, 1993).

Under Section 202 of the UMRA, an agency must prepare a written ''qualitative and quantitative assessment'' of the anticipated costs and benefits of any Federal regulation creating a mandate that ''may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more'' in any one year. 2 U.S.C. 1532(a). As discussed in section VI of this preamble (''Final Economic and Voluntary Regulatory Flexibility Analysis''), the Agency estimates that this final rule will require private sector employers annualized expenditures of $201 million per year. However, OSHA's final rule does not place a mandate on State or local governments, for purposes of the UMRA, because OSHA cannot enforce its regulations or standards on State or local governments. (*See* 29 U.S.C. 652(5).) Under voluntary agreement with OSHA, some States enforce compliance with their State standards on public sector entities, and these agreements specify that these State standards must be equivalent to OSHA standards. The OSH Act also does not cover tribal governments in the performance of traditional governmental functions, though it does when tribal governments engage in commercial activity. However, this final rule does not require tribal governments to expend, in the aggregate, $100,000,000 or more in any one year for their commercial activities. Thus, although OSHA may include compliance costs for affected governmental entities in its analysis, this rulemaking did not trigger the requirements of UMRA based on its impact on State, local, or tribal governments.

Based on the analysis presented in the Final Economic Analysis (section VI above), OSHA has determined that this final rule will impose a Federal mandate on the private sector in excess of $100 million in expenditures in any one year, and is thus subject to the requirements under UMRA for review of private sector costs. The Final Economic Analysis in section VI, satisfies these requirements, and provides a written statement containing the qualitative and quantitative assessment of costs and benefits as is required under Section 202(a) of UMRA (2 U.S.C. 1532).

XI. Protecting Children From Environmental Health and Safety Risks

E.O.13045 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 must 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 may (1) be economically significant under E.O.12866 (*i.e.,* a rulemaking that has an annual effect on the economy of $100 million or more, or would adversely effect 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, product use). This final rule is economically significant under E.O.12866 (*See* section VI of this preamble). However, after reviewing this final rule, OSHA has determined that the standard would not impose environmental health or safety risks to children as set forth in E.O.13045.

XII. Environmental Impacts

The Agency reviewed this final rule according to the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), the regulations of the Council on Environmental Quality (40 CFR part 1500), and the Department of Labor's NEPA procedures (29 CFR part 11).

As a result of this review, OSHA has determined that this final rule will have no impact on air, water, or soil quality; plant or animal life; or the use of land or aspects of the external environment. Therefore, OSHA concludes that this final rule will have no significant environmental impacts.

XIII. Summary and Explanation of the Final Rule

This final rule is based on the public record developed during the rulemaking. As described in Section II, an advance notice of proposed rulemaking (ANPR) was published by OSHA on September 12, 2006 (71 FR 53617). The ANPR included a series of questions to solicit information on a number of specific topics. The responses from more than 100 commenters were used by the Agency to help prepare the required analyses for the proposed rulemaking, as well as to make determinations regarding the proposed text. The notice of proposed rulemaking (NPRM) was published by OSHA on September 29, 2009 (74 FR 50280). Public comments were received during a 90-day comment period that ended on December 29, 2009. Subsequently, public hearings were convened in March 2010 in Washington, DC, and Pittsburgh, PA, for the Agency to receive oral testimony from interested parties. Following completion of the hearings, participants were given an opportunity to provide additional information to OSHA during a post-hearing comment period, as well as submit briefs summarizing their views for the record. The public record upon which OSHA is basing the final standard includes all of the comments, testimony, and supporting information submitted by rulemaking participants, as well as by OSHA.

Support for the rulemaking. Many of those who responded to the ANPR expressed their support for adoption and implementation of the GHS. The supporters far outnumbered those who opposed or questioned adoption (*See, e.g.,* Document ID #0003, 0007, 0011, 0033, 0038, 0047, 0050, 0052, 0062, 0106, 0123, 0130, 0151, 0163, and 0171). The reasons presented for this support varied, but included the belief that adoption of the GHS will bring consistency and clarity to hazard communication (*e.g.,* Document ID #0038, 0046, 0059, and 0081); will help to ensure that employees have reliable, consistent, comprehensive, and comprehensible information (*e.g.,* Document ID #0030, 0037, and 0124); will help to enhance human health and the environment (improved worker safety) (*e.g.,* Document ID #0032, 0064, 0081, and 0128); and will reduce burdens associated with preparing multiple classifications and labels for the same product (*e.g.,* Document ID #0030, 0048, 0080, and 0123).

Support for implementation of the GHS by OSHA was expressed by both users and producers of chemicals who responded to the ANPR (*See, e.g.,* Document ID #0038, 0054, 0064, and 0124). While support for implementation of the GHS was widespread in the ANPR comments, these supporters also recognized the challenges associated with implementation. For example, it was noted by a number of commenters that there will be short-term costs associated with implementation, and they urged OSHA to take steps to minimize them by providing a reasonable time period for phase-in, coordinating with other agencies, and providing extensive outreach (*See, e.g.,* Document ID #0032, 0111, 0155, 0157, and 0162). Others were concerned that the GHS is not completely harmonized because it allows countries, and agencies within countries, to select from among a collection of building blocks when determining the scope of their requirements (*e.g.,* Document ID #0076).

In addition to those who supported implementation, but raised areas of concern regarding the way in which it is pursued, there were others who did not support implementation (Document ID #0004, 0065, 0068, and 0108). These commenters argued that it would be too burdensome (Document ID #0004); delegates power to an international body, which can only be accomplished through a treaty, if at all (Document ID #0065); would change the current hazard communication scheme and thus potentially impair safety (Document ID #0065); and should not be applied to pesticides because they are already heavily regulated (Document ID #0108).

In the NPRM, OSHA addressed each of these concerns and concluded that evidence, arguments, and accompanying analyses supported pursuing the modifications to the HCS. OSHA preliminarily determined that these modifications would enhance employee protection and facilitate compliance for all workplaces that produce or use hazardous chemicals.

While OSHA did not include questions regarding the support of stakeholders for adoption of the GHS, it was clear that a majority of those responding to the ANPR supported moving forward with the rulemaking. The arguments presented by those few who actively objected to adoption were addressed in the NPRM and the analyses for the rule, and were not found by OSHA to be persuasive. Other issues raised by supporters as concerns, or suggestions for addressing concerns, were also addressed in the proposed rule.

OSHA indicated in the NPRM (74 FR 50281, Sept. 30, 2009) that the Agency had made a ''preliminary determination that the proposed modifications to the HCS would increase the quality and consistency of information provided to employers and employees.'' OSHA also indicated that the ''standardized label elements would be more effective in communicating hazard information;

standardized headings and a consistent order of information would improve the utility of SDSs; and training would support and enhance the effectiveness of the new label and SDS requirements.'' Participants were asked if they agreed with this assessment, and also to provide information that reflected on the effectiveness of the proposed modifications in protecting employees from chemical hazards in the workplace.

Many participants responded, and the vast majority agreed with OSHA's preliminary determination that the proposed modifications would be effective in protecting employees, as well as the conclusions as to the reasons why it would be effective, and thus supported the rulemaking (*See, e.g.,* Document ID #0336, 0338, 0339, 0376, 0377, 0382, 0402, 0403, 0404, and 0412). These commenters reflected on a number of different aspects regarding effectiveness when indicating their support. For example, in comments provided on behalf of the American Iron and Steel Institute (AISI) and the American Coke and Coal Chemicals Institute (ACCCI), it was stated (Document ID #0360):

AISI and ACCCI support OSHA's assessment that modifications to the Hazard Communication Standard (HCS) would increase the quality and consistency of information provided to employers and employees. Two improvements are expected with the changes OSHA has proposed:

a. Standardized criteria to evaluate chemicals and communicate the hazards via Safety Data Sheets (SDSs) and labeling should assure consistent communication and lower the likelihood of miscommunication and misinterpretation.

b. Standardized criteria to evaluate chemicals should facilitate training. With a single teaching format for SDSs and Labels, understanding, regardless of an employee's educational background, should be improved.

Comments of the Society of Chemical Manufacturers and Affiliates (SOCMA) express support, while highlighting some of the potential implementation challenges that will have to be addressed (Document ID #0402). SOCMA's comments are illustrative of those provided by other commenters who qualified their support by expressing issues that would have to be addressed in order for the benefits to occur *(See also, e.g.,* Document ID #0369):

SOCMA members are generally very supportive of the implementation of GHS for workplace hazard communication in the United States, and for over the past forty years, we have spent millions of dollars and dedicated an insurmountable amount of time towards evaluating potential chemical hazards, communicating hazard information and protecting workers. The proposed rule may have a disproportionate economic impact on small business chemical manufacturers, particularly companies that are already struggling in these unstable economic times. A majority of these burdens can be mitigated, though, if the most affected entities are given adequate time to transition and proper compliance assistance is provided.

* * * Once overcome though, the potential benefits of implementing GHS in the United States are highly anticipated by SOCMA members, some of which include: The harmonization of incompatibilities and inconsistencies in labeling and classification, more uniformity in both substance and format, the elimination of language and reading barriers through pictograms, and the facilitation of control banding.

OSHA addresses the suggestions of SOCMA and other commenters on ways to mitigate implementation issues in discussions of specific provisions below. The Agency believes it has taken the legitimate concerns of stakeholders into consideration when determining the final provisions of this rule.

The National Institute for Occupational Safety and Health (NIOSH) has extensive experience in another international effort to harmonize information on chemicals—development of International Chemical Safety Cards under the auspices of the World Health Organization (WHO) and the International Program on Chemical Safety (IPCS). In their comments, they highlighted the advantages of internationally-harmonized classification criteria (Document ID #0412):

NIOSH recognizes OSHA's Hazard Communication Standard (HCS) as one of the most important U.S. regulations in occupational safety and health and concurs with OSHA on the need for a revised HCS. A significant advantage of the proposed standard is the detailed criteria for classification will improve accuracy and consistency in the information provided to employers and employees on chemical hazards and protective measures. Those criteria will reduce the likelihood of differing interpretations of the same data. In addition, the specified hazard categories will convey the severity of the effect, unlike the hazard classes in the current HCS.

Worker representatives also supported the proposed rulemaking. For example, comments on behalf of the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union (AFL/CIO.CLC), stated (Document ID #0403.2):

The committees which designed the GHS agreed on an important principle early in the work: The final harmonized system should not weaken the protection afforded by any existing system. That in itself was a significant accomplishment. However, in the United States, adopting the GHS will go a step further—the revised, GHS-compliant Hazard Communication rule will greatly improve the comprehensibility of labels and safety data sheets, giving workers and employers—especially employers in small business—information they can more easily understand and use.

While stakeholder support for the rule was extensive, there were some stakeholders who did not support pursuing a final rule to modify the HCS, sought to exempt their constituents from its provisions, or supported a different approach. For example, the American Composite Manufacturers Association (ACMA) argued that the protections of the current rule are sufficient, and implementation of the revisions would be too burdensome for their industry (Document ID #0407). No data were provided to support these contentions. The North American Insulation Manufacturers Association (NAIMA) indicated they support harmonization, but argued that the proposed standard will not achieve global harmonization for a number of reasons, including conflicting domestic requirements (*See* discussion below), administrative hurdles to regularly revising the GHS to remain current with the international version, and obstacles to keeping the GHS current (Document ID #0411). And the National Propane Gas Association (NPGA) stated that only those who operate in an international market will benefit, and that does not include the propane industry (Document ID #0400). Similarly, the Intercontinental Chemical Corporation (ICC) argued that companies not involved in international trade should be allowed to continue complying with the existing standard, and that those who are involved can comply with the revised provisions (Document ID #0502).

OSHA does not find any of these arguments persuasive. With regard to NAIMA, OSHA indicated in the NPRM how it plans to maintain the necessary consistency with the GHS through the various rulemaking options available to the Agency, and that it continues to participate in the international GHS activities in order to be involved in maintenance of the system itself. We do not agree that these are insurmountable concerns that argue against adopting the provisions, or changing the approach in a significant way.

OSHA agrees with ACMA and ICC that the existing standard provides extensive protections to exposed employees. However, the analyses presented in support of the proposed and final rules demonstrate that these protections could be improved by adopting the revised provisions. See Sections IV and VI of this document. In addition, the argument of NPGA that benefits only accrue to companies involved in international trade is not accurate. The improved protections of the rule due to standardization of classification criteria and harmonization of communication on labels and safety data sheets apply equally to employees of companies involved in international trade, and to those in companies that are not involved in such trade. Workers who use hazardous chemicals produced for the domestic market are entitled to the same level of protection as those who use chemicals produced for the international market, and any standard that treated them differently might well be inconsistent with the OSH Act. As indicated in the regulatory analyses for the proposed and final rules, the revisions are economically and technologically feasible for all businesses, including small businesses. See Section VI of this document.

Other general issues. Commenters also raised a number of other issues related to the rulemaking that were not directed to specific paragraphs of the HCS in responses to both the ANPR and the NPRM. Some respondents indicated that OSHA should limit changes to the HCS to those required to align with the GHS, thus keeping the framework of the existing HCS (*See, e.g.,* Document ID #0047, 0080, 0104, 0123, 0145, 0163, 0167, and 0170). For example, ORC Worldwide (Document ID #0123) stated in ANPR comments:

> * * * OSHA can help minimize the cost to businesses by only modifying those sections of the OSHA Hazard Communication Standard (HCS) that must be changed to be consistent with GHS. Therefore, we strongly support OSHA's stated intent to maintain the current scope, application, and interpretations of the HCS, and only modify those sections of the standard necessary for consistency with the GHS. Not only will this help minimize the implementation burden on industry, it should also serve to minimize confusion among employers and employees during the implementation period.

OSHA agreed with these commenters, and made every effort in the NPRM to maintain the framework of the current HCS in the proposed revisions. The modifications proposed were believed by OSHA to be those that were required to align the current HCS with the GHS, but did not address provisions of the current standard that are not addressed in the GHS. Thus, for example, the scope and application paragraph remained largely unchanged, as did the paragraph addressing trade secret protection. The primary modifications proposed in those paragraphs were changes in terminology required to ensure consistency.

A number of commenters addressed this issue in their NPRM comments and testimony as well. For example, Dow Chemical Corporation indicated (Document ID #0353) that OSHA should follow two overarching principles as it revises the HCS. The first is to ''implement the GHS with as little US customization as possible,'' and the second is to ''make only those changes to the HCS that are necessary to facilitate GHS implementation.'' (*See also, e.g.,* Document ID #0370.) Both of these principles were, in fact, followed by OSHA when preparing the NPRM.

Others commenters recognized this was OSHA's approach, and supported it. For example, the Defoamer Industry Trade Association (DITA) noted (Document ID #0367):

> DITA applauds the fact that OSHA did not modify the GHS definitions to a great degree. These definitions reflect a consensus scientific process for the review of the hazards that chemicals can present and the toxicology data that predicts the likelihood of hazard occurring. Accordingly, this should lead to a high level of harmonization on the classification of chemical substances between the EU and the US. A high degree of harmonization is desirable so that manufacturers do not need different SDSs that satisfy the requirements of different countries.

In the final rule, OSHA has continued to remain as consistent as possible with the provisions of the GHS. In general, OSHA has not changed the language of GHS provisions unless necessary to conform with the regulatory requirements of the HCS. Country-specific deviations are very limited, and are intended to ensure that the protections of the current rule are maintained in the final rule. This is consistent with the principle of the GHS developers that no country should have to reduce protections in order to harmonize. OSHA does not believe that any of the deviations in the final rule conflict in a substantive way with the GHS itself.

Many commenters to the ANPR also suggested that OSHA should coordinate implementation of the GHS with other Federal agencies. These included primarily EPA, DOT, and CPSC (*See, e.g.,* Document ID #0048, 0050, 0053, 0076, 0104, 0111, 0123, 0134, 0154, 0162, and 0170). For example, the Soap and Detergent Association (Document ID #0170) stated:

> SDA urges OSHA to coordinate implementation of revisions to the HCS related to the GHS with the Environmental Protection Agency (EPA), Department of Transportation (DOT), and the Consumer Product Safety Commission (CPSC), which all have announced their intentions to implement GHS provisions in their regulations. Workplace hazard communication occurs in a stage of the overall life cycle of chemicals and finished products. Coordination and synchronization of implementation timing could greatly improve the efficiency of implementation of the GHS by industry.

Others mentioned coordinating implementation with the Mine Safety and Health Administration (MSHA) (Document ID #0049, 0101, and 0111).

Similar comments were received in responses to the NPRM (*See, e.g.,* Document ID #0344, 0345, 0350, 0351, 0375, 0376, 0403, and 0411). OSHA agrees with these commenters that the U.S. government agencies should continue to coordinate their activities with regard to implementation of the GHS. In terms of adopting the GHS provisions, DOT has substantially aligned the criteria for physical hazards in their regulations with those of the GHS under the HM–215I rulemaking (71 FR 78596, Dec. 29, 2006). DOT and OSHA arguably have the greatest interface in covered chemical products, and thus adoption of this final rule will result in greater consistency between these two agencies. EPA and CPSC have not initiated rulemaking on the GHS. However, as will be discussed later in this preamble, EPA and OSHA have worked together to develop a common position on coverage of pesticides and chemicals covered by the hazard communication requirements of the Toxic Substances Control Act's (TSCA's) significant new use rules. Clearly, there is no way to coordinate timelines for adoption given that OSHA is at the final rule stage, and neither EPA nor CPSC has started a rulemaking process. As rulemaking develops in these Agencies, discussions will continue to take place in the interagency committee on this subject. With regard to MSHA, Department of Labor rulemaking activities are coordinated through Department officials, and MSHA has been apprised of OSHA's activities in order to determine what action may be appropriate for them to pursue in this area.

A number of commenters to the ANPR also argued that OSHA should coordinate implementation with major U.S. trading partners (*See, e.g.,* Document ID #0042, 0048, 0101, 0116, 0128, 0141, 0155, and 0170). Similarly, several argued that countries should limit modifications to the GHS that are country-specific, and that the UN process should be used to control such changes (Document ID #0018, 0042, 0134, 0154, 0163, 0164, and 0171). For example, the American Petroleum Institute (API) addressed these issues as follows (Document ID #0171):

API strongly recommends that OSHA ensure that timing and coordination of GHS implementation schedules are in line with those of other countries, allowing sufficient time for companies to organize and accomplish necessary work. In order to achieve international harmonization of hazard communication materials and to avoid undue burden on companies, OSHA must stay engaged with all other actors to encourage even and consistent implementation of GHS by individual countries. Further, API recommends that OSHA work closely with other government agencies and countries to ensure alignment to the UN endorsed version of the GHS. As the implementation of the GHS by countries deviates from the UN version of GHS, the perceived benefits of harmonization substantially decrease.

Similar comments were received by participants in the rulemaking after the NPRM was published. For example, 3M indicated (Document ID #0405):

3M agrees that the potential benefits identified in the proposed NPRM may be achieved through global implementation of GHS. However, 3M emphasizes that the potential benefits of GHS will depend on countries around the world aligning as closely as possible with the GHS. The potential benefits of GHS will be substantially undercut by country-specific differences or additions that would require companies to have multiple SDSs and labels for the same product.

Michele Sullivan, an independent consultant, recognized OSHA's approach as being appropriate, and argued for coordination among trading partners (Document ID #0382):

Consistent implementation among the major trading partners of the world is crucial to realize the benefits of the GHS system. For this reason, the alignment, insofar as possible, of all national and regional GHS systems with the UN GHS system is critical. In addition, any national or regional GHS implementation effort must retain enough flexibility to continually adapt the system as necessary to harmonize as closely as possible with the UN GHS system.

OSHA agrees with these commenters that coordination among trading partners would enhance harmonization and facilitate implementation. The Agency remains active in the UN process, participating in the Sub-committee of Experts on the GHS (UNSCEGHS), as well as the United Nations Institute for Training and Research (UNITAR) Programme Advisory Group. There is increased emphasis in the Sub-committee on implementation issues as well as coordination. OSHA is leading a correspondence group of interested members established by the Sub-committee that is reviewing practical classification and hazard communication issues, and proposing modifications to the Sub-committee to clarify such provisions when identified. There are also other correspondence groups that are addressing implementation issues as they are raised to the Sub-committee. OSHA tries to participate in all of this work in the Sub-committee to help ensure that any U.S.-identified issues are raised and addressed. Essentially all of the countries involved in implementation participate in the Sub-committee, so this is OSHA's best opportunity to coordinate with them.

The Agency has also had bilateral discussions with Canada, as well as the European Union (EU), on issues related to implementation. These discussions continue periodically to address mutual issues of concern.

Canada has not yet proposed modifications to their system to achieve harmonization, but they are planning to in the near future. The EU has adopted the GHS, and according to a press release on January 4, 2011, from the European Chemicals Agency (ECHA), recently reached a significant implementation milestone for its Classification, Labelling and Packaging (CLP) regulation. (*http://echa.europa.eu/news/pr/201101/pr_11_01_clp_deadline_20110104_en.asp*):

By 3 January 2011, ECHA received 3,114,835 notifications of 24,529 substances for the Classification and Labelling Inventory. By this deadline, industry had to notify the classification and labelling of all chemical substances that are hazardous or subject to registration under the REACH regulation and placed on the EU market.

* * *

The Classification, Labelling and Packaging regulation relates to chemical substances and mixtures. It introduces into the EU the criteria of the United Nations' Globally Harmonised System for classifying and labelling chemicals. One of the aims of the CLP regulation is to improve the protection of human health and the environment by providing criteria for defining when a substance or mixture displays properties that lead to its classification as hazardous.

CLP applies to manufacturers, importers, users or distributors of chemical substances or mixtures. They must classify, label and package any substance or mixture, regardless of its annual tonnage, in accordance with the Regulation.

The largest number of the notifications, over 800,000, came from Germany. Over 500,000 notifications were submitted from the United Kingdom and nearly 300,000 from France. All together over 6,600 companies notified at least one substance.

Canada and the EU are two of the major trading partners for the U.S. When OSHA prepared the NPRM, it examined the CLP to coordinate where possible on approaches to implementation. However, the primary principles followed by OSHA in developing this proposal were to ensure that the modifications maintain or enhance the protections of the current standard, and that the modifications are consistent with the negotiated provisions of the GHS.

One of the issues of concern regarding implementation by some other countries has been deviation from the GHS itself. Because GHS is intended to be globally implemented, efforts by countries to deviate in a collective manner from the GHS, rather than maintaining consistency, defeats the purpose and, consequently, lessens the benefits of the GHS. OSHA will continue to seek opportunities to ensure coordination of implementation and promote harmonization, both internationally and bilaterally.

It should also be noted that the GHS is a living document, and the UN actively reviews it and considers possible changes based on implementation experiences and other information. These changes are made on a two-year cycle, referred to as a biennium. The OSHA proposal and the final rule are based on Revision 3 of the GHS. Revision 3 was adopted by the UN Committee and Sub-Committee of Experts on the GHS in December 2008, and is available as a publication and on the UN Web site. In December 2010, the UN Committee and Sub-committee of Experts on the GHS adopted additional changes that will be issued as Revision 4.

It is expected that as the UNSCEGHS fulfills its mandate to ensure that the GHS is up-to-date and relevant, further changes will be adopted on a biennium basis. If the change(s) is substantive and controversial, OSHA will have to engage in notice-and-comment rulemaking in order to amend the HCS. However, for non-substantive or clarification changes, other rulemaking options are available that can be utilized to implement the changes more quickly than the full notice-and-comment rulemaking process.

Two possible means are the Standards' Improvement Process (SIPs) or a Direct Final Rule (DFR). Each of these options gives the public notice and opportunity to comment, but has the advantage of a faster process. Either method could be used to ensure that the HCS remains current with the GHS.

A number of NPRM participants commented that OSHA should establish a stakeholder process for input into U.S. government positions on issues raised at the UN (*See, e.g.,* Document ID #0376, 0377, 0381, 0382, and 0411). OSHA is always open to receiving suggestions from stakeholders regarding issues raised in the UN process. The working papers are made publicly available on the UN Web site some 12 weeks before meetings. Public meetings are scheduled to receive input in some situations, and stakeholders may also contact the primary OSHA delegate directly to discuss any of the issues raised. Stakeholders can participate in the Sub-committee discussions directly as well through organizations that have recognized status in the Sub-committee. As already noted, changes to the OSHA HCS as a result of modifications to the GHS in the future will be subject to a public rulemaking process where all stakeholders have the opportunity to participate.

In the NPRM (74 FR 50288, Sept. 30, 2009), OSHA noted that one advantage of adopting a system with harmonized hazard statements is that it would facilitate the use of ''control banding'' in the U.S. Control banding is an approach to selecting control measures for workplace chemical exposures. Basically, the employer can, with the use of information readily available in the workplace, use the approach to determine the appropriate control measures for a chemical. The harmonized hazard statements are key to assessing the hazards, and the degree of severity of the hazards. In combination with data about physical and chemical characteristics, quantities used, and the types of processing, the employer can access recommended control measures. It is particularly helpful in situations with common operations (*e.g.,* bagging operations), and chemicals with well-known hazards that are not severe (*e.g.,* it would not generally be applied to a carcinogen—the control banding guidance would inform the employer that professional assistance must be acquired to address such a hazard). Control banding has been used successfully by small and medium-sized businesses that don't have extensive health and safety expertise in these types of situations.

There is considerable international interest in this approach, and there have been a number of research studies conducted to refine the approach and determine its applicability. Both OSHA and NIOSH have taken part in activities to further investigate its utility in the U.S. NIOSH has extensive information available on its Web site at *http://www.cdc.gov/niosh/topics/ctrlbanding/*. As they indicated in their comments (Document ID #0412):

> The use of control banding to provide guidance for chemical safety and health approaches in U.S. workplaces cannot be accomplished until harmonized hazard statements are readily available. Adoption of the GHS and its phrases would open up the possibility that control banding guidance can be used in the United States to help small- and medium-sized employers select and implement appropriate control measures [NIOSH 2009].

The American Society of Safety Engineers (Document ID #0336) is also a strong proponent of control banding. However, their position was that OSHA should have included control banding in the NPRM, and thus in the HCS:

> * * * ASSE believes OSHA should update the HCS to incorporate elements of control banding. Assuming that most elements of GHS will be adopted and a national database for safety data sheets (SDSs) and chemical classifications will be established to support the transition to GHS from current practice, building a system that would allow guided review of materials and processes such as control banding would be a relatively small additional step. We encourage OSHA to take that step now and avoid revisiting this issue when it becomes unavoidable as control banding grows in use internationally as well among leading employers in this nation.

While OSHA agrees with ASSE that control banding may be a very useful approach to controlling workplace exposures to chemicals, it does not agree that this rulemaking is the appropriate place to address this issue. As noted by both OSHA and NIOSH, adoption of the GHS will facilitate the use of control banding in the U.S. by making harmonized hazard statements readily available on labels and SDSs. This will allow the adaptation of the approach in a way that could not be readily accomplished with the current performance orientation of the HCS. However, it is generally viewed as a guidance approach where it is currently used, and not a mandatory requirement. Furthermore, control banding continues to be refined in terms of application, and is not harmonized. Adoption of it in the HCS would also not be consistent with the principles OSHA has followed in devising the NPRM, *i.e.,* to limit changes to those required to align with the GHS, and to be as consistent as possible with the GHS provisions. Therefore, while OSHA believes the utility of control banding should continue to be assessed and evaluated in the U.S., it is premature to consider the approach as a mandatory requirement and part of the revised HCS.

Outreach/compliance assistance. The ANPR included a series of questions to solicit input from the public on what outreach or compliance assistance materials would be appropriate and useful. OSHA received many comments in response to these questions, with a number of creative and interesting suggestions for outreach products. The Agency will use this input to develop an outreach plan and prepare materials for distribution when the rulemaking is completed. In addition, and as suggested by a number of ANPR commenters (*See, e.g.,* Document ID #0018, 0025, 0047, 0065, 0081, 0104, and 0154), OSHA will continue working with interested parties to examine projects that could be completed by them, or in coordination with them, that could be targeted to specific industries or interest groups.

OSHA solicited additional ideas for outreach or compliance assistance in the NPRM, and many commenters provided such information (*See, e.g.,* Document ID #0332, 0344, 0356, 0370, 0382, 0405, 0408, 0410, and 0414). There was a wide range of suggestions, including training programs, workshops, web resources, and enforcement tools addressing different aspects of the modified standard. OSHA has already developed some compliance assistance products—or updated products available for the existing standard—and will be developing and distributing these and others as resources are made available. There are also tools being developed internationally that will be available for employers undertaking compliance, such as training materials in preparation by the United Nations Institute for Training and Research (UNITAR). OSHA has provided support to this activity, and expects these materials will be made available on its Web site when completed. OSHA encourages trade associations, professional societies, and others to develop materials that are specific to certain interest groups or industries, thus providing a more focused compliance assistance approach than can be done by OSHA at the national level.

The final standard. The following is a description of the provisions of the final standard, along with a discussion of what was proposed and the information provided by rulemaking participants. As noted above (and supported by rulemaking participants), OSHA's approach has been to confine changes to the standard to those required to align it with the GHS. Therefore, provisions that do not require changes for that purpose have been left the way they are in the current HCS. While participants supported this approach in general, suggestions were made that involved changes to the current text in areas unaffected by the GHS. Since OSHA did not propose to open these parts of the rule in the proposed rulemaking, and the analyses did not involve such changes, the Agency will not be adopting them in the final rule.

Similarly, as OSHA indicated in the NPRM, the Agency's approach was also to be as consistent as possible with the GHS itself. Editing was limited to what was required to make the provisions mandatory in the context of OSHA rulemaking, and using the regulatory language required for that purpose. Additionally, as described in the NPRM, OSHA did not propose adopting language from the GHS that was strictly provided for guidance purposes (such as the decision logics in the chapters in the GHS that describe the physical and health hazard criteria). There is no question that other changes could be made to the language to make it more readable, or to state it in American English. However, introducing different terminology also introduces the possibility that readers will believe that OSHA means something different than the GHS because we have used different language. Since this is not the intent, the Agency has avoided doing this.

Nevertheless, many such editorial changes were suggested. While OSHA has reviewed all of them, and adopted a few that seemed appropriate or necessary, in general the Agency did not engage in extensive editing of agreed text for fear of changing the meaning, or giving the impression that the meaning has changed. In particular, Dow Chemical submitted extensive suggested edits in both its initial comments on the NPRM and in post-hearing comments (Document ID #0353 and 0526). Most of these issues were not raised by any other participants. Given the large number of such editorial suggestions from Dow, OSHA does not discuss each one in this preamble, but simply notes where changes have been made to the text. OSHA, however, gave each of Dow's suggestions full consideration.

(a) Purpose. The HCS includes a paragraph that states the purpose of the rule. This stated purpose is two-fold. First, the paragraph indicates that the standard addresses assessment of the hazards of workplace chemicals, and the transmittal of that information to employers and employees. It also describes the contents of a comprehensive hazard communication program as being container labeling and other forms of warning, material safety data sheets, and employee training.

The second part of the paragraph addresses the preemption of State or local laws by this Federal standard. It indicates that OSHA is addressing comprehensively the issues described, and thus the standard preempts States, and political subdivisions of States, from addressing these issues except under the authority of a Federally-approved State plan under Section 18 of the OSH Act. While Section 18 applies to every occupational safety and health standard that OSHA promulgates, the HCS raises particular issues because of the nature of the provisions. It requires chemical manufacturers and importers to evaluate the hazards of the chemicals they produce or import, and to prepare labels and safety data sheets based on those evaluations to transmit hazard information and appropriate precautionary advice to users downstream. This is a unique but highly appropriate approach for an OSHA standard, as it recognizes that chemical manufacturers and importers are in the best position to assess the hazards of their products and develop appropriate information for labels and SDSs.

There is a national, indeed international, marketplace for industrial chemicals, and thus chemical manufacturers and importers affect commerce within the meaning of the OSH Act and therefore fall under OSHA's jurisdiction. If a State, or a political subdivision of a State, were to establish different requirements for labels and safety data sheets, such requirements would have an impact on chemical manufacturers and importers that are not located in that State. This is a burden that the HCS eliminates by establishing national requirements.

The proposed revisions to the HCS had essentially the same purposes, and thus the NPRM included only minor modifications to this paragraph. OSHA proposed to modify paragraph (a)(1) to change the language regarding the assessment of hazards to indicate that the hazards will be "classified" rather than simply assessed or evaluated. This is consistent with the approach in the GHS. In addition, OSHA proposed to modify this paragraph to clearly indicate that the standard is intended to be consistent with the GHS, Revision 3. That change is a reflection of the purpose of this rulemaking to harmonize the existing requirements with the provisions of the GHS, which is the international instrument that includes globally harmonized provisions on hazard communication. In addition, in this paragraph and succeeding paragraphs of the revised rule, the term "material safety data sheet" was modified to "safety data sheet" to reflect the terminology of the GHS.

The only modifications proposed to paragraph (a)(2) also addressed terminology, using "classifying" instead of "evaluating", and "safety data sheet" instead of "material safety data sheet".

There were a few comments that were related to the Purpose paragraph provisions. One comment suggested that the standard should be limited to a purpose of international communication so as not to trigger hazard assessments under other OSHA standards that address respiratory protection, personal protective equipment, or process safety management (Document ID #0049). There were several other comments that indicated that new assessments would have to be done for these standards (Document ID #0111, 0134, 0164, and 0178). Arguments were made that this would lead to extensive additional costs for new engineering controls, respirators, or other personal protective equipment.

As discussed above, there is no identified link to these other standards in the stated purpose of the HCS either currently or with the proposed modifications in the NPRM. While the current HCS and this final standard require the provision of information on recommended control measures, including respiratory protection, personal protective equipment, and engineering controls, there is no requirement for employers to implement the recommended controls. An employer should use all available information when designing an appropriate protective program, but a recommendation on a safety data sheet by itself would not trigger the need to implement new controls.

Furthermore, these comments seem to imply that there will be major changes in the classification of the hazards of chemicals as a result of implementation of the GHS provisions. Both the HCS and the GHS are based on identifying and communicating the inherent hazards of chemicals. Thus the biggest change for most chemicals under the final rule will be in categorizing the chemical's hazards. Under the current standard, for example, a chemical either is, or is not, a carcinogen. Under the revised HCS, if a chemical is a carcinogen, it would be categorized as a Category 1 or a Category 2 carcinogen. Such a change would provide additional information for the downstream user, but would not generally result in a need to change engineering controls or respiratory protection.

It is possible that a chemical may be classified under the final rule as having a hazard it did not have before, but OSHA believes that this is not likely to happen frequently given the broad coverage of the current rule. Furthermore, the physical and chemical characteristics of the chemical—which affect the types of protection required—would not be changed as a result of this proposal. OSHA believes that these revisions would result in few, if any, changes in protective measures required under other OSHA standards.

Several commenters to the ANPR noted what they believed to be the continued need to address the preemption of State standards (*See, e.g.,* Document ID #0036, 0048, 0056, 0080, 0123, 0135, and 0178). In addition, commenters also noted that the impact of GHS adoption on State and local laws should be considered in the process (for example, California Proposition 65), and that differences between such laws and the revised HCS should be discouraged (Document ID #0015, 0038, 0042, and 0072).

It was also indicated that changes in State laws should be coordinated with the Federal changes to facilitate implementation (Document ID #0146). *See* Section VIII and IX of this preamble for a comprehensive discussion regarding Federalism and State plans.

There were a number of comments received in response to the NPRM that addressed the Purpose paragraph provisions. For example, the Styrene Information and Research Center (Document ID #0361) indicated that OSHA should revise paragraph (a)(1) to say that it is intended to be consistent with the GHS ''with some exceptions,'' since there are some deviations from the GHS. OSHA does not agree with this suggestion. The language proposed, and in the final rule, is accurate—it is consistent with the provisions of the GHS. The GHS is not a model regulation, and it is not intended that countries will adopt the actual text of the GHS. Furthermore, there is allowance for flexibility and differences where necessary to accommodate a country's specific needs. There was nothing in the NPRM that was inconsistent with the GHS, and neither is the final rule inconsistent.

Dow Chemical (Document ID #0353), argued that paragraph (a)(2) should state that OSHA is preempting personal injury suits alleging that labels provided inadequate warnings. The Industrial Minerals Association-North America (Document ID #0394) indicates that the new rule must make clear that it preempts state law tort claims alleging failure to warn. OSHA declines these invitations. As recently explained in the Solicitor of Labor's letter to Stephen Wodka, dated October 18, 2011, in general the HCS does not preempt state tort failure to warn lawsuits, and OSHA does not intend to change that position in the final rule. Indeed, the OSH Act's ''savings clause'' explicitly preserves, rather than preempts, State tort law. OSH Act § 4(b)(4), 29 U.S.C. 653(b)(4); *Lindsey* v. *Caterpiller, Inc.,* 480 F.3d 202, 209 (3d Cir. 2007); *Pedraza* v. *Shell Oil Co.,* 942 F.2d 48, 53–54 (1st Cir. 1991). While a limited preemption might be possible to the extent a state tort rule directly conflicted with the requirements of the standard, no commenter has provided any evidence of such a conflict. For example, the record contains no evidence that a manufacturer might be held liable under a State's tort law rules for complying with the GHS. However, to eliminate any confusion about the standard's preemptive effect, and to be consistent with the President's May 20, 2009 Memorandum on Preemption, OSHA has made two small changes to (a)(2) in the final rule, changing the words ''legal requirements'' to ''legislative or regulatory enactments'' in the provision's first sentence and eliminating the words ''through any court or agency'' in the last sentence.

Similarly, DuPont (Document ID #0329) says OSHA should convince States to voluntarily rescind their ''right-to-know'' laws, or make them consistent with the HCS final rule. And the National Paint and Coatings Association (NPCA) (Document ID #0328) believes that OSHA should not allow States to promulgate a standard that is different from the Federal rule. As indicated in paragraph (a)(2), States with OSHA-approved State Plans will have to adopt standards that are at least as effective as this final rule. (*See,* generally, 62 FR 31159, Jun. 6, 1997.) Those standards will be reviewed by Federal OSHA. Other States are preempted from covering these areas with regard to workplace protections. OSHA has no authority with regard to provisions that are intended to address non-workplace situations.

Therefore, OSHA has concluded that the changes it proposed to Paragraph (a) are appropriate, and those changes are being incorporated into the final rule. No other revisions are being made.

(b) Scope and application. The HCS is a generic standard that has very broad provisions in terms of chemicals addressed and workplaces covered. It also interfaces with a number of requirements of other Federal agencies that address labeling of chemical hazards. Paragraph (b) thus includes all of the practical modifications the Agency has developed to ensure that employers and employees understand how the standard is to be applied, and to accommodate various circumstances that potentially affect the application of the standard.

The provisions of paragraph (b)(2) in the HCS address the overall scope of the standard as applying to ''any chemical which is known to be present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency.'' This provision addresses many questions that are raised about the application of the standard.

In general, OSHA does not expect significant changes in the chemicals covered by the HCS under the final rule as compared to the current standard. The scope of hazards covered by the GHS is very similar to what is covered by the current HCS. Additional chemicals may be considered to be acutely toxic due to the proposed adoption of Category 4 in acute toxicity, which would expand the criteria for inclusion from the current definition (*See* the discussion under ''Hazard classification''). However, these chemicals are already covered under the voluntary national industry consensus standard on precautionary labeling of industrial chemicals that many manufacturers follow in their labeling programs (ANSI Z400.1/Z129.1–2010, *Hazardous Chemicals—Hazard Evaluation and Safety Data Sheet and Precautionary Labeling Preparation),* as well as being covered in the requirements that apply to chemicals shipped to the EU. Thus many manufacturers are already classifying and labeling these chemicals as acute toxins. The final rule is also likely to cover fewer mixtures as acute toxins than the current rule given the hazard classification approach in the GHS that uses a calculation based on proportionality to determine whether a mixture is covered, rather than the strict percentage cut-off of 1% in the current HCS. Other definitions of health hazards would maintain the current broad HCS scope.

In addition to the overall scope statement, the final rule, like the current rule, provides for limited coverage in workplace situations that have special circumstances, including laboratories (paragraph (b)(3)) and work operations where employees only handle chemicals in closed containers (paragraph (b)(4)).

OSHA also addresses the interface with other Federal agency requirements by either exempting the products covered from additional OSHA labeling (such as pesticides required to be labeled by the EPA) (paragraph (b)(5)), or completely exempting the product (such as hazardous waste regulated by EPA) (paragraph (b)(6)). These accommodations help to ensure that

Federal requirements do not conflict or duplicate each other.

Under the GHS, such provisions are left under the purview of the ''competent authority.'' In developing the GHS, it was recognized that countries' regulatory authorities would need to have the discretion to address such 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.

OSHA reviewed the current provisions of paragraph (b), and determined that no significant changes were required to be consistent with the GHS. Several minor changes to revise terminology were retained from the proposal (*i.e.,* adopting the terms ''classifying'' and ''safety data sheets''), but OSHA is not modifying any of the remaining provisions of paragraph (b). The Agency is also deleting Appendix E of the current HCS, which was guidance for application of the standard, and thus is deleting the reference to it in paragraph (b)(1). The Sheet Metal and Air Conditioning Contractors National Association (SMACNA) (Document ID #0415) suggested in response to the NPRM that OSHA update Appendix E and continue to include it in the standard. OSHA will update Appendix E, and make it available as a compliance assistance product. It was always available as a pamphlet in any event, and has been very useful in helping small employers who are users of chemicals comply with the standard. And as noted above, new outreach and compliance assistance materials are being prepared as well.

Several commenters to the ANPR indicated that OSHA should adopt exemptions included by the European Union in its requirements. Specifically, these exemptions address non-isolated intermediates, chemicals involved in research and development, and waste (Document ID #0049, 0134, and 0164). In response to the NPRM, the Society of the Plastics Industry (SPI) (Document ID #0392) continued to argue that the EU exemptions should be adopted. All of these situations are already addressed in paragraph (b), and OSHA does not agree that it is appropriate or necessary to change them.

In terms of non-isolated intermediates, the overall scope provision in paragraph (b)(2) adequately addresses this situation. This was described in the preamble to the 1983 final rule (48 FR 53335, Nov. 25, 1983):

> That is, the term ''known'' means the employer need not analyze intermediate process streams, for example, to determine the presence or quantity of trace contaminants. However, where the employer knows of such contaminants, and they are hazardous, then they fall under the provisions of the standard.

With regard to chemicals involved in research and development, paragraph (b)(3) limits coverage in laboratories, and partially addresses this situation. Where there is no knowledge of the hazards of such chemicals, the HCS does not apply at all since there is no requirement to generate new hazard information. Where information is available, it must be provided to exposed employees, consistent with paragraph (b)(3) when it is in a laboratory situation. Therefore, it appears to OSHA that this situation is also adequately addressed under the current provisions. Hazardous waste as regulated by EPA is already exempted under paragraphs (b)(6)(i) and (ii).

The North American Metals Council (NAMC) (Document ID #0377) argued in response to the NPRM that OSHA should use the EU approach to exempt metals in their massive form, alloys, and other preparations that do not present a hazard. Provisions already exist in the current HCS, and are included in the final rule, that address these issues (*See, e.g.,* definition of article (paragraph (c)), special labeling provisions for solid metals (paragraph (f)(4))).

There were commenters who suggested that OSHA maintain current exemptions or limitations in the revised GHS, including the consumer product exemption (Document ID #0064), guidance on byproducts (Document ID #0064), the relative roles of manufacturers and employers (Document ID #0064), and the article exemption (Document ID #0160). OSHA agrees and all of these accommodations remain the same in the revised rule. The Agency is not changing those parts of the HCS that are not affected by the GHS.

There were also a few comments regarding the scope of the revised rule in terms of provisions of the GHS that affect the environment or transportation (*See, e.g.,* Document ID #0072 and 0179). OSHA does not have the authority to require information in these areas since they are not directed to the protection of employees under its jurisdiction. However, OSHA does not prohibit this type of information on labels or safety data sheets, and is aware that it is often included on labels and safety data sheets currently developed to comply with the HCS. OSHA expects that chemical manufacturers will continue to voluntarily include such data on their labels and safety data sheets to meet the requests of their domestic and international customers. Commenters to the NPRM continued to state that OSHA should allow environmental information although it is not required (Document ID #0344 and 0381). OSHA maintains the position proposed that manufacturers are free to provide additional information on labels and safety data sheets to address environmental concerns, as well as aspects of concern in other areas such as transportation. (74 FR 50387, Sept. 30, 2009)

Few comments were received on this paragraph in the NPRM. Dow Chemical (Document ID #0353) suggested that paragraph (b)(5)(iv) be updated to reflect the changed name of the Bureau of Alcohol, Tobacco, Firearms, and Explosives (the word ''Explosives'' has been added to their name). This has been done. In addition, two typographical errors in (b)(6)(ii) have been corrected.

The North American Insulation Manufacturers Association (NAIMA) (Document ID #0411) states that OSHA has given unwarranted exemption by ceding authority for products regulated by other agencies. In particular, NAIMA is concerned about coverage by CPSC, and indicates that CPSC addresses the fire hazards of cellulose insulation, but not the health hazards, in its label requirements. NAIMA argues that OSHA should not allow consumer product labels to supersede OSHA requirements.

OSHA considered this issue at length in previous amendments to the HCS (53 FR 29822, 29834–38, Aug. 8, 1988; 59 FR 6126, 6150–52, Feb. 9, 1994; *See also* 52 FR 31852, 31862–63, Aug. 24, 1987). After noting that CPSC labels often do not contain all hazard information relevant to worker exposures, OSHA concluded that:

> OSHA nevertheless decided to permit the CPSC labels to suffice so as not to disrupt the extensive labeling conducted in accordance with those rules. OSHA believed that this could be justified on the basis that some information is provided on the labels that would be useful to workers, and that the requirement for MSDSs would provide what information is necessary to supplement the labels. 48 FR 53289. This additional information is critical to ensuring that training can be properly conducted, and that adequate protective measures are used in the workplace.

(53 FR 29834, Aug. 8, 1988; *See also* 59 FR 6151, Feb. 9, 1994.) Thus, under the current HCS, SDSs and employee training are required where employee exposure to a consumer product exceeds

the range that ''could reasonably be experienced by consumers when used for the purpose intended.'' 29 CFR 1910.1200(b)(6)(ix). OSHA sees no need to revisit this issue now, and in any event it is outside the scope of this rulemaking, which is aimed at the changes necessary to bring the HCS in conformity with the GHS.

A few comments were received in response to the ANPR regarding EPA labels for pesticides, noting that signal words in these labels would change if GHS is adopted (Document ID #0178), and noting that the requirements for these labels are dictated by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which also controls the SDS content (Document ID #0108). A commenter also argued that FIFRA pesticide labels are more useful because they are risk-based rather than hazard-based (Document ID #0108). These concerns were not related to the proposal which maintained the exemption for additional labels on containers that are labeled in accordance with EPA requirements. If EPA decides to adopt the GHS, then labels for pesticides would be consistent with OSHA labels on other types of products. With regard to SDSs, these are required by the HCS, not FIFRA, and therefore such SDSs must be consistent with GHS provisions as adopted in this final standard.

A number of additional comments, and oral testimony, were received in response to the NPRM from representatives of the pesticide industry regarding potential conflicts between OSHA and EPA requirements (*See, e.g.,* Document ID #0352, 0385, 0387, and 0468). OSHA does not require additional labels on pesticides that require labels under EPA requirements. However, OSHA does have SDS requirements that must still be applied, and have been applied since the HCS first went into effect. Pesticide industry representatives believe that the SDS requirements as aligned with the GHS would conflict with the EPA-approved labels because they may have different information on them for OSHA than what is included in the pesticide label. For example, EPA has three signal words for pesticides (danger, caution, and warning), while OSHA will have the two specified by the GHS (danger and warning). There are also other differences. For example, chronic health effects are rarely addressed on pesticide labels as the risk mitigation measures are intended to minimize the possibility of their occurrence. However, OSHA would require such effects to be included when appropriate. The commenters also argue that EPA ''labels'' include any information related to the product, and thus SDSs would be preempted by the EPA labeling requirements. Therefore, they argue that pesticides should be exempted from the HCS. For example, the American Chemistry Council's Biocides Panel says the reasons for exempting pesticides are as follows (Document ID #0385):

> The principal reasons for this are: (i) Requiring GHS compliant SDS's but not pesticide labels will result in significant confusion in workplaces in which pesticides are used; (ii) imposing GHS-based SDS's would be inconsistent with EPA's interpretation of FIFRA, which includes all material that may be shipped with a pesticide, including SDS's, as part of its definition of labeling; and (iii) applying GHS to pesticide SDS's will not provide any additional substantive information, as EPA's evaluation of pesticides before approving them for sale includes all aspects of potential occupational exposures.

OSHA considered exempting pesticides from the final rule. However, exempting pesticides would reduce protections for those workers under OSHA's jurisdiction. For example, OSHA's jurisdiction extends to employees in pesticide manufacture and formulation. While EPA approves the label on the final product shipped out of these facilities, and that label includes information needed when the products are used by applicators, EPA does not have hazard communication requirements for the protection of workers in production facilities. Such protection is covered by OSHA, and OSHA requires labels on containers that are not subject to EPA labeling, as well as SDSs and training. The workplace exposures of these workers are of great concern. The chemicals are generally designed to be biologically active, and the exposures can be quite different than they would be for applicators, for example, who may use them only on an intermittent basis.

In testimony during the public hearing, representatives from the ACC Biocides Panel and CropLife America, Inc., agreed that EPA does not cover workers in pesticide manufacturing or formulating facilities (*See* Document ID #0495 Tr. 248–250). An exemption from the HCS would provide reduced protection for these workers.

As a result of receiving these comments, and the concerns about removing current protections from the final rule, OSHA considered several options. OSHA considered allowing the SDS preparer to use the EPA classification in section 2 of the SDS to ensure consistency with the FIFRA label. However, in doing this the SDS would then be inconsistent with other chemicals in the production of pesticides. In the pesticide manufacturing workplace the pesticide chemical ''active'' ingredients would bear a FIFRA label but would have an OSHA SDS, however other chemicals in the workplace such the ''inactive'' ingredients or cleaning products might still be considered hazardous under the HCS would contain an OSHA label and an OSHA SDS. An added complication is that an identical chemical (for example, chlorine) could potentially be in a pesticide manufacturing workplace where in one situation it could contain a FIFRA label and another it could bear an OSHA style label depending on its end use (e.g., a disinfectant). Adding a different SDS would create additional confusion not only for the worker handling the chemicals but also the personnel in charge of chemical management as well. Therefore, OSHA and EPA met to discuss what would be an appropriate resolution. First, with regard to the argument that SDSs are part of labels, and therefore preempted, EPA has long had an interpretation that they will not apply their review requirements to SDSs (US EPA Pesticide Registration Notices 92–04). Based on our discussions, OSHA does not anticipate that this policy will change. Secondly, EPA has indicated that they are committed to working with OSHA to develop an approach that will provide both appropriate protection for employees, as well as the environment, through workable guidance for the pesticide industry. OSHA anticipates that EPA will provide guidance to their regulated community (such as through a Pesticide Registration Notice) on how to develop an OSHA GHS-compliant SDS that will not be in conflict with the pesticide label. Therefore, pesticides will continue to be covered in the same manner as has been done under the HCS since its inception, and the exemption requested by pesticides industry rulemaking participants for such products is not granted.

Although the OSHA ICR (OMB Control No. 1218–0072) that is currently pending review and approval by OMB addresses the information collection activities associated with preparing the entire SDS as prescribed by the OSHA final rule, the approach OSHA anticipates will be provided in the EPA guidance for pesticide registrants was not considered by OSHA at the proposed rule stage. While OSHA preliminarily believes it has taken sufficient time in its paperwork estimate to cover compliance with the anticipated EPA guidance, the public has not had the opportunity to comment on the paperwork burdens created by that guidance. As such, EPA and OSHA are collaborating on a subsequent revision to OSHA's ICR to ensure that it addresses the activities in the EPA guidance. EPA intends to solicit public comment on an ICR revision that addresses the information collection activities and related burden estimates associated with the EPA guidance as part of its release of that guidance. After public comments are considered by both agencies, OSHA intends to ask OMB to revise its ICR approval, identified under OMB Control No. 1218–0072, to capture the information collection activities and burden adjustments, if any, related to EPA's guidance.

(c) Definitions. This paragraph in the HCS includes the terminology used with the corresponding definitions. Comprehension of the appropriate definitions is critical to understanding the provisions of the standard. In some cases, terms are defined somewhat differently than when used in other contexts, so familiarity with the standard's definitions is important.

In the proposed revisions, OSHA retained as many definitions as possible from the current HCS. Changes were proposed only when there was a new term used that needed to be defined, or there is a different definition in the GHS, and consistency with the international definition was needed for harmonization purposes. As with the preceding paragraphs, minor modifications were proposed to ensure terminology is appropriate—primarily the use of terms related to classification and safety data sheets. These modifications were retained in the final rule. There were relatively few comments submitted on the proposed revisions to the definitions, other than those referring to the new definition OSHA proposed to address ''unclassified hazards'' and the definition for ''pictogram'' that references a red border frame.

One important difference between the HCS and GHS in terminology involves the use of the term ''chemical.'' The HCS has used this term since it was originally promulgated, and defines it to include elements, chemical compounds, and mixtures of elements and/or compounds. It has been a convenient way to describe the coverage of the rule. The GHS, like some other international standards, uses the terms ''substance'' and ''mixture''. OSHA has decided to retain a definition of ''chemical'' in the revised standard, which minimizes the number of terminology changes that have to be made to the regulatory text, as well as providing a shorthand way to define the scope to include both individual substances and mixtures of substances. This term is used in the body of the regulatory text of the final standard, similar to its use in the current HCS. However, the modifications also include definitions for ''substance'' as well as ''mixture'' to align with the GHS, and both of these terms are used as well. In particular, in the appendixes that are adopting GHS language, the separate terms ''substance'' and ''mixture'' are used consistent with the GHS.

''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.'' Dow Chemical (Document ID #0353) objected to this definition, and suggested that it should be ''chemical elements and compounds in their natural state or obtained by any production process.'' OSHA has concluded that it is appropriate to maintain the GHS language for this definition to help to ensure consistent application, and thus the revised rule includes the definition of substance that was proposed.

A ''mixture'' is defined as a ''combination or a solution composed of two or more substances in which they do not react.'' This is consistent with the GHS definition—and while slightly different than the definition in the current HCS, means the same thing. Dow Chemical (Document ID #0353) suggested that OSHA maintain part of its current definition in order to avoid inadvertently changing the scope of coverage by adding ''if the combination is not, in whole or in part, the result of a chemical reaction.'' OSHA does not believe that the scope is changed by the GHS definition, and has retained the GHS-consistent language that was proposed.

OSHA also proposed to maintain the term ''hazardous chemical'' in this revised standard as used in the current standard (a chemical which is a physical or health hazard), except to add the term ''classified'' to indicate how it is determined that it is a physical or health hazard. OSHA also proposed to include unclassified hazards in this definition, but, as will be described below, has chosen a different approach in the final rule. Instead, the definition of ''hazardous chemical'' in this final rule is ''any chemical which is classified as a physical hazard or a health hazard, a simple asphyxiant, combustible dust, pyrophoric gas, or hazard not otherwise classified.'' The term is used throughout the standard to indicate that the classification process is completed, and the chemical manufacturer has determined that the chemical poses a hazard. Most of the substantive requirements of the rule apply to hazardous chemicals.

Dow Chemical (Document ID #0353) indicated that OSHA should drop the use of the word ''substance'' altogether, and instead use the word ''chemical.'' As noted in the definition of ''chemical,'' however, it is to be used when a reference is to both substances and mixtures. Where a provision or statement refers only to a substance, or only to a mixture, those terms are used in lieu of ''chemical'' or ''hazardous chemical.'' These individual designations are used most commonly in the appendixes, particularly in the classification criteria. OSHA has maintained consistency in the criteria with the GHS insofar as is possible with regard to this terminology.

Another proposed modification to the definitions paragraph was to move the specific physical hazard definitions to an appendix. In the current HCS, health hazard definitions are addressed specifically in Appendix A, but the physical hazard definitions were included in paragraph (c). In the final standard, health hazard definitions continue to be addressed in Appendix A, but a new Appendix B addresses physical hazards. Both of these appendixes are discussed below under the summary and explanation of paragraph (d) ''Hazard Classification.''

As noted in Section III above, the physical hazard definitions in the GHS are drawn from the United Nations' Recommendations on the Transport of Dangerous Goods. Since DOT has already adopted this international approach, the GHS definitions are substantially harmonized with the U.S. requirements for labeling of dangerous goods in transport. All chemicals that are shipped in the U.S. have already been classified according to DOT's physical hazard definitions. This will reduce the burdens associated with classifying physical hazards under the revised HCS. The primary differences involve exceptions that make the definitions more applicable to workplace situations (for example, coverage of flammable liquids that are currently defined as combustible under the HCS). Modifying the HCS to align with the GHS thus serves the purpose of harmonizing many of these definitions domestically, and results in shippers only having to classify their chemicals once for most physical hazards.

OSHA also has updated the definition of the term ''classification'' to reflect the additional hazards in this final rule (simple asphyxiant, combustible dust, and pyrophoric gas). The definition for classification will now read: ''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 include the determination of the degree of hazard, where appropriate, by comparing the data with the criteria for health and physical hazards,'' Dow Chemical (Document ID #0353) suggested that the language be changed to read ''for health hazards and for physical hazards.'' OSHA does not find this to be a necessary revision, and has adopted the definition as proposed. This definition is 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. This reflects the GHS approach of having categories for each class of hazard. Under the current HCS, there are some definitions that have categories in a hazard class (*e.g.,* acute toxicity, flammability), but other definitions are simply one category (*e.g.,* carcinogenicity). The additional breakdown in the GHS of classes into categories that reflect different severities or levels of effect will provide both employers and employees with more precise information to understand the hazards, to consider when evaluating workplace conditions to determine the risks in the workplace, and to respond to exposure incidents.

OSHA has also retained in the final rule the proposed definitions for ''hazard class'' and ''hazard category'' to further explain the approach of breaking down the hazardous effects into levels of severity. A ''hazard class'' is defined as ''the nature of the physical or health hazards, *e.g.,* flammable solid, carcinogen, oral acute toxicity.'' The definition of ''hazard category'' is ''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 generally.'' Both of these definitions are taken from the GHS. Dow Chemical (Document ID #0353) suggested that the last sentence of the definition of ''hazard category'' should be deleted or moved to Appendix A because it is ''non-definitional information.'' Given that it is included in the GHS definition, OSHA has adopted it in the final standard.

OSHA has retained the proposed definition of ''health hazard'' to reflect the specific hazards defined in the GHS. While the overall scope of what is covered is essentially the same as the current HCS, the hazards may be identified slightly differently. For example, the current HCS covers reproductive toxicity as a target organ effect, and includes all aspects of the effect under that hazard. The GHS has a separate definition for germ cell mutagenicity, which is considered part of reproductive toxicity in the current HCS. The definition of ''health hazard'' was thus proposed to be ''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.''

Both the American Chemistry Council (ACC) (Document ID #0393) and Dow Chemical (Document ID #0353) suggested that OSHA modify the phrase ''any route of exposure,'' which refers to ''acute toxicity.'' ACC suggested it list the three specific routes of exposure in the criteria, and Dow suggested that it include ''relevant'' to modify routes of exposures. OSHA does not believe either of these changes is necessary. The definition already uses the term ''classified'' to refer to each of the health hazards listed, and the acute toxicity criteria include three routes of exposure for classification. Dow further suggested that ''serious eye damage'' be modified to say ''by chemical action.'' Again, the classification process is for chemicals, and the definition already indicates that it is covered as a health hazard when classified. Similarly, Dow suggested that ''aspiration hazard'' be modified to say ''aspiration toxicity hazard.'' The proposed language is consistent with the GHS, and OSHA is maintaining it for harmonization purposes in the final standard.

A revised definition of ''physical hazard'' was proposed to reflect the physical hazards covered in the GHS. While these are similar to the coverage of the HCS, they are in some cases described differently. The definition proposed for ''physical hazard'' is ''a chemical that is classified as posing one of the following hazardous effects: Explosive; flammable (gases, aerosols, liquids, or solids); oxidizer (liquid, solid or gas); self-reactive; pyrophoric (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; or in contact with water, emits flammable gas. *See* Appendix B to § 1910.1200—Physical Hazard Criteria.'' This definition has been adopted in the final standard with one change. OSHA did not include pyrophoric gas in the definition in the proposal. There is no definition for pyrophoric gas in the GHS, which is covered under the current HCS, and OSHA inadvertently left it out in the proposed standard when the generic definition for pyrophorics was removed. This omission was pointed out by commenters (*e.g.,* Document ID #0382 and 0530). OSHA is therefore returning the pyrophoric gas definition from the current rule to paragraph (c), and making it specific to just gases since the current rule covers all physical states. Thus, pyrophoric gas is defined 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.'' Label elements are provided in C.4.30. The signal word will be danger; the pictogram is the flame; and the hazard statement is ''Catches fire spontaneously if exposed to air.''

Procter & Gamble (Document ID #0381) noted that the definition for ''flashpoint'' was missing from the NPRM and suggested that it should be put back into the rule. However, the meaning of the term ''flashpoint'' is already addressed in the criteria for ''flammable liquid'' in Appendix B by specifying the test methods to determine it. OSHA has also included a definition for flashpoint in the criteria chapter, rather than in the definitions paragraph.

The definition of ''label'' in the GHS is slightly different than what is currently in the HCS, and OSHA proposed to modify the HCS to be consistent with the GHS. The proposed definition of ''label,'' which has been retained in the final rule, is ''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.'' The GHS label is more specific than what is required in the current HCS, and includes certain core information that must be presented. Thus, a definition for ''label elements'' was also proposed and adopted in the final rule as ''the specified pictogram, hazard statement, signal word, and precautionary statement for each hazard class and category.'' ACC (Document ID #0393) noted that this definition is different from what is in the GHS. OSHA modified the definition by making it plural to reflect the way it is used in this section to refer to the OSHA-required label elements for each GHS label. The GHS definition in this case defines the singular term ''label element'' as ''one type of information that has been harmonized for use in a label, *e.g.,* pictogram, signal word.'' OSHA has listed all of the label elements, including precautionary statements since they are mandatory under the revised rule. OSHA believes its definition is consistent with the GHS but more appropriate for the revised rule, and has adopted it in this final standard.

''Safety data sheet (SDS)'' is defined in both the NPRM and the final rule as ''written or printed material concerning a hazardous chemical which is prepared in accordance with paragraph (g) of this section.''

Definitions for terms that describe information required to be provided on labels were also proposed to be added to the HCS and are included in the final rule. These terms include ''hazard statement,'' ''pictogram,'' ''precautionary statement,'' ''product identifier,'' and ''signal word.'' These new definitions will help to clarify the specific requirements for labels under the revised HCS, and are consistent with similar definitions in the GHS.

''Hazard statement'' is ''a statement assigned to a hazard class and category that describes the nature of the hazards of a chemical, including, where appropriate, the degree of hazard.'' This is essentially what is defined as a hazard warning under the current rule. An example of a hazard statement under the GHS is: ''Causes serious eye damage.'' These statements have been codified, meaning that numbers have been assigned to them. They are available in all of the official languages of the United Nations, and thus translation will not be a problem when shipping to countries using those languages. Having standardized statements is expected to facilitate translation into other languages as well. The definition for ''hazard statement'' is being adopted as proposed.

There were a few comments about specific hazard statements, such as an objection from the National Propane Gas Association (Document ID #0400) indicating the statement for flammable gas is ambiguous, and lacks substantiation and scientific credence. They object to labeling propane as ''extremely flammable,'' which is the required statement for Category 1 for flammability hazards. This objection was also raised in a comment to the ANPR (Document ID #0068). OSHA responded in the NPRM that it would not be making chemical-specific changes to hazard statements (74 FR 50399, Sept. 30, 2009). The point of having harmonized statements is that all chemicals with the same degree of hazard have the same statement. OSHA also indicated that some in the industry already use the ''extremely flammable'' terminology. NPGA responded that not everyone is familiar with it, or uses it. That is why OSHA is establishing a standardized approach, so everyone in an industry with a common product like propane uses the same language to convey the hazard. This consistency will help people understand what the hazards are, and simplify the process of conveying them since everyone will use the same approach. As noted previously, examples of where the hazard statement ''extremely flammable'' are currently being used for propane are readily found (*e.g.,* Document ID #0554). Therefore, OSHA does not agree with NPGA that the hazard statement is inappropriate or should be modified.

A few commenters suggested that where hazard statements include two hazards, separating them should be permitted when data indicate that only one is applicable to the product involved (for example, it causes infertility but not developmental hazards) (Document ID #0344, 0376, 0377, 0381, 0382, and 0393). OSHA agrees that such separation should be permitted. The following provision has been added to Appendix 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.''

Additionally, OSHA permits chemical manufacturers and importers to combine hazard statements where the information is related and the combination can shorten the text required on the label. Appendix C.2.2.1 states: ''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.'' OSHA also allows additional hazard statements under supplementary information, as long as they are accurate and do not conflict with the required statements. ''Pictogram'' is defined as 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.'' This definition covers both pictograms in the transport sector, and those in other sectors covered by the GHS. The pictograms are required as part of the core information provided on a label to describe the hazards of a chemical. ACC (Document ID #0393) and Procter & Gamble (Document ID #0381) noted that the proposed definition of pictogram, which was retained in the final rule, is slightly different than what is in the GHS: ''a graphical 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.'' OSHA added ''about the hazards of a chemical'' because that is the only type of information that will be conveyed by the pictograms in the HCS. The definition is being adopted as proposed.

The workplace pictograms proposed were a black symbol on a white background with a red diamond border frame. Some ANPR commenters noted that the frame should be permitted to be black for domestic shipments as allowed under the GHS (*See, e.g.,* Document ID #0032 and 0163). However, as described in Section IV of the proposed preamble, there are clear safety and health benefits associated with the use of the red frame in terms of recognition and comprehensibility. Thus OSHA proposed to allow only the red frame to be used, whether the shipment is domestic or international.

Many of the rulemaking participants recognized the communication benefits of the red border, and supported the proposed requirement for a red border frame for all shipments (*See, e.g.,* Document ID #0313, 0324, 0330, 0335, 0336, 0339, 0341, 0365, 0383, 0408, 0410, 0412, and 0456). For example, Product Safety Solutions (Document ID #0313) stated:

> OSHA requests comment on whether pictogram borders should be required to be in red or should be allowed to be printed in black. While the use of a red border may increase the cost of printing some labels, the use of color to draw attention to a potential hazard is a useful tool and is likely to enhance the communication of safety information. As products may also be exported to other countries, the use of the red border would be consistent with the establishment of a globally recognized hazard symbol. Imported products likewise, would have to contain the red symbol border and this would have to be made abundantly clear to Customs Agents and others responsible for monitoring the importation of chemical products.

However, others argued that black frames should be permitted on domestic shipments, and that the use of red borders is too costly and burdensome in terms of printing costs in particular (*See, e.g.,* Document ID #0328, 0338, 0344, 0352, 0370, 0376, 0389, 0399, 0405, and 0411). For example, ISSA (Document ID #0399) claims:

If OSHA were to require only the red frame for pictograms, it would require those formulators that presently print single color labels to utilize different systems for producing labels of this nature, requiring a substantial capital investment which in turn will add greatly to the cost of transitioning to the revised HCS. OSHA must keep in mind, that small and medium sized formulators handle hundreds of products, each of which in turn are sold under multiple private labels. Thus a change in color requirements for labels generally will literally require a formulator to revise hundreds, if not thousands, of individual labels.

Further, we believe the use of a black frame will not present a threat to worker health and safety. ISSA disagrees with OSHA's conclusion that a red frame would significantly enhance the communicative value of the label. In citing studies, OSHA does not take into account that the use of the new labels will be the subject of intensive employee training that will more than mitigate the use of a black frame over a red frame.

In the NPRM regulatory analyses, OSHA did not assess the specific costs associated with red versus black borders, but has done so in the analyses for the final rule. *See* Section VI. As noted by proponents of the black border option for domestic shipments, the costs of a red border are greater. However, OSHA's analysis shows that they are economically feasible. In addition, OSHA believes that it is likely additional, cheaper printing options will be developed to comply with this requirement in the final rule. The EU requires red frames for pictograms: ''Hazard pictograms shall be in the shape of a square set at a point. They shall have a black symbol on a white background with a red frame sufficiently wide to be clearly visible.'' (*http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/chemical_products/ev0013_en.htm*) Application of this requirement in the twenty-seven (27) EU member states is expected to lead to new printing options for compliance.

OSHA believes that the increased comprehension that will be provided by the red border frame is compelling. The red color will clearly delineate the hazard symbols from the other information on the label, and the prominence will lead to increased attention and recognition of the hazards. The transport labels and placards that have been in use for many years have multiple colors in their pictograms, and yet compliance has been achieved. Plus most product labels have various colors related to their logos, brands, etc., so clearly it can be done.

There are also some logistical issues that would make compliance more difficult with two different colored frames. First, it is unlikely that it would always be known whether a product would be exported at the point of labeling it at the end of the manufacturing process. Many containers are simply shipped to distributors, and the original manufacturer does not know where they will be sent after that—thus raising the question of whether a manufacturer or importer would know when to apply a black versus a red frame. In addition, workers exposed to chemicals purchased from different sources might have different frames, requiring additional training to avoid potential confusion. The final rule remains as proposed, and requires pictograms to have a red frame, with a black symbol on a white background, for all shipped chemicals regardless of destination.

Several commenters (Document ID #0318, 0382, and 0393) also raised issues regarding whether pre-printed labels with blank red frames could be used. The manufacturer would simply add the symbols to the frames when printing the required label information. If a manufacturer or importer took this approach, a particular label might have one or more empty red diamonds in addition to any required pictograms. OSHA does not believe that this would be appropriate. Blank frames would still attract attention, but workers could be confused about what they mean and whether something is missing from the information. While blank frames could be marked to indicate they are intentionally left blank, they will still contribute to clutter on the label and distract from the primary messages (*See, e.g.,* Document ID #0284). Blank frames are not considered acceptable by DOT. (*See* 49 CFR 172.401, Prohibited labeling; PHMSA Interpretation 02–0088). OSHA does not believe this is a good alternative for compliance either, and the final rule prohibits blank frames on the label (Appendix C.2.3.1).

Under the GHS, a symbol is generally assigned to each hazard class and category. There are nine agreed symbols under the GHS to convey the health, physical and environmental hazards. Eight of these symbols were proposed for adoption in this rulemaking, the exception being the environmental symbol. Six of these symbols have been used for many years in the international transport requirements, so some employers and employees will already be familiar with them.

The symbols in the proposed rule are adopted in the final rule. Dow Chemical (Document ID #0353) noted that the pictograms are not entirely self-evident. While this may be true, the rule requires training workers so they will know what the symbols mean and how to respond.

It should be noted that in the NPRM, the pictogram for C.4.17 (oxidizing gases) was published with a ''flame'' symbol, rather than the ''flame over circle'' symbol that was appropriate, and was described. OSHA has corrected this error in the final rule, and has inserted the appropriate ''flame over circle'' symbol in Appendix C.4.17 for oxidizing gases.

The ''precautionary statement'' is ''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.'' The precautionary statements specified in Appendix C will be required on containers under the final rule. An example of a precautionary statement is: ''Wear protective gloves.'' The precautionary statements in the GHS are assigned to certain hazard classes and categories.

Precautionary statements are not required under the current HCS, although many chemical manufacturers include them on their labels for safe handling and use. These statements are codified under the GHS, meaning that numbers have been assigned to them. The precautionary statements in the GHS are not harmonized like the hazard statements are, and the regulatory authority is free to use the statements in the GHS annex or to use alternative statements when adopting the current version of the GHS. Using the GHS statements has the advantage of adopting statements that have undergone expert review by the UN Sub-committee, are assigned to the appropriate hazard class and category, and have been translated into six languages. Work continues on them in the Sub-committee to combine or edit the precautionary statements to reduce repetition and the complexity of the label. The precautionary statements may be considered harmonized in the future.

Other countries are already using them (*e.g.,* in Europe). Since OSHA did not previously require the use of precautionary statements, and had no such recommended statements to provide, the Agency decided to use those in the GHS as the mandatory requirements. This will make it easier for compliance since chemical manufacturers and importers will not need to develop, maintain, and translate precautionary statements on their own. It will also help employees since they will be seeing the same language on labels regardless of the supplier of the chemical. Such standardization improves comprehension, and thus the effectiveness of the information transmitted under the standard.

While the definition of precautionary statement itself did not seem to raise questions with rulemaking participants, there were a number of comments on the proposal to make the GHS precautionary statements mandatory. Many commenters agreed with OSHA that the statements should be on the label, and should be mandatory (Document ID #0328, 0329, 0335, 0336, 0347, 0352, 0365, 0370, 0372, 0377, 0379, 0389, 0402, 0408, 0410, 0412, and 0456). Commenters mentioned increased comprehensibility, as well as available translations, as some of the reasons why they support this approach. It was also noted by a number of commenters that OSHA should permit additional precautionary statements to cover situations without an available statement in Appendix C (Document ID #0313, 0324, 0327, 0329, 0335, 0352, 0365, 0370, 0376, and 0402). Others supported making them mandatory when they are harmonized in the GHS (Document ID #0351 and 0405). And at least one participant argued that precautionary statements should not appear on labels, just SDSs (Document ID #0338).

Other commenters did not support the mandatory approach, and thought that manufacturers should be able to continue to use their own precautionary statements (Document ID #0321, 0330, 0344, 0353, 0363, 0376, 0381, 0382, 0393, and 0399). It was also suggested that the UN needs to provide further guidance on when precautionary statements can be combined or omitted (Document ID #0328, 0370, and 0376), or that the number of phrases appearing on a label should be limited (Document ID #0329 and 0405).

In the final standard, OSHA has maintained the proposed provision to require the precautionary statements in the GHS to be used on labels. As noted previously, the use of prescribed precautionary statements is consistent with the other label elements, and provides the significant benefits of improved communication of information through increased comprehensibility and familiarity. In terms of flexibility, chemical manufacturers and importers are free to put additional precautionary statements on the label from other sources in the supplementary information area. As long as the information provided is accurate, and does not conflict with the required information, this is permitted.

OSHA will also permit the statements to be combined as appropriate, and states in Appendix 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.''

In addition, where there are concerns, supported by evidence, about the applicability of a statement to a particular product, the chemical manufacturer or importer may revise the statements as appropriate for the situation. Appendix C.2.4.8 states: ''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.''

Thus, the final rule adopts the precautionary statements, which are taken from the GHS. However, it allows the use of additional statements where necessary, as long as they are accurate, do not conflict, and are placed in supplementary information. Additionally, chemical manufacturers and importers can use their judgment to combine related statements to shorten the amount of information on a label, as well as omit any statements that can be demonstrated to be inapplicable to the particular chemical involved. OSHA believes this approach maximizes the comprehensibility of the precautionary statements, as well as simplifies compliance for employers. Nevertheless, there are allowances for unique situations, and thus assurances that the information will be accurate.

It was suggested that the precautionary statements should be written in plain language (Document ID #0321). There were some specific changes to particular statements that were suggested (such as a statement regarding fighting fires near explosives, Document ID #0353). OSHA is not going to modify any of the statements as published in the GHS in terms of technical information. These have been reviewed by many experts. Changes should only be made to them through the UN Sub-committee process at this point, as they are close to being harmonized.

However, OSHA has made a few minor changes to precautionary statements in this final rule to address clarity and related issues. These changes were adopted by the Sub-committee of Experts on the GHS at its December 2010 meeting, and are expected to be included in Revision 4 of the GHS. Most changes simply amend the precautionary statement to clarify its meaning by making the statement more concise, or stating it in plain language. Others either provide added flexibility in applying the precautionary statement, or provide instructions for the classifier on the conditions relating to use of the precautionary statement. Examples of each type are presented below.

Examples of precautionary statements for physical hazards that were clarified in the final rule are presented below:

Precautionary statement in proposed rule	Precautionary statement in final rule
Keep away from any possible contact with water.	Do not allow contact with water.
In case of fire: Use * * * for extinction.	In case of fire: Use * * * to extinguish.

An example of a precautionary statement providing instructions for the classifier on the conditions relating to use of the precautionary statement is provided below for the health hazard class Skin corrosion/irritation, Category 1A to 1C (for the illustration, the instructions for use are provided in italics). In this example, note that the precautionary statement was clarified and the conditions relating to use of the precautionary statement were added.

Precautionary statement in proposed rule	Precautionary statement in final rule
Immediately call a poison center/or doctor/physician.	Immediately call a poison center/ doctor/ * * * *Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.*

The final example of the precautionary statement changes is provided below for instructions for the classifier on the conditions relating to use of the precautionary statement. In certain situations, text in a precautionary statement may not be appropriate. To address this issue, a new paragraph C.2.4.5 has been added to explain the use of text provided in square brackets ([ ]). Paragraph C.2.4.5 states: ''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.''

OSHA has included these non-substantive, minor changes approved by the UN Sub-committee, because they make the statements more readable, allow added flexibility, and are consistent with the latest version of the GHS.

Container labels will also be required to include a ''product identifier.'' The proposed definition for this term, which was retained in the final rule with a clarifying change (discussed below), was ''the name or number used for a hazardous chemical on a label and 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 required list of hazardous chemicals, the label, and the SDS.'' In other words, the product identifier is essentially the same as the ''identity'' under the current HCS. The GHS allows competent authorities for workplace requirements to choose not to require specific chemical identities of ingredients to be listed on the label, as long as they are on the SDS. This is the approach OSHA currently uses in the HCS, and it has been effective. OSHA will continue to require chemical identities only on SDSs, and has proposed a definition for ''product identifier'' that is consistent with the current definition for ''identity'' (which has been deleted from the final rule) to maintain this approach. ACC (Document ID #0393) and Procter & Gamble (Document ID #0381) suggested that OSHA should clarify what the ''required list of hazardous chemicals'' refers to in the definition. This terminology has been in the HCS since the original standard was published in 1983, and refers to the only list of chemicals required by the HCS, which is in the written hazard communication program. Therefore, OSHA has modified the language in the final rule to read: ''among the list of hazardous chemicals required in the written hazard communication program, the label and the SDS.''

Another new concept in the NPRM for HCS labels is inclusion of a ''signal word'' to bring attention to the hazardous effects, as well as to contribute to the recognition of the severity of the hazard. Signal words have been used for many years in the United States on consumer and pesticide labels. The proposed definition is ''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.'' OSHA received no objections to the proposed definition of ''signal word'' and it is being carried through to the final rule.

OSHA proposed to add a definition to the HCS for ''unclassified'' hazards. As has been noted, the current HCS is performance-oriented, and takes a very broad approach to defining hazards covered by the rule. The GHS is similarly broad in approach, but includes very specific definitions of criteria to apply when determining whether a chemical poses a physical or health hazard. This specification approach has significant benefits associated with it, including providing more guidance to help ensure a consistent approach to determining hazards. It also allows more information to be developed that provides an indication of the severity of effect.

OSHA proposed to add a definition to the HCS for ''unclassified'' hazards. As has been noted, the current HCS is performance-oriented, and takes a very broad approach to defining hazards covered by the rule. The GHS is similarly broad in approach, but includes very specific definitions of criteria to apply when determining whether a chemical poses a physical or health hazard. This specification approach has significant benefits associated with it, including providing more guidance to help ensure a consistent approach to determining hazards. It also allows more information to be developed that provides an indication of the severity of effect.

In the ANPR, OSHA asked for comment on whether the GHS criteria are sufficient to cover the hazards present in the workplace. While the Agency believed the scope of coverage is similar between the two approaches, OSHA wanted to be sure that the new approach is as comprehensive as the existing standard. In the NPRM (74 FR 50390, Sept. 30, 2009), OSHA noted two hazards of concern—combustible dust and simple asphyxiants. Both of these are mentioned in the GHS in the SDS annex as examples of hazards not classified that should be addressed on the SDS.

It is possible that there are other hazards that may not yet be specifically defined. Rulemaking participants have mentioned several (*e.g.,* static accumulators) (Document ID #0382 and 0402). The addition of the definition for unclassified hazards was intended to address these situations. Where a classifier has identified evidence of a hazard, but the evidence does not meet the currently specified criteria for hazards covered by the rule, the definition for unclassified hazards captures those effects to ensure that the final rule is appropriately protective, and covers all of the hazards covered by the current rule. During the negotiations for the GHS, U.S. industry representatives often raised the issue of ensuring that they could provide additional hazard information in order to satisfy product liability laws in the U.S. This was the rationale for allowing such information to be included on labels under supplementary information, and on SDSs under Section 2. OSHA believed that addition of the proposed definition of ''unclassified hazards,'' and specific recognition of the need to provide information when such effects arise, would help U.S. industry address its product liability concerns as well as protect exposed workers (74 FR 50390, Sept. 30, 2009).

OSHA proposed to require the chemicals posing unclassified hazards to be treated as hazardous chemicals under the rule. The Agency anticipated that this information would appear in Section 2 of the SDS (Hazard Identification)—the GHS already identifies this as the appropriate place in its guidance on the contents of SDSs (A4.3.2.3, *Other hazards which do not result in classification*), and proposed Appendix D included the requirement to list unclassified hazards. In terms of labeling, there are no specified label elements in the GHS for chemicals that pose unclassified hazards. OSHA proposed to require that the label for such hazards must name the chemical, and describe the hazardous effects under supplementary information on the label, as well as provide any appropriate precautionary information. OSHA also expected that such hazards would be addressed in worker training programs.

It is important to understand that the Agency anticipated that there would be relatively few situations where there would be scientific evidence or data indicating an effect that is not currently classified, and merely wanted to ensure that this information is captured and conveyed to employers and employees. OSHA also indicated that it would be appropriate to establish a feedback mechanism, where classifiers could inform OSHA of situations where the current criteria are insufficient, and the Agency can then suggest to the United Nations that appropriate criteria be developed and added to the GHS. This is consistent with the overall approach to hazard classification in the GHS that OSHA proposed to adopt—that specific criteria be provided to help ensure that classification is appropriate, and information transmittal is consistent from company to company. Therefore, the use of the definition of unclassified hazard was to be a temporary situation for these hazards, ensuring information is provided until such time as the criteria are added to the rule.

There were many comments received regarding the NPRM definition and concept of ''unclassified hazards.'' A number of participants agreed with OSHA that there is a need to cover some hazardous effects that have not yet been spelled out in the GHS with criteria (Document ID #0313, 0327, 0347, 0363, 0365, 0366, 0367, 0410, and 0412). Others suggested that it was an appropriate interim step, while working with the UN to get criteria added to the GHS (Document ID #0329, 0330, 0335, 0339, 0352, 0370, 0376, 0383, 0405, and 0414). Some argued that these hazardous effects should have specific criteria so employers would know with certainty what is covered (Document ID #0327, 0361, 0366, 0377, and 0392).

With regard to the actual definition, some thought it was too broad and ambiguous (Document ID #0344, 0379, 0381, and 0399). The U.S. Chamber of Commerce (Document ID #0397) argued that the definition should be withdrawn, or substantially revised, and that OSHA was exceeding its authority. There were other commenters who thought the effects should be called ''hazards not otherwise classified'' or ''additional hazards'' rather than ''unclassified hazards.'' *See, e.g.,* Document ID #0328, 0344, 0363, 0370, 0376, 0393, and 0405. It was also suggested that the approach should only cover those hazards currently covered by the HCS (Document ID #0338).

OSHA has considered all of these comments, and the need to provide sufficient protection for exposed employees, in devising an approach for the final rule. First, OSHA agrees with commenters that using the term ''hazards not otherwise classified'' is a better designation. Secondly, OSHA has revised the language to clarify the intent and address what was perceived as ambiguity. The definition in the final rule, which replaces and amends the proposed definition of ''unclassified hazard,'' now reads: '''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 or 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).''

Additionally, and importantly, OSHA has deleted proposed paragraph (f)(2), which specified information to include on labels for the HNOC chemicals. Given that there are no harmonized label elements available for these effects, it appears that this could be confusing to both the label preparers and the users of the chemicals. However, provision of an SDS for HNOC chemicals is required under the final rule, and information regarding their hazards is to be included in Section 2.

The U.S. Chamber of Commerce objected to the inclusion of ''unclassified hazards'' in the final rule because, in its view, the proposed definition is ''broad,'' ''expansive,'' and will ''impose new requirements on employers without undertaking all of the steps in a full OSHA rulemaking'' (Document ID #0397). OSHA appreciates the concerns and has carefully considered (and in some respects revised) the provision with those concerns in mind. OSHA does not intend to impose new requirements, or to bypass rulemaking, but includes the definition to continue the longstanding requirements that such hazards be disclosed. As finalized and clarified, the relevant provision does not expand on those requirements or add new burdens; on the contrary, it preserves requirements in the current rule. The following discussion is designed to clarify these points.

As noted above, the final rule retains the proposed requirement, using the term ''hazard not otherwise classified'' (HNOC) instead of unclassified hazard. In essence, this definition requires classifiers who find ''scientific evidence'' that a chemical can cause death, illness, or injury to workers in a way not currently covered by the GHS classification criteria to disclose that fact on the SDS. This is meant to be a modest and narrow requirement. It is triggered only when the classifier has objective, scientific evidence of the hazard. OSHA believes that there are likely to be few such hazards outside those covered by the specific criteria in the final rule, which are the product of over thirty years of international experience in hazard communication.

It is important to understand that the HNOC definition essentially preserves (and does not expand) the scope of the current rule, which is not as tightly bound to specific criteria as the GHS. The HNOC definition should be interpreted and understood with this preservative goal in mind. For example, under the current rule, ''health hazard'' means a chemical for which there is at least one statistically significant scientific study showing that ''acute or chronic health effects may occur to exposed employees.'' Indeed, while mandatory Appendix A of the current standard lists criteria for specific health effects, it also notes that these criteria are not intended to be an exclusive categorization scheme, but rather any available scientific data on the chemical must be evaluated to determine whether the chemical presents a health hazard. Likewise, though the current definition of physical hazard is tied to a specific list of effects, some of these can also be quite broad. For example, under the current rule, ''flammable solid'' includes a material ''which can be ignited readily and when ignited burns so vigorously and persistently as to create serious hazard.''

The essential point is that the HNOC definition is designed so as to prevent the final rule from being less protective than the current standard by picking up any hazards that might fall within the definitions of the current rule, but might fall outside the GHS hazard classes. As discussed above, it is OSHA's intent that the HNOC classification would be an interim measure, used until harmonized criteria for a hazard can be adopted at the UN Sub-committee level, and subsequently incorporated into the HCS through rulemaking.

If the provision is understood in light of the foregoing points, this rulemaking is all the OSH Act and the Administrative Procedures Act (APA) requires of OSHA before adopting the HNOC requirement. By preserving the requirements equivalent to those in the current rule, all the final rule does is to require chemical manufacturers and importers with reliable information that exposure to their chemical can cause illness, injury or death to an employee to disclose that fact on an SDS. OSHA has the authority to regulate hazard communication on a general level; indeed it must if it is to provide comprehensive worker protection in this area. *See National Ass'n of Manuf.* v. *OSHA,* 485 F.3d 1201, 1204 (D.C. Cir. 2007); *Associated Bldrs & Contrs. Inc.* v. *Brock,* 862 F.2d 63, 68 (3d Cir. 1988). Stakeholders have had a chance to comment on the HNOC requirement, and this rulemaking proceeding satisfies OSHA's statutory obligations.

With regard to the three hazards specifically mentioned during the rulemaking (pyrophoric gases, simply asphyxiants, and combustible dust), OSHA is handling them as follows in the final rule.

OSHA inadvertently removed the definition of pyrophoric gases from the proposal when it removed the generic definition for pyrophorics. The American Chemistry Council (ACC) correctly pointed out that excluding the pyrophoric gases, even though there is no corresponding definition in GHS, would mean that they would not be labeled or classified appropriately (Document ID #0393). OSHA agrees and has included the definition of pyrophoric gas in the current HCS in this final rule. Pyrophoric gases must therefore be addressed both on container labels and SDSs, and in worker training programs. Therefore, OSHA has retained the definition for pyrophoric gases from the current HCS and has added pyrophoric gases to the definition of ''hazardous chemical''. Label elements are provided in C.4.30. The signal word will be danger; the pictogram is the flame; and the hazard statement is ''Catches fire spontaneously if exposed to air.''

For the two examples of effects not addressed in the GHS that were raised in the proposal (simple asphyxiants and combustible dust), OSHA is addressing them specifically in the final rule rather than covering them under the HNOC definition. Using comments in the record, and commonly applied voluntary industry consensus standards, the Agency has designated chemicals with these properties under the definition of ''hazardous chemical.'' The chemicals posing such effects must therefore be both labeled where appropriate, and addressed on SDSs and in training. In addition, OSHA has added C.4.30 to Appendix C to provide the label elements for OSHA defined hazards.

With regard to simple asphyxiants, OSHA had indicated in Issue #8 (74 FR 50282, Sept. 30, 2009) that it believed it might be more appropriate to simply add a definition of this effect to the final rule rather than covering it under the ''unclassified hazard'' approach. A definition was proposed as follows:

> ''Simple asphyxiants'' are substances that displace oxygen in the ambient atmosphere, and can thus cause oxygen deprivation in exposed workers that leads to unconsciousness and death. They are of particular concern in confined spaces. Examples of asphyxiants include: nitrogen, helium, argon, propane, neon, carbon dioxide, and methane.

OSHA also solicited comments on proposed specific label elements. No symbol would be required, but the signal word ''warning'' would be used, with the hazard statement ''may be harmful if inhaled.'' In addition, a precautionary statement such as the following would be required: ''May displace oxygen in breathing air and lead to suffocation and death, particularly in confined spaces.''

A number of commenters agreed with the definition and the approach (Document ID #0339, 0347, 0351, 0365, 0366, 0370, 0405, 0408, and 0456). Others had specific comments on what was proposed, such as arguing for simplification of the language (Document ID #0414); proposing to replace the definition with the NFPA 704 definition of ''simple asphyxiant'' (Document ID #0330); suggesting a reference to ''suffocation'' (Document ID #0329 and 0335), or indicating that the hazard statement is really a precautionary measure, or vice versa (Document ID #0376, 0382, 0393, and 0405). Procter & Gamble suggested it should not be covered since it is not an inherent toxicity (Document ID #0381).

OSHA disagrees with Procter & Gamble's argument. Chemicals with certain properties can displace oxygen and cause asphyxiation. Not every chemical has those properties, so the asphyxiation hazard is inherent and chemical-dependent. Moreover, OSHA has provided longstanding interpretations that indicate simple asphyxiants are covered under the current HCS (*e.g.,* OSHA interpretation, March 4, 1993) and therefore industries working with these substances have provided labels and SDSs on simple asphyxiants in accordance with HCS requirements.

OSHA believes that coverage of simple asphyxiants is very important to the HCS. Such substances result in fatalities in the workplace, particularly in confined spaces, and need to be warned about effectively. The definition has been revised based on the comments received, and included in paragraph (c): '' '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.'' Label elements are provided for simple asphyxiants in Appendix C.4.30. Simple asphyxiants will require the signal word ''warning'' and the hazard statement ''may displace oxygen and cause rapid suffocation.'' In addition, OSHA has added ''simple asphyxiant'' to the definition of ''hazardous chemical.'' Thus all of the provisions of the rule that apply to hazardous chemicals will apply to simple asphyxiants as well.

OSHA will continue to work with the UN to add this hazard to the GHS. (The U.S. has raised this issue in the UN Sub-committee, but it has not yet been resolved. Some of the Sub-committee members share the view that it should not be covered since, according to them, it is not an inherent hazard.) We will evaluate the need for additional rulemaking to change the definition and label elements if the UN incorporates simple asphyxiants into the GHS.

For combustible dust, OSHA has also already 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, OSHA* (3371–08 2009), and its Combustible Dust National Emphasis Program Directive CPL 03–00–008. As described in the preamble to the NPRM (74 FR 50395, Sept. 30, 2009), this was an issue that many ANPR commenters had provided information on, and is clearly a concern in the workplace. There have been a number of workplace incidents involving combustible dust, and the U.S. Chemical Safety and Health Investigation Board highlighted the need to address this specifically in the HCS (Document ID #0110):

> The CSB therefore recommends that OSHA amend the HCS to explicitly address the fire and explosion hazards of combustible dusts, and those materials that could reasonably be expected to produce combustible dusts, among the substances covered by the standard, and also that the Agency require inclusion of dust fires and explosions among the physical hazards that must be addressed in Material Safety Data Sheets. The CSB also requests that OSHA advocate similar changes to the GHS through appropriate international mechanisms.

OSHA has introduced this issue to the UN Sub-committee as well, and is leading a correspondence group on it. However, one of the problems in pursuing this approach is that some countries' systems are limited to supply chain requirements, and do not cover hazard communication issues that arise in the workplace as a result of processing. OSHA's rule does cover such workplace hazards, and requires the provision of information to downstream customers when known processing approaches will result in a hazard. Therefore, discussions continue, but the Sub-committee will not resolve this for at least two years.

In light of the important nature of the issue, a number of public comments, and the need to provide clarity sooner than the UN Sub-committee will complete its work, OSHA is including combustible dust in the definition of ''hazardous chemical'' in this final rule. We have noted that many commenters agreed that there was a need to provide hazard communication on combustible dust, as has been required by OSHA under the current rule. But there were also suggestions that criteria and greater clarity were needed in order to avoid confusion. A few commenters argued that OSHA should not cover combustible dust since it is not an intrinsic hazard of a product (*See, e.g.,* Document ID#0393). However, OSHA believes that similar to the situation with simple asphyxiants, all dusts in the workplace are not combustible, and processing of them does not always result in combustible atmospheres. Consistent with Executive Order 13563 and its emphasis on reducing uncertainty, OSHA agrees with commenters noted above that employers need certainty to properly cover it.

It is true that a separate rulemaking is ongoing on this topic in OSHA, and some commenters suggested that the combustible dust issue should therefore not be addressed in this rulemaking. Such an approach would, however, eliminate safeguards that have long been in place (since 1983). Similar to the situation with simple asphyxiants, OSHA has provided longstanding interpretations that indicate combustible dusts are covered under the current HCS (*e.g.,* OSHA interpretation, January 16, 1986). Specifically, under OSHA's existing Hazard Communication Standard, combustible dust is addressed under the broad definition as both a flammable solid and an explosive hazard. Therefore, not addressing combustible dust in this rulemaking would fail to meet the requirements—which are central to the existing standard—that chemical manufacturers and importers provide information on hazardous chemicals.

While OSHA is currently in the preliminary stages of developing a proposed rule to address combustible dust, the new standard is not expected to be completed for some time. It is also important to note that there is a clear distinction between coverage under the HCS, and potential provisions promulgated under a specific rulemaking for combustible dust. The rulemaking on combustible dust is a much broader approach to the issue, and will likely establish methods to control and address such dusts in the workplace. The HCS is an information transmittal standard. Provision of information to downstream employers is critical now, as it can alert them to the need to have a protective program. This is a fundamental purpose of the HCS—to provide employers and employees with information about hazards so they can take steps to protect their employees and themselves. A failure to continue to address the combustible dust issue in the HCS at this time would eliminate current protections. Therefore, the Agency is clarifying its position that it will continue to regard combustible dust as a serious hazard for which chemical manufacturers and importers must provide information to downstream employers.

The Agency is not adding a definition for combustible dust to the final rule given ongoing activities in the specific rulemaking, as well as in the UN Sub-committee. However, guidance is being provided through existing documents, including the Combustible Dust National Emphasis Program Directive CPL 03–00–008. This directive includes an operative definition, as well as provides information about current responsibilities in this area. In addition, there are a number of voluntary industry consensus standards (particularly those of the NFPA) that address combustible dust, and were noted by commenters as providing further guidance in this area. (*See, e.g.,* Document ID #0379 and 0530). Chemical manufacturers and importers must be aware of the hazards of their products, both in the shipped form, and under normal conditions of use or foreseeable emergencies in downstream workplaces, in order to comply with the HCS. Information about these hazards is required to be transmitted through labels and SDSs as specified in the standard. The protection of workers in downstream workplaces depends on the provision of accurate information to their employers.

Label elements are also provided for combustible dust in C.4.30 requiring, when appropriate, the signal word ''warning'' and the hazard statement ''May form combustible dust concentrations in air'' (similar to ANSI Z400.1/Z129.1—2010 statements).

Concerns were raised by commenters that labels with a signal word and hazard statement may not be appropriate in some situations, because the combustible dust is created through processing downstream, and the product may not present a hazard in its shipped form. (*See, e.g.,* Document ID #0050 and 0353.) Dow (Document ID #0353) pointed out: ''Over-warning would dilute the message.''

OSHA has already addressed a similar situation under paragraph (f)(4) of the final standard, which addresses solid metal, solid wood, plastic, and shipments of whole grain that present no hazard in shipping, but which are used in such a way in downstream operations that employees can be exposed to hazards. In this situation, the downstream employer needs label information about the hazards to protect employees, but OSHA determined that such label information does not need to accompany the product. Therefore, paragraph (f)(4) allows the chemical manufacturer or importer to transmit the label to the customer at the time of the initial shipment, but the label does not need to be included with subsequent shipments unless it changes. This provides the needed information to the downstream users on the potential hazards in the workplace, while acknowledging that the solid metal or other materials do not present the same hazards that are produced when these materials are processed under normal conditions of use.

Many products that are a combustible dust hazard when processed are similar in nature, and therefore paragraph (f)(4) would apply. A shipment of grain, for example, does not present a combustible dust hazard in the shipped form. But when processed downstream in a plant, such hazards are a concern, and the employer needs the label information to properly address the hazard in the workplace. Since this is a normal condition of use for the grain, the chemical manufacturer or importer must provide the information at the time of the initial shipment, and in the future if there is new information regarding the hazards or protective measures. An SDS must always be provided.

In other situations where the material is shipped in a dust form that is potentially combustible without further processing, the chemical manufacturer or importer must have appropriate labels on the containers when shipped under the requirements of paragraph (f)(1). If the chemical manufacturer labels the product for combustible dust, the label must use the required labeling elements in C.4.30.

Combustible dust has been added to the definition for hazardous chemical, and thus all of the provisions of the standard as amended by the final rule that apply to hazardous chemicals will also apply to combustible dusts, including safety data sheets and worker training. Employers with workplaces where combustible dusts are generated must comply with the workplace labeling requirements in paragraph (f)(6).

As with simple asphyxiants, OSHA will continue to encourage the UN Sub-committee to deal with combustible dusts and develop criteria to be adopted by countries such as ours where workplace exposures are a key part of the hazard communication system.

(d) Hazard Classification

Hazard determination under the current standard. Under the current HCS, chemical manufacturers and importers are required to evaluate the scientific data available regarding each chemical they produce or import, and determine whether the chemical is hazardous within the meaning of the standard. This requires a thorough search of the scientific literature on both the health and physical hazards that the chemical may pose. The identified information must be evaluated within the parameters established in the standard to determine whether the chemical is considered to pose a hazard. Paragraph (d), Hazard determination, provides the regulatory approach for evaluation. This approach is to be implemented using the definitions provided in paragraph (c) as well as in Appendix A, which provides further elaboration on the nature and breadth of health hazards covered. Appendix B provides additional requirements for identifying and evaluating data regarding hazards. Both of these appendixes are mandatory.

In order to ensure the broadest dissemination of information, and to reduce the number of situations where conflicting determinations may be made for the same chemical by different suppliers, the current HCS considers one study, conducted according to established scientific principles and producing a statistically significant result consistent with the definitions of hazard in the standard, to be sufficient for a finding of health hazard under the rule. *See* 29 CFR 1910.1200(d)(2) and Appendix B. This approach was the broadest among those systems that were used as the basis for the development of the GHS.

Most of the definitions under the current HCS simply lead to a conclusion that the chemical involved poses that hazard or it does not. For example, a chemical might be found to be a carcinogen under the rule based on one study indicating that it poses a carcinogenic effect. The current standard does not generally address the degree of severity of the hazardous effect in most of the definitions—so a chemical is either a carcinogen, or it is not. However, while a one-study determination leads to providing information about that hazardous effect on a safety data sheet, it may not lead to a hazard warning on a label. The current HCS requires such warnings to be ''appropriate,'' and there are situations where the data do not support warning about the hazard on the label because of other negative studies or information. *See* 29 CFR 1910.1200 (f)(1)(ii). Thus, there is consideration of the weight of evidence when deciding what to include on a label. Chemical manufacturers and importers may also review the weight of evidence in preparing SDSs, and are permitted to discuss negative evidence and other constraints when reporting the information. Under the current standard, OSHA expects the hazard evaluation process to go beyond simply identifying one study, and include a complete evaluation of all of the information available when determining what information to transmit to users of the chemical.

This hazard evaluation process is consistent with product stewardship processes that have evolved in the chemical industry. (*See, e.g.,* the Responsible Care® program implemented by chemical manufacturers.) Under such processes, chemical manufacturers develop and maintain thorough knowledge of their chemicals. This knowledge is critical to the safe handling and use of the chemicals in their own facilities, as well as in their customers' facilities. It is also critical to handling product liability concerns for their materials.

The current HCS requires chemical manufacturers to remain vigilant regarding new information about their chemicals, and to add significant new information about hazards or protective measures to their hazard communication documents within three months of learning about them. *See* 29 CFR 1910.1200(f)(11), (g)(5). This has always been seen by OSHA as a more rigorous, but essential, requirement than some other countries' provisions, which only require these documents to be reviewed every few years. It should be noted that OSHA has not been enforcing the current requirement to change labels within three months of getting new information. This stay on enforcement began some years ago when the standard was first promulgated, and involved concerns about existing stockpiles of chemicals and other related information. The stay does not apply to safety data sheets. OSHA proposed to reinstate the requirement and lift the stay, making the updating period consistent with that required for safety data sheets (*See* the discussion below on labels).

At the time the HCS was promulgated, the standard's provisions and approach were quite novel, and there were concerns that chemical manufacturers and importers would need more guidance regarding what chemicals to consider hazardous. Thus OSHA included provisions in the hazard determination paragraph that established certain chemicals as being hazardous. Chemical manufacturers and importers still had to complete a hazard evaluation and determination of what hazards were posed, but for these designated chemicals, there was no decision to be made as to whether they were hazardous or not. These chemicals were considered to be a ''floor'' of chemicals covered by the rule, and included those for which OSHA has permissible exposure limits in 29 CFR Part 1910, as well as those for which the American Conference of Governmental Industrial Hygienists (ACGIH) has recommended Threshold Limit Values (TLVs). In addition, given that carcinogenicity was the most controversial and difficult health effect to address, OSHA indicated that, at a minimum, chemicals found to be carcinogenic in the National Toxicology Program's biennial Report on Carcinogens (RoC), or in monographs published by the International Agency for Research on Cancer, were to be considered to be carcinogens in addition to those regulated by OSHA as carcinogens.

The current HCS also includes provisions regarding hazard determinations for mixtures. 29 CFR 1910.1200(d)(5). Where such mixtures have been tested to determine their hazardous effects, the data on the mixture as a whole are used. Where testing has not been done, OSHA promulgated an approach based on the percentage of a hazardous chemical in a mixture to determine if the mixture is hazardous. Therefore, if a mixture contains one percent (by weight or volume) or more of a chemical determined to present a health hazard, the mixture is assumed to have the same effect. The one exception is carcinogens—a mixture is considered to be carcinogenic if it contains 0.1% or more of a chemical found to be carcinogenic.

In all cases, a mixture will still be considered to be hazardous if there is evidence that it poses a health risk when the hazardous chemical is present in concentrations below the cut-offs. This was included to ensure that chemicals that can have effects at very low concentrations, such as sensitizers, will be adequately addressed.

For physical hazards, the evaluator must determine based on whatever objective evidence is available whether the hazardous effect is still possible in smaller concentrations. This recognizes that, for physical effects, such a determination may be made based on factors such as dilution, and there are readily available means to make an appropriate assessment.

The approach in the current HCS is considered to be a self-classification system. In other words, the chemical manufacturer or importer reviews the available information, and makes the determination as to whether the product presents a potential hazardous effect. This is different than some other systems where the regulatory authority makes the determination, and publishes a list of hazardous chemicals that must be used by the chemical manufacturer or importer.

The hazard determination is to be completed based on available information. The current HCS does not require testing of chemicals to produce information where it is not available.

The hazard determination approach in the current HCS recognizes that information about chemicals changes, new chemicals are introduced, others cease to be used—in other words, the world of chemicals in the workplace changes constantly, and the standard is designed to ensure that employees receive the most up-to-date information available regarding the chemicals to which they are currently being exposed.

Employers who simply use chemicals, rather than producing or importing them, are permitted to rely on the information received from their suppliers. 29 CFR 1910.1200(d)(1). This downstream flow of information recognizes that the chemical manufacturers and importers have access to information about the chemicals they sell that is not available to those who only use them. It also reduces duplication of effort by focusing the hazard determination process at the source, rather than having everyone who uses a chemical trying to complete such a process.

The current HCS requires chemical manufacturers and importers to maintain a copy of the procedures they follow to make hazard determinations. 29 CFR 1910.1200(d)(6). If OSHA finds errors in a label or SDS, the chemical manufacturer or importer that prepared the document will be held responsible—not the employer using the chemical.

The hazard determination procedures in the current HCS, including the definitions and Appendixes A and B, have been in place since the standard was promulgated in 1983.

Hazard classification under the GHS. The challenge in negotiating an international approach was to create a system that did not require frequent changes yet remained current and protective, incorporating the best parts of the approaches in the existing systems. The GHS embodies an approach that is very similar to the current HCS in scope and concept, but builds in additional details and parameters to help to ensure consistency worldwide. Like the HCS, the GHS approach is based on a downstream flow of information from suppliers to users; self-classification; use of available information with no new testing; and a broad approach to definitions of hazard. The GHS has further refined the approach to include addressing the degree of severity of the hazardous effects by assigning categories of hazard within hazard classes; providing detailed scientific approaches to evaluating the available data to help ensure that multiple evaluators produce similar results when classifying hazards; and allowing a broader use of available data by establishing principles where data can be extrapolated in situations regarding mixtures. OSHA believes that these additional provisions in the GHS enhance employee protection in addition to the benefits of having an internationally harmonized approach when preparing labels and SDSs.

To accommodate these refinements, and improve protection for employees exposed to chemicals in the U.S., the final rule modifies the current HCS as follows. First, paragraph (d) is re-named ''hazard classification'' rather than the current ''hazard determination.'' This re-naming is consistent with the approach and terminology used in the GHS.

Similarly, final paragraph (d)(1), like the proposal, modifies the current HCS to indicate that chemical manufacturers and importers are required to classify the chemicals' health and physical hazards in accordance with this section. For each chemical, the chemical manufacturer or importer must determine the hazard classes, and the category of each class, that apply to the chemical being classified.

Final paragraph (d)(1) allows employers to rely on information received from suppliers (*i.e.,* chemical manufacturers or importers). In the final rule, OSHA made two minor changes to the proposed text. Instead of saying that chemical manufacturers would be required to classify ''their'' physical and health hazards, OSHA has replaced ''their'' with ''the chemicals'' for clarification purposes. In addition, OSHA has added the phrase ''where appropriate'' to add clarity that not all hazard classes have more than one category. The final paragraph (d)(1) now reads as set forth in the regulatory text of this final rule.

Final paragraph (d)(2), which is identical to the proposal, similarly modifies the current HCS's terminology regarding classification. However, the final paragraph also includes modifications to address the evaluation process and the role of testing. The paragraph specifically states that evaluation of the hazards of chemicals requires the evaluator to ''identify and consider the full range of available scientific literature and other evidence concerning the potential hazards.'' This is consistent with the current HCS, but re-emphasizes the responsibility to fully characterize the hazard of the chemicals. To clarify that available evidence is to be used, final paragraph (d)(2) specifically states that there is no requirement to test a chemical to classify its hazards under the modified provisions—just as there is no such requirement under the current HCS. Dow Chemical Company (Document ID #0353) suggested that OSHA revert to the current text of paragraph (d)(2), which simply referred to Appendix B for the parameters of the hazard determination. This would not be appropriate since Appendix B no longer exists in its current form. But OSHA does not believe that what is written in paragraph (d)(2) is inconsistent with what is currently required in Appendix B. It is not intended to mean (and does not say) that an evaluator must identify every ''shred'' of information as Dow has indicated in its comment, but rather that the evaluator cannot, for example, only review acute toxicity data and consider that a complete evaluation. The extent of the literature search must be what the reasonably prudent classifier would do to assure themselves that evidence for the range of hazards covered by the rule has been identified, and a thorough evaluation has been done of the potential effects. That is what is required today under the current HCS.

On the other hand, the Styrene Information and Research Center (SIRC) (Document ID #0361) commented on the same paragraph as follows:

> SIRC supports hazard classification for carcinogenicity and other endpoints based on a comprehensive assessment of the ''full range of available scientific literature and other evidence concerning the potential hazards,'' within a best available science framework. This approach should provide optimum precision assessing potential hazards and a sound basis for maintaining a safe and healthy workplace.

Final paragraph (d)(2) refers to Appendixes A and B for further information on classification as in the current standard. However, the Appendixes have been completely changed from the current text. New Appendix A includes the criteria for classification of health hazards, and new Appendix B includes the criteria for classification of physical hazards. These mandatory appendixes have to be used for the hazard classification process under the revised standard. The Appendixes have been adopted in the final rule, with some changes as described below.

Reference to these appendixes is also included in final paragraph (d)(3), which addresses mixtures. Final paragraph (d)(3)(i), like the proposal, states that chemical manufacturers and importers must follow the procedures in Appendixes A and B to classify hazards for mixtures as well as for individual chemicals. Proposed paragraph (d)(3)(ii) stated that the chemical manufacturer or importer ''shall be responsible for the accuracy of the classification even when relying on the classifications for individual ingredients received from the ingredient manufacturers or importers on the safety data sheets.'' SIRC expressed reservations about this proposed paragraph (Document ID #0494 Tr. 128–29; *See also* Document ID #0361). In commenting on this provision, SIRC said it was uncertain whether this provision meant that a classifier could rely on the classifications found in SDSs from the ingredient supplier, or whether the classifier was required to ensure that the supplier's classification was correct. It was OSHA's intent in the proposal to clarify that generally classifiers may rely on the classifications found on the SDSs received from suppliers. The final rule revises (d)(3)(ii) to state that when chemical manufacturers and importers are classifying mixtures, they may rely on the information provided on current safety data sheets of the individual ingredients, except where the chemical manufacturer or importer knows, or in the exercise of reasonable diligence should know, that the safety data sheet misstates or omits required information.

In reconsidering the language proposed, OSHA wanted to ensure that chemical manufacturers and importers know that, in most cases, they can continue to rely on their suppliers' SDS information for ingredients they will be using in formulations. However, where they know information is incomplete or wrong, they have some responsibility for ensuring they have the correct information before using it for their own evaluations.

During implementation of the current HCS, OSHA allowed formulators of chemicals to develop an SDS by simply providing the SDSs for all the ingredients rather than compiling a specific SDS for the product. OSHA does not believe that this practice of providing the SDSs for all the ingredients is widely pursued, but it will not be permitted under the final rule. The revisions to the approach to classifying mixtures do not lend themselves to such a practice. Hazard classification requires consideration and application of bridging principles based on the constituents, as well as the application of a formula when there are multiple ingredients with acute toxicity. These approaches require the evaluator to determine a classification for the mixture as a whole. In addition, this practice places more of a burden on the user of the product to sort out the relevant information for protection of their employees. The formulator is in a better position to assess the information and provide what is needed to their customers.

Under the current HCS, paragraph (d)(6) requires chemical manufacturers, importers, or employers performing hazard determinations to keep a copy of the procedures they follow in the hazard determination process. This provision has been deleted in the final rule because the hazard classification procedures have been specified, and thus all evaluators are following the same process.

Final paragraph (d) is thus much shorter and less detailed than paragraph (d) in the existing standard. This is largely due to the approach in the GHS to include the details regarding classification in hazard-specific discussions that address both the individual substance and that substance in mixtures. Given the volume of these criteria, it appeared to OSHA that presenting the relevant information in mandatory appendixes was a more efficient way to describe the criteria than including it all in the primary text of the standard. This is particularly true for those many employers reading the standard who do not have to perform hazard classification—the revisions only apply to chemical manufacturers and importers, unless an employer chooses not to rely on information received from them.

The GHS criteria. A number of commenters expressed their general support for the GHS criteria, and agreed that the criteria will result in thorough, harmonized hazard evaluations (*See, e.g.,* Document ID #0329, 0330, 0335, 0339, 0370, 0375, and 0389). In adopting the GHS approach, the final rule deletes from the hazard classification requirements the ''floor'' of hazardous chemicals described above—established lists of chemicals that are considered hazardous under the HCS in all situations. In addition, OSHA deleted the across-the-board ''one study'' rule described above, wherein one good scientific study established that a substance is a hazard. However, the one-study approach is still included in some of the criteria in the GHS, and thus in the revised OSHA rule.

With the detailed criteria, and the weight of evidence approach in the GHS, OSHA indicated in the NPRM that it appeared to no longer be necessary to have such a floor or the one study rule. Many commenters agreed with OSHA (*See, e.g.,* Document ID #0313, 0327, 0328, 0336, 0338, 0339, 0344, 0351, 0361, 0363, 0365, 0367, 0370, 0371, 0375, 0376, 0377, 0379, 0381, 0382, 0383, 0393, 0399, 0405, 0408, and 0410). For example, the Alliance of Hazardous Materials Professionals (Document ID #0327) indicated:

> Elimination of the ''floor'' definition of hazardous (as consistent with the GHS) would require producers and users to more closely examine the properties of the materials they produce or handle. While this would increase the effort necessary to determine that some substances are hazardous, it would also force a more careful examination of the underlying reasons that the substance is hazardous.

There were few comments that questioned taking the floor out of the requirements given the detailed nature of the criteria to evaluate hazards. It was noted that the lack of a floor may result in some inconsistencies in evaluations (Document ID #0352). There were also some concerns about removing IARC and NTP as sources to evaluate chemicals (Document ID #0321). Conversely, others supported elimination of these resources because inclusion violated the Data Quality Act (Document ID #0417)—a conclusion that OSHA does not believe is accurate. Evaluation of carcinogens will be addressed further below. OSHA has not included a ''floor'' of hazardous chemicals in the final standard.

As OSHA indicated in the proposed rule (74 FR 50282, Sept. 30, 2009), the Agency planned to adopt all of the health and physical hazard classes in the GHS, but not all of the hazard categories. In keeping with its intent to maintain the scope of coverage of the existing rule to the extent possible, as well as to be as consistent as possible with the scope of the European implementation of the GHS, OSHA did not propose to adopt Acute Toxicity, Category 5; Skin Corrosion/Irritation, Category 3; and Aspiration Hazard, Category 2.

Many commenters agreed that the categories selected in the proposal were appropriate (*See, e.g.,* Document ID #0313, 0327, 0329, 0330, 0338, 0344, 0351, 0353, 0365, 0367, 0370, 0376, 0377, 0379, 0381, 0382, 0383, 0393, 0399, 0402, 0408, and 0410), although there were some who thought all hazard categories should be adopted to be completely consistent with the GHS (*See, e.g.,* Document ID #0328, 0335, 0336, and 0339). There were other comments that supported streamlining the document by omitting the guidance portions of the GHS (Document ID #0328, 0399, and 0408); stated that the goal should be harmonization with trading partners, so if they exclude categories, OSHA should exclude them too (Document ID #0335 and 0389); or indicated that OSHA should accept labels and SDSs that include the excluded hazard categories (Document ID #0328, 0379, and 0405). OSHA indicated in the NPRM (74 FR 50383, Sept. 30, 2009) that additional information could be included on labels and SDSs in any event, and that is the position in the final rule as well. *(See* (g)(2); Appendix C.3.)

While the decision logics for the health and physical hazard criteria were omitted from the regulatory text, OSHA indicated that it would consider publishing them as guidance. Commenters agreed with this concept (*See, e.g.,* Document ID #0344, 0351, 0370, 0381, 0410, and 0453). It was further suggested that the diagrams be made simple so all workers can understand them (Document ID #0336). The decision logics are already part of the GHS, and are graphic representations of the process of determining each type of hazard. As such, they are tools for preparers of labels and SDSs, rather than for exposed workers. Another comment was that public comment should be sought on the decision logics before publishing them (Document ID #0379). Given that they are already part of the agreed text of the GHS, and are guidance, OSHA will make them readily available on the Agency's Web page.

There were also comments that OSHA should publish guidance on its interpretation of criteria application, and indicate whether it agrees or disagrees with interpretations published by other countries (Document ID #0382). OSHA is considering many different types of guidance documents, but has not made final decisions in this regard.

Background on Appendices A and B

The text of Appendixes A and B is the bulk of what was proposed to be adopted essentially verbatim from the GHS. While some of the provisions of the GHS have been adopted into the final rule with OSHA-developed language that is specific to the regulatory system of the U.S., OSHA has strived in these appendixes to retain the text of the GHS intact. In order to understand the context of this language, and OSHA's approach to its inclusion, a brief history of its development is necessary.

Most people think of the labels and SDSs as the products of the GHS that are harmonized since they are the system's ''output'' that are seen most frequently. But harmonization of these documents cannot occur unless the underlying criteria are harmonized, and countries adopting them implement them similarly. The health hazard criteria were developed in the Organization for Economic Cooperation and Development (OECD)—an organization of 34 countries that ''provides a forum in which governments can work together to share experiences and seek solutions to common problems.'' *See www.oecd.org.* One of the areas in which the OECD has long been actively involved is chemicals. As such, the OECD provides a forum for countries' experts to discuss and resolve issues of mutual concern. In addition, the OECD works with business, through the Business and Industry Advisory Committee, and with labor, through the Trade Union Advisory Committee. Perhaps its most visible contribution in the area of chemicals is test guidelines to assess the hazards of chemicals. These test guidelines address many different health effects; are considered to be scientifically robust, validated test methods; and are widely used around the world.

It was this expertise and recognition that led to the OECD being the ''focal point'' for development of the health hazard criteria. The OECD also uses a process of consensus to develop their documents, requiring agreement from all countries to move forward rather than a simple majority vote. Working on a consensus basis is much more difficult to accomplish, but is advantageous in other ways since it helps to ensure that the concerns of all parties are taken into consideration, and thus are more likely to remain consistent with the results.

A disadvantage is that the text must satisfy all parties, and thus it is not always written in the clearest fashion. The text was also reviewed further when it was submitted to the UN Sub-committee, and additional editing was done to address concerns. Therefore, it is fair to say that it was written by expert committees, and reflects the involvement of many different people and ideas.

The criteria in Appendix B, unlike those in Appendix A, were not developed ''from scratch,'' but were based on the harmonized criteria developed to classify the physical hazards of chemicals involved in transport by the UN Sub-committee of Experts on the Transport of Dangerous Goods (TDG). The TDG Sub-committee includes many subject experts in areas such as explosives and flammability. The TDG Sub-committee and the International Labor Organization (ILO) were jointly tasked to review the TDG criteria for application to other sectors such as the workplace. This review not only took advantage of the UN and ILO expertise, but also created a system that is harmonized with transport in terms of criteria.

When OSHA developed the proposed rule, it considered editing the text of the criteria for purposes of improving the language. However, the trade-off is inconsistency with the GHS, and the potential for people to believe that OSHA means something different because the text has been revised. Thus, as noted in the NPRM (74 FR 50392, Sept. 30, 2009), OSHA chose to take the approach of adopting the language as stated in the GHS. Editing of the criteria focused on what needed to be changed for purposes of putting it into mandatory regulatory language, including deleting what was clearly identified as guidance.

Therefore, while we have reviewed every suggestion that was made to the text of the Appendixes, our general approach was not to make changes unless they were truly necessary. Editorial changes for purposes of clarification are more appropriately made through the UN Sub-committee process, and OSHA participates actively in that activity, and chairs the primary correspondence group. Those changes that were suggested that OSHA believes have merit in terms of clarifying provisions will be worked through this correspondence group so the UN Sub-committee can make the changes. Then OSHA will adopt them into the revised standard through rulemaking processes discussed elsewhere in this preamble. To avoid giving this same response repeatedly, OSHA will not be individually addressing the many suggestions for clarifications in this preamble.

In general, there were very few substantive technical comments provided on the approaches in the criteria, and OSHA assumes that reflects the fact that the criteria were developed by technical experts from countries and stakeholder organizations. There were some suggestions received that certain parts of Appendix A be withdrawn so OSHA can consult with toxicologists (Document ID #0353). Numerous toxicologists and other health professionals from the U.S., as well as many other countries, have been involved in the development and review of the text in Appendix A, and it has been subject to extensive scientific and policy discourse. Furthermore, this rulemaking was also the opportunity for others who have not been involved to provide input. If OSHA had received significant comments on the technical aspects of the criteria that indicated a systemic concern about the criteria, it may have been cause for reconsideration. But most of the comments that were received were more reflective of differences on policy positions than truly technical issues. Therefore, there are relatively few changes to Appendixes A and B as a result of record input. These changes are discussed below.

As described in the NPRM and this document, in Appendixes A and B OSHA has maintained its general approach (supported by stakeholders) of: (a) Limiting changes to the HCS to those that are required to align with the GHS; and (b) remaining as consistent with the GHS as possible within the need to use appropriate regulatory language and maintain or enhance current protections. OSHA has also remained mindful of the approaches of its trading partners, although it notes that some proponents of that principle were quite inconsistent themselves when using this particular argument. Therefore, while this argument was used to support choosing higher cut-offs for mixtures, for example, some of these same commenters also suggested not covering hazard classes or categories that are both covered by the EU and currently addressed by OSHA (*See, e.g.,* Document ID #0344, 0381, and 0393). These comments are addressed below.

Appendix A, Health Hazards. Proposed Appendix A began with an introduction that includes material related to principles of classification taken from Chapter 1 of the GHS. These address both weight of the evidence, and the approach to mixtures. In A.0.3.2, the proposed text referred to both positive and negative results being ''assembled together.'' Dow (Document ID #0353) expressed concern about the implications of the word ''assembled.'' In the final rule, OSHA has revised this language throughout the chapter to say ''shall be considered together.'' Dow also commented that in the discussion regarding acceptable data in A.0.2.2 and A.0.2.3, the text should refer to ''valid'' methods, rather than ''validated.'' OSHA does not agree that this change is warranted. To be ''valid'' data, the methods used to produce the data must be validated. In order to clarify the discussion, OSHA has revised the text by adding two sentences from the GHS to A.0.2.3 as follows:

> 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.

As mentioned below in the discussion on mixtures, OSHA has also revised Appendix A to use ''cut-offs/concentration limits'' everywhere one of these terms was formerly used in order to be consistent, and make clear the terms are interchangeable.

The remainder of Appendix A is taken from Chapter 3 of the GHS on Health Hazards. OSHA has included the specific discussions of all of the health hazards covered by the HCS in proposed Appendix A, extracted from Chapter 3 of the GHS. OSHA removed the decision logics that are in the GHS from the criteria, and is considering including them in a guidance document to be made available at the time the final rule is published. As discussed above, stakeholders generally supported this approach. The hazard communication portions of the criteria chapters have also been removed since all of this information is already available in Appendix C and would thus be duplicative. In addition, edits have been made where OSHA is not adopting all of the categories of a particular hazard class.

The chapters on Skin Corrosion/Irritation (Chapter A.2) and Serious Eye Damage/Irritation (Chapter A.3) have been modified more extensively than the other chapters on health hazards in the GHS. In these chapters, the GHS leads the evaluator to conduct additional testing on the chemical when information is not available. While the GHS does not require such testing, the criteria for these effects imply that it should be conducted to complete an evaluation. The HCS is based solely on available information, and no testing is ever required. Therefore, OSHA has modified these chapters to eliminate any references to additional testing and limit the evaluation to what is known based on available information. It should be noted that the UNSCEGHS has initiated work to edit these chapters and make them easier to follow. OSHA will continue to participate in this activity.

Coverage of Mixtures

The coverage of mixtures in terms of health hazards is addressed in two places in the revised rule. First, general principles that apply to multiple effects are addressed in the introductory part of Appendix A in Chapter A.0, ''General Classification Considerations.'' Second, each hazard class discussion includes the criteria for classifying a substance or a mixture. Unlike the current HCS, which defines across-the-board percentage cut-offs for all health hazard classes, the GHS employs a tiered approach to classification. Like the HCS, classification would be based on test data for a mixture as a whole for most hazard classes where it is available. However, where it is not available, but there are data on ingredients and similar mixtures, the GHS allows extrapolation or bridging of data to classify a mixture. This allows greater use of available data before resorting to a percentage cut-off or similar approach. Where such data are not available, the criteria address how to classify mixtures based on cut-offs specific to that hazard. In the case of acute toxicity, this includes calculations based on the acute toxicity of each ingredient in the mixture.

The tiered scheme is somewhat different for certain hazard classes. As described, usually the evaluation is based first on test data available on the complete mixture, followed by the applicable bridging principles and, lastly, cut-offs/concentration limits or additivity. The criteria for Germ Cell Mutagenicity, Carcinogenicity, and Reproductive Toxicity take a different approach by considering the cut-off levels as the primary tier and allowing the classification to be modified on a case-by-case basis based on available test data for the mixture as a whole. This approach is related to the sensitivity of available test methods to detect these types of effects at small concentrations in the mixture as a whole.

The approach to mixture classification may result in some mixtures that are currently considered to pose a particular hazard not being so classified under the GHS. OSHA believes that the protections of the GHS approach are appropriate, and that these changes will not result in an inappropriate reduction in protection. For example, if there is a mixture that is comprised of 1% of an acutely toxic material, regardless of the severity of that effect, and 99% water, the current HCS would require that mixture to be considered acutely toxic. Under the GHS, it is unlikely to be considered as such. Based on the dilution effect of the water, the acute toxicity is no longer a concern. Thus the bridging principles under the GHS allow for a more accurate assessment of the potential harm of the mixture, whereas the strict cut-off approach under the current HCS may provide hazard information in cases where the exposure is minimal and the occurrence of an adverse effect is unlikely. In the example described, the presence of the water in the mixture as used by the workers reduces the potential for exposure to the hazardous ingredient to such a small amount that no effect is expected to result. The GHS approach is not as simple to apply as the current HCS, but the resulting approximation of the hazards of the mixture will be more accurate.

The GHS uses both the term ''cut-off'' (which is what is used in the current HCS), and ''concentration limit'' (which is used in the EU requirements). The terms are used interchangeably and often appear together (*i.e.,* cut-offs/concentration limits). Several commenters indicated that OSHA should define these terms (Document ID #0344, 0381, and 0393). There are no definitions in the GHS since the terms are self-evident when viewed in the context of how they are used. OSHA does not believe that definitions are needed for these terms. However, Appendix A has been reviewed to make sure the terms are both used consistently throughout the Appendix. The GHS was also reviewed, and it appears the terms are not necessarily used consistently in that text.

Several commenters indicated that language in A.0.5.1.1(a), in the bridging principle that addresses dilution, was inappropriately changed from ''may'' to ''shall'' in the NPRM (*See, e.g.,* Document ID #0344, 0381, 0382, and 0393). OSHA changed the language to track the mandatory nature of the provision when present in a standard versus a non-mandatory recommendation such as the GHS. Therefore, the language remains as ''shall'' in the final rule.

In another part of the bridging principles, the term ''commercial product'' is used in the GHS, and was thus used by OSHA in the NPRM (A.0.5.1.2). Commenters asked that this term be defined (Document ID #0344 and 0381). OSHA reviewed the text, and has changed the term to ''mixture'' instead of ''commercial product''. This is accurate, and the term is already defined.

There are several hazard classes in the GHS that give competent authorities such as OSHA a choice of cut-offs/concentration limits to apply when classifying a mixture containing ingredients that pose these effects (*e.g.,* reproductive toxicity, sensitization, target organ effects). The reason the GHS includes a choice of cut-offs to trigger label disclosure is that countries involved in the negotiations on mixtures had different views on the issue that could not be resolved. All countries agreed to use the lower of the two cut-offs for SDSs, so information will be provided consistently for those documents in all cases. But for labels, some countries had what were described as ''downstream consequences'' that were linked to label disclosures, and therefore did not want to adopt the lower level and trigger those consequences (*e.g.,* banning the use of the chemical for consumer products).

In North America, Canada and the U.S. do not have such consequences linked to label statements, and their requirements are based on giving workers the right-to-know about the hazards and identities of the chemicals in their workplaces. Additionally, Canada has the lower cut-offs in most cases in their current requirements, and OSHA already has the 0.1% cut-off for carcinogenicity. Adoption of the lower cut-offs for both labels and SDSs was supported by both Canada and the U.S. from the outset.

As has been described, OSHA has used consistent cut-offs for purposes of hazard determination for mixtures since the HCS was promulgated in 1983. OSHA described the proposal as follows in the 1983 final rule preamble (48 FR 53290, Nov. 25, 1983):

> The rationale of the proposal was that when the hazard of a mixture is unknown, all hazardous ingredients should be indicated on the material safety data sheet. The user would then have the most complete information available to predict the potential hazards of the mixture. The one percent exclusion was included to absolve the employer from having to evaluate and list chemicals in small quantities, which are not likely to result in substantial exposures.

In the 1982 proposal, the one percent cut-off would have applied to all health and physical hazards. As a result of the comments submitted to the record, OSHA took a different approach to physical hazards in the final rule (no percentage cut-off applies to physical hazards), and also lowered the cut-off for carcinogenicity to 0.1 percent. In addition, a provision that required inclusion of chemicals below these cut-offs in certain situations was also part of the 1983 final rule.

In proposing the one percent cut-off, OSHA noted that ''there was no scientifically correct delineation, but that the one percent cut-off is apparently considered reasonable by a number of parties'' (47 FR 12102, Mar. 19, 1982). OSHA's intent was ''to absolve the employer from having to evaluate and list chemicals present in mixtures in small quantities, which are not likely to result in substantial exposures'' (48 FR 53290, Nov. 25, 1983). These cut-offs were practical accommodations, had been used in other regulatory settings (*See, e.g.,* 29 CFR 1910.1003(a)(2), 13 Carcinogens), and in the 1983 final rule were accompanied by a provision that also covered those situations where the cut-offs were too high for protection purposes. Science regarding potential health hazards in the workplace does not provide evidence that would allow the Agency to draw a bright line to indicate specific concentrations of a chemical in a mixture are, or are not, a potential hazard to workers. Therefore, the establishment of such cut-off levels is a policy decision based on scientific considerations, as well as concerns regarding practicality and utility, but not on studies that can be linked to a particular level for each type of health effect.

That being said, however, the scientific knowledge about these health effects has increased significantly since the HCS was first adopted, as has the concern about their occurrence in the work force. At that time, carcinogenicity was the primary concern in terms of chronic and/or significant health effects, and this concern was reflected in the lower cut-off value adopted by OSHA for that effect. Most of OSHA's substance-specific rulemakings were done for the purpose of addressing carcinogenicity. Now, however, there is more evidence that raises significant concerns about other types of effects.

Sensitization is a key example. Respiratory sensitization leads to asthma, and substantial evidence has developed over the last few decades showing this effect is of increasing concern. For example, a study by Frazier *et al.* (2001, Document ID #0587) notes that the incidence of occupational asthma has increased by 50% over the last two decades, and that population-based surveys have reported that 5% to 21% of asthma cases are caused or exacerbated by occupational exposure. The authors extrapolated this to the estimated 12 million adults who have asthma in the U.S., and concluded that this suggested that between 500,000 and 2.5 million Americans had occupational asthma. This study was published in 2001, and the numbers are likely to be larger today. The study also examined SDSs for chemicals containing toluene diisocyanate, a known respiratory sensitizer, and found only half the SDSs noted asthma as a potential health effect, and one in four noted neither asthma nor respiratory sensitization effects. Other studies have also examined the increasing concerns about occupational asthma (Document ID #0588, 0591, 0592, and 0593).

Further, the most recent science shows that respiratory and skin sensitization can be caused at very low concentrations. A 2006 paper by Arts *et al.* summarizes human and animal studies on skin and respiratory sensitizers, and finds that sensitization effects often result from exposures to chemicals at concentrations below 1% in studied populations (Document ID #0593). Likewise, the World Health Organization's report, ''Skin Sensitization in Chemical Risk Assessment,'' also reports positive results for skin sensitization well below the 1% cut-off used by the current HCS (Document ID #0586). Moreover, once an individual is sensitized, a response can be triggered at even lower levels than those required initially to induce sensitization (Document ID #0585 and 0593). OSHA has often used sensitizers as an example of why SDS preparers need to consider whether information should be provided below the 1% cut-off. For example, in OSHA's compliance directive for the HCS (CPL 02–02–038), the following guidance is given:

> If the components of a mixture could be released in concentrations which would exceed an OSHA PEL, an ACGIH TLV, or could present a health risk to employees, information on these components must be included on the MSDS regardless if their final concentration in the mixture is less than 1% (or 0.1% for carcinogens). For instance, TDI is a sensitizer at very small concentrations and despite its low concentration in a mixture, can be offgassed in quantities which may present a health risk that must be noted on the MSDS.

But sensitization is not the only effect of concern. Reproductive toxicity is a serious hazard that includes both fertility and effects on the offspring. Recent research concerning endocrine disruptors suggests that these chemicals can have adverse reproductive effects at very low levels (Document ID #0583, 0584, and 626). Likewise, occupational disease mortality and morbidity statistics indicate a number of cases related to target organ effects as well (Document ID #0291, *e.g.,* heart disease and renal effects).

OSHA proposed to use the most protective of the GHS concentration limits for these hazard classes. For sensitizers and reproductive toxins, the final rule requires information to be provided on labels and safety data sheets at concentrations above 0.1%. Other countries may choose to only provide the information on SDSs when the concentration is higher. However, as indicated, these particular health effects are among the most significant to employees, and OSHA believes the provision of information on labels will help both employers and employees ensure that appropriate protective measures are followed. (On the other hand, it should be noted that OSHA was persuaded that the current 1% cut-off may be too conservative for many acute toxins and Category 3 Single Target Organ Toxicants, and the final rule is likely to result in fewer mixtures being covered for these effects than under the current approach.)

In addition to concerns regarding protection for these health effects, there is also a concern about the communication difficulties of having different hazard information on a label versus a safety data sheet. As indicated, the GHS negotiators agreed that all countries would use the lower levels in the criteria for providing information on SDSs. Using a different cut-off for labels would create a situation where there may be hazards on the SDS that do not appear on a label. This inconsistency makes training more difficult, and creates confusion for downstream employers as well when they are deciding about appropriate protective measures. Under the current rule, the mixture cut-offs apply to both the label and the SDS. Several commenters indicated that OSHA should provide guidance indicating specific threshold cut-offs (Document ID #0344, 0381, and 0399). The table below indicates what the cut-offs are for different health hazards. These commenters also suggested OSHA provide guidance on opting out of the cut-offs if data override the threshold. This is already addressed in 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/concentration limit, the mixture containing that ingredient shall be classified accordingly). A.0.4.3.3 also allows the cut-off/concentration limit to be higher in exceptional cases. The evaluator must have conclusive data demonstrating that the hazard of an ingredient will not present a health risk. OSHA anticipates that the criteria of A.0.4.3.3 would rarely permit this approach to be used.

TABLE XIII–1

Hazard class	Label cut-offs	SDS cut-offs
Respiratory/Skin sensitization	≥0.1%	≥0.1%
Germ cell mutagenicity (Category 1)	≥0.1%	≥0.1%
Germ cell mutagenicity (Category 2)	≥1.0%	≥1.0%
Carcinogenicity	≥0.1%	≥0.1%
Reproductive toxicity	≥0.1%	≥0.1%
Specific target organ toxicity (single exposure)	≥1.0%	≥1.0%
Specific target organ toxicity (repeated exposure)	≥1.0%	≥1.0%
Specific target organ toxicity Category 3	>20%	>20%

During the hearing, worker representatives were asked to comment on whether consistency between the information on the label and the SDS was important for worker protection. They all indicated that it was important. For example, Mr. Platner, who represented the Building and Construction Trades Department of the

AFL–CIO stated (Document ID #0494 Tr. 25):

Oh, absolutely. An example of a sensitizer that's very common is isocyanate components or polyurethane spray foams or coatings. They're potent sensitizers, and that information very rarely gets to the label. It's usually appropriately in the MSDS, but it rarely makes it to the label.

Similarly, Mr. Kojola of the AFL–CIO, commented (Document ID #0494 Tr. 33):

Oh, absolutely. What it does is it provides a consistent message that workers are getting both in labels and on safety data sheets. And I think it enhanced the ability to, for example, translate that information into other languages, so I think that alone is a major step forward in enhancing worker protection.

Some commenters argued that OSHA should adopt the higher cut-off levels where given a choice by the GHS (Document ID #0344, 0361, 0367, 0371, 0376, 0381, 0392, and 0393). They questioned whether there was a scientific justification for the lower levels, and suggested that the U.S. should harmonize with the EU approach.

As OSHA described above, there are two primary reasons for the lower levels. First, OSHA believes it is important for effective communication to have the same hazards on the label and SDS to as great a degree as possible. Labels are in an employee's work area, and thus provide the most immediate source of information. While SDSs must be available, they are longer and more complicated, and workers are less likely to review them on a regular basis. For downstream employers, it is also important to maintain consistency and reduce confusion where possible by having the information on hazards the same on the label and SDS.

Secondly, as discussed above, increased knowledge of these health effects in the scientific literature, as well as studies indicating that they are often not reported when they should be, or the information is lacking, has led OSHA to the conclusion that communication at the lower levels is appropriate and necessary for worker protection. It is particularly critical in the area of sensitizers since the incidence of occupational asthma is increasing, and sensitization can occur at lower levels as it progresses. But with the advent of information on effects like those of endocrine disruptors, and the increased awareness of the possible effects of low levels of exposure, it is necessary for all of these effects.

As for the argument regarding consistency with the EU, OSHA has sought to be consistent where possible. However, the EU has a different regulatory structure for dealing with these effects downstream, and what is appropriate for their classification and labeling system is not necessarily appropriate for ours in the U.S. (*See, e.g., http://ec.europa.eu/environment/chemicals/dansub/pdfs/30_atp.pdf:* ''Under Directive 76/769/EEC on the restrictions of certain dangerous substances and preparations, the Commission is, in principle, obliged (within six months of the publication of the classification) to propose a ban on their placing on the market and use by consumers as substances or in preparations (above specified concentrations).'')

There are relatively few chemicals for which there are data indicating the types of effects of concern with regard to these lower cut-offs (*e.g.,* sensitizers), and fewer still that would fall into the range between the lower and higher cut-offs (*e.g.,* between 0.1% and 0.3% for reproductive toxicity). Furthermore, as suggested in one comment, disclosing at different levels on labels versus SDSs may actually create a product liability issue under U.S. law that would argue against taking such an approach (Document ID # 0353). While product liability is not one of the issues that influenced OSHA's decision-making, it may be important to these commenters in the future.

The American Chemistry Council asked during the hearing why OSHA adopted the cut-off levels 25 years ago if the Agency thought they weren't protective, or whether there is information to indicate that they have not been protective (Document ID # 0494 Tr. 174). In response to questions from OSHA as to what the scientific basis would be for communicating a hazard on an SDS and not a label, they responded (Document ID # 0494 Tr. 177): ''A scientific basis? Well, most of these are obligatory regulatory cut-offs for mixtures. There really is not much scientific basis for any of the mixture cut-offs.'' In other words, ACC concedes that there is also no scientific basis for the higher cut-offs it advocates—rather the EU cut-offs are simply policy choices made by a different authority with a distinct regulatory structure. As described previously, OSHA believes there is evidence that these cut-offs are no longer sufficiently protective in light of additional information developed since the HCS was adopted in 1983. Furthermore, having inconsistencies in information on a label versus a safety data sheet impacts the effectiveness of the communication to workers and downstream employers. The cut-offs/concentration levels in the final rule are the same as proposed, and are the lower levels of those the GHS allows countries to choose from when implementing.

The Styrene Information and Research Center (SIRC) argues that OSHA may not lower the mixture cut-off thresholds for sensitizers and reproductive toxicants without establishing that a significant risk exists at that lower threshold (Document ID #0361, 0467, and 0642). OSHA disagrees.

As discussed in Section V, Pertinent Legal Authority, OSHA has found that inadequate hazard communication creates a significant risk and that the final rule will reduce that risk. Contrary to what the SIRC says, OSHA need not support each requirement in a standard with its own significant risk finding. *Public Citizen Health Research Group* v. *Tyson,* 796 F.2d 1479, 1502 n. 16 (D.C. Cir. 1986). Indeed, when the Supreme Court first construed the OSH Act as imposing a significant risk requirement, it spoke in terms of the Agency making findings about unsafe *workplaces,* not individual hazards. *Benzene,* 448 U.S. at 642 (''before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe [and] * * * a workplace can hardly be considered 'unsafe' unless it threatens the workers with a significant risk of harm''). *See* also, for example, *id.* (framing the ''significant risk'' requirement as requiring OSHA ''to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices.''); *Texas Indep. Ginners Ass'n* v. *Marshall,* 630 F.2d 398, 400 (5th Cir. 1980) (''The Supreme Court recently ruled that the Act requires OSHA to provide substantial evidence that a significant risk of harm arises from a workplace or employment.''). Moreover, courts have held that the OSH Act does not require the disaggregation of significant risk analyses along other lines. *See,* for example, *Lockout/Tagout II,* 37 F.3d at 670 (upholding OSHA's decision not to conduct individual significant risk analyses for various affected industries); *American Dental Ass'n* v. *Martin,* 984 F.2d 823, 827 (7th Cir. 1993) (OSHA is not required to evaluate risk ''workplace by workplace''); *Associated Builders and Contractors, Inc.* v. *Brock,* 862 F.2d 63, 68 (3d Cir. 1988) (''the significant risk requirement must of necessity be satisfied by a general finding concerning all potentially covered industries'').

Indeed, a contrary rule would impose an unworkable burden on OSHA. As the Third Circuit held *Associated Builders and Contractors, Inc.* v. *Brock,* 862 F.2d 63 (3rd Cir. 1988), stating:

The holdings in *USWA I* and *USWA II* sustained a general significant risk finding. Assuming, however, that those opinions were construed as leaving open the significant risk issue, as presently presented, the outcome would be no different. This rulemaking proceeding produced a performance-oriented information disclosure standard covering thousands of chemical substances used in numerous industries. For such a standard the significant risk requirement must of necessity be satisfied by a general finding concerning all potentially covered industries. A requirement that the Secretary assess risk to workers and need for disclosure with respect to each substance in each industry would effectively cripple OSHA's performance of the duty imposed on it by 29 U.S.C. § 655(b)(5); a duty to protect all employees, to the maximum extent feasible.

Id. at 68. Thus, OSHA need not make the sort of significant risk finding suggested by SIRC.

Rather, once OSHA makes a general significant risk finding in support of a standard, the next question is whether a particular standard's requirements are reasonably related to the purpose of the standard as a whole. *Asbestos Information Ass'n/N. Am.* v. *Reich,* 117 F.3d 891, 894 (5th Cir. 1997); *Forging Indust. Ass'n* v. *Secretary of Labor,* 773 F.2d 1436, 1447 (4th Cir. 1985); *United Steelworkers of Am., AFL–CIO–CLC* v. *Marshall,* 647 F. 2d 1189, 1237–38 (D.C. Cir. 1980). The use of a threshold to govern when the standard applies is reasonably related to the purposes of hazard communication. It limits communication to those situations in which a chemical is present in sufficient quantities that workers might experience substantial exposures to its hazards. Hazard communication can be undermined just as much by overcommunication of risks as by undercommunication. An avalanche of information about less significant hazards on a label or SDS could obscure important information on substantial hazards faced by the worker. Thresholds also save manufacturers and importers the burden of evaluating and listing chemicals present in only small quantities and not likely to result in substantial exposures (48 FR 53280, 53290 (Nov. 25, 1983). And as noted above, OSHA has provided a justification for the lower levels challenged by the Styrene Institute and Research Center: chemicals presenting these hazards may be especially hazardous at low levels, and the potential effects are of high concern.

In addition, SIRC seems to challenge only the reduction of the threshold for disclosure on labels, not the identical reduction of the threshold for disclosing the hazard on SDS for these hazards. Under the final rule, the same information for sensitizers and reproductive toxicants must appear on both the label and the SDS, avoiding the potential for confusion. The reproductive toxicant and sensitizer cut-offs are reasonably related to the purposes of the Hazard Communication Standard.

The courts have upheld similar requirements even in the absence of a significant risk finding, provided the requirements were reasonable. In *National Cottonseed Products Ass'n* v. *Brock,* 825 F.2d 482, 487 (D.C. Cir. 1987), the court upheld medical monitoring for cottonseed workers where OSHA found no significant risk. OSHA had eliminated the PEL but imposed the monitoring as a ''backstop'' to the ''no significant risk'' determination, and the court upheld the monitoring requirement because the ''evidence indicates that there is a real possibility of significant health risks'' where no PEL was imposed. Likewise, in *National Mining Ass'n* v. *MSHA,* 116 F.3d 520, 527–28 (D.C. Cir. 1997), the court upheld MSHA's decision to require oxygen at a 19.5% level, even though the evidence only showed that adverse worker effects were experienced at a lower level of 18%. The proper minimum oxygen level was ''a technical decision entrusted to the expertise of the agency,'' which was ''entitled to 'err' on the side of overprotection.'' *Id.* at 528. And in *Public Citizen,* the court upheld a requirement to post signs to warn employees of the hazards presented by ethylene oxide exposures without a separate significant risk determination, noting that signs and labels were specifically contemplated by section 6(b)(7) of the OSH Act and a ''reasonably necessary and appropriate'' part of a standard. 796 F.2d at 1502 n.16.

As explained in the Pertinent Legal Authorities section, the mixture cut-off levels are part of the HCS's general approach of providing prophylaxis against the exposure to significant risks, similar to the medical monitoring requirement in *National Cottonseed,* the higher oxygen level requirement in *National Mining Ass'n,* and the sign requirement of *Public Citizen.* The mixture cut-off thresholds are supported by substantial evidence, as discussed above and, therefore, authorized by the Act.

A related issue is the cut-off in Category 3 of Specific Target Organ Toxicity, both in Single Exposure and Repeat Exposure. Under the GHS, a cut-off/concentration limit of 20% is suggested as guidance. It is an additive cut-off, meaning that the percentages of the ingredients that meet the definition for Category 3 would be added together and compared to the cut-off. Consistent with other revisions to the GHS language that are appropriate for a mandatory standard versus a non-mandatory recommendation, OSHA proposed to make the 20% cut-off mandatory, but requested comment on it. (74 FR 50282, Sept. 30, 2009; see also A.8.3.4.5 and A.9.3.4.4.) A limit that is not mandatory will be difficult for chemical manufacturers to know how to comply with, and it will also be difficult for OSHA to enforce. Furthermore, OSHA views this provision as relaxing the current requirement, which is a cut-off of one percent for each of the ingredients in the mixture that are in and of themselves hazardous. However, consistent with A.0.4.3.2, if the classifier has information that the hazard will be evident below the specified concentration limit, the mixture is to be classified accordingly. Therefore, where the 20% is too high, the classifier will nevertheless be required to classify it appropriately below that level.

There were a number of commenters who supported making the 20% level mandatory, suggesting that it was reasonable for the U.S., promoted consistency, and that the level could be lower if data warrant (*See, e.g.,* Document ID #0313, 0324, 0327, 0329, 0330, 0338, 0339, 0353, 0365, 0381, 0410, and 0412). Others did not agree (Document ID #0323, 0328, 0344, 0376, 0379, 0382, 0393, 0399, and 0405). Some of these commenters suggested that OSHA should provide data to support making it mandatory. The GHS is drafted in voluntary terms, but the HCS is a mandatory standard, meaning that all of its provisions are mandatory as well. OSHA is unaware of specific data one way or the other on the question, but notes that this is a significant relaxation of the applicable cut-off under the current rule. Given the minor hazard presented by these chemicals, OSHA believes the 20% cut-off is appropriate to guard against overwarning. Because no alternatives were presented (other than making the provision voluntary, which is not an acceptable solution), OSHA has included the mandatory requirement in the final rule. Again, as noted above, chemical manufacturers or importers are still required to classify mixtures at lower concentrations if they have evidence that it presents a hazard, so OSHA does not believe the final rule is less protective.

Acute toxicity. In Appendix A, Chapter A.1 (''Acute Toxicity''), OSHA proposed to adopt GHS Categories 1 through 4, but not 5. The current coverage of the HCS is greater than Category 3 of the GHS, but does not include all of Category 4. If OSHA were to adopt only three categories, it would reduce protections with regard to acute toxicity. Adopting Category 4 expands coverage somewhat. However, chemicals meeting the definition of Category 4 are already covered under the national consensus standard on labeling that many chemical manufacturers already follow (ANSI Z129). In addition, the EU covered them under their previous classification, packaging, and labeling of dangerous substances (*Directive 67/548/EEC*) and preparations (*Directive 1999/45/EC*) directives, and their adopted GHS provisions. These countries comprise the largest trading partner in chemicals for the U.S. Thus, many manufacturers are already classifying their chemicals as acutely toxic to comply with European requirements.

Adopting Category 5 would not only expand coverage significantly, it would lead to inconsistency with Europe and with the current national consensus standard. OSHA also believes that exposures of this magnitude are not likely to be encountered in the occupational setting, and that such coverage would be excessive.

Since OSHA raised this issue for comment in the ANPR, a number of respondents specifically addressed acute toxicity. The responses varied, although a number supported the approach proposed to cover through Category 4 (Document ID #0021, 0046, 0047, 0077, 0104, 0123, 0135, 0145, 0155, 0163, and 0171). For example, Dow (Document ID #0047) stated:

> Dow believes that OSHA should adopt all health hazard criteria and categories, except Acute Toxicity Category 5. While this category may be useful for characterizing consumer products, its use with the substances characterized under the HCS would be confusing and unnecessary. Dow understands that the EU and Australia have both chosen not to include Acute Toxicity Category 5 in their implementation of the GHS and that Canada is currently considering doing the same. Dow believes that the U.S. should be consistent with these other major trading partners by not including this category when it adopts the GHS.

Others suggested that OSHA propose to adopt Categories 1 through 3 (Document ID #0034, 0128, and 0141). Some argued that all categories should be adopted to ensure harmonization (*See, e.g.,* Document ID #0018, 0036, 0050, 0078, 0106, and 0116).

OSHA believes that coverage provided by Categories 1 through 4 is appropriately protective for the workplace, and leads to the greatest harmonization with workplace authorities in other countries. With regard to coverage provided by Category 5, OSHA does not preclude inclusion of information on Category 5 on the label or the SDS. Thus chemical manufacturers or importers who wish to have one label that suffices for the workplace and the consumer sector, for example, could do that and still be in compliance with the HCS. As noted earlier, commenters on the NPRM supported the categories chosen by OSHA, except for a few who thought OSHA should adopt all categories in the GHS to promote complete harmonization. However, OSHA believes that this concern is addressed by permitting such categories to be addressed on labels and SDSs with no penalty.

OSHA did not propose to adopt Category 5. The final standard does not adopt Category 5, nor include it in Table A.1.1, which describes the criteria for acute toxicity. However, calculations for the acute toxicity of mixtures that are comprised of one or more ingredients that fall into Category 5 must include the acute toxicity estimate for the Category 5 ingredients. Proposed Paragraph A.1.3.6.1(a) indicated that the calculation of the acute toxicity of mixtures would ''[i]nclude ingredients with a known acute toxicity, which fall into any of the acute toxicity categories.'' This is consistent with the GHS (Subparagraph 3.1.3.6.1(a)).

As discussed in the Proposal, OSHA believes that the exclusion of Category 5 from the criteria Table A.1.1 may lead to classifiers overlooking substances falling into this category in the mixture calculation, which could result in a higher (less protective) classification. This could also mean a lack of harmonization within the U.S. if other Federal agencies adopt Category 5, potentially requiring inclusion of these data in the calculation. To avoid this situation, OSHA has clarified the text for the mixture calculation to ensure that the ingredients that would be classified as Category 5, and thus would not be classified under the HCS, are included in the mixture calculation. Paragraph A.1.3.6.1(a) has been modified to indicate the calculation must ''[i]nclude ingredients with a known acute toxicity, which fall into any of the acute toxicity categories, or which have an oral or dermal LD_{50} greater than 2000 but less than or equal to 5000 mg/kg body weight (or the equivalent dose for inhalation);''.

OSHA has modified the text of Note (d) to Table A.1.1 to help clarify the requirements. This was done in response to a comment from Dow (Document ID #0526), which stated that they were ''confused about the table,'' and that OSHA should revisit the table and the definitions to properly harmonize the provisions.

Several commenters noted that there were errors in Table A.1.2 in the NPRM (Document ID #0376, 0393, and 0405). The errors have been corrected in the final rule.

One commenter stated that the criteria seem to assume that acute lethality data are available in all situations, and they are not (Document ID # 0321). As with all other health hazard criteria in the standard, the HCS does not require data to be generated to comply with the standard. And the final rule recognizes that many chemicals have not been tested to ascertain their hazards. For example, the formula used to calculate the acute toxicity of a mixture makes an adjustment for ingredients whose acute toxicity is unknown. In addition, the fact that a mixture contains an ingredient of unknown toxicity must be indicated on the label and SDS. This is important because in some mixtures the unknown percentage could be significant, and therefore the estimation of toxicity for the mixture has less credibility than in a situation where the majority of the ingredients have data available.

It was also suggested that the formula used for acute toxicity be displayed in a way that is more commonly used for such equations (Document ID #0641). OSHA agrees that it could be displayed in a different way, but wanted to ensure it appeared the same in the regulatory text as it appears in the GHS. However, in guidance for application of the final rule, OSHA will include the formula in the alternative format as well to assist in understanding it.

The Styrene Information and Research Center (SIRC) challenged the proposal's requirement to disclose the concentration of ingredients in a mixture whose acute toxicity was unknown (Document ID #0361). It argued that ''[i]t is unclear how that requirement would pass a significant risk test'' and that ''[i]t seems unlikely to make the user more cautious.'' However, the record shows the contrary. Both workers and union representatives testified at the public hearing on this rulemaking that workers would be more cautious when dealing with chemicals of unknown toxicity and would look for substitutes where possible (Document ID #0494). Further, Cathy Cole, President of the American Industrial Hygiene Association, testified that industrial hygienists use the fact that a chemical's acute toxicity is unknown when they perform qualitative risk assessments. She testified (Document ID #0496 Tr. 425):

> [W]e would take that information and use it to weigh it against all the other information within that mixture. If there's an unknown, then we would most likely provide a safety factor as we did our risk assessment * * *. If there's a mixture that has a number of unknowns, then we would treat that very carefully and we would have a high risk ranking for it.

The final rule's hazard classification scheme for mixtures presenting acute toxicity hazards treats unknown toxicity in a similar way. When testing data on the mixture as a whole are not available, the acute toxicity of the mixture is determined by assuming that the nontoxic ingredients dilute the toxicity of the acutely toxic ingredients. (*See* A.1.3.6.2.) However, where the acute toxicity of a particular ingredient is not known, the final rule excludes it from the toxicity calculation. (A.1.3.6.2.4.) In effect, this means that ingredients with unknown toxicity are assumed not to dilute the toxicity of the known acute toxicants. This approach reflects the same cautious treatment of ingredients having unknown acute toxicity that the witnesses testified to, as discussed above. In addition, it is necessary to disclose the concentration of ingredients with unknown toxicity because downstream users need that information to classify any products they make with the mixture.

OSHA has also made two minor, clarifying changes to paragraph A.1.3.6.2.4 that are consistent with changes that were approved by the UN Sub-committee in December. The word ''relevant'' has been added in front of ''ingredient,'' and the word ''total'' was deleted before ''percentage.'' Therefore, A.1.3.6.2.4 in the final rule requires that if the total concentration of the relevant ingredient(s) with unknown acute toxicity is ≤10% then the following formula must be used:

$$\frac{100}{\mathrm{ATEmix}} = \sum_{\mathrm{n}} \frac{\mathrm{Ci}}{\mathrm{ATE}_{\mathrm{i}}}$$

However, if the total concentration of the relevant ingredient(s) with unknown acute toxicity is >10%, the formula presented above is corrected to adjust for the percentage of the unknown ingredient(s) as follows:

$$\frac{100-\left(\sum C_{unknown} \text{ if } >10\%\right)}{ATE_{mix}} = \sum_{n} \frac{Ci}{ATE_{i}}$$

The above discussion shows that SIRC's concerns about the unknown toxicity requirement are unfounded. Employers use the fact that a chemical's acute toxicity is unknown in determining how chemicals should be handled. As such, the disclosure requirement is reasonably related to the purpose of hazard communication and, therefore, within OSHA's authority. In addition, by providing the worker with information about the limits of the known information, the requirement provides the sort of prophylactic function that has been upheld even in situations where the Agency has not made a significant risk finding. The unknown toxicity requirement is consistent with the OSH Act.

Another commenter suggested the trade secret provisions should apply to the requirement for disclosing the concentration of ingredients with unknown toxicity (Document ID #0353). The revised rule (and the GHS) do not suggest that the names of the components be disclosed—simply the aggregate percentage of the total composition that has unknown acute toxicity. So if there are three ingredients in a mixture that have no acute toxicity data available, and they comprise 20% of the mixture, the label and SDS must indicate that 20% of the mixture has unknown acute toxicity. The names of the chemicals do not have to be disclosed, and neither does the number of chemicals involved. Therefore, there should be no trade secret issue.

Skin corrosion/irritation. OSHA proposed to adopt Categories 1 and 2, but not Category 3, for skin corrosion/irritation. Category 3 covers more than the criteria for this hazardous effect under the current HCS. In addition, the irritant effects covered by Category 3 are very minor and transient, and of limited applicability in the workplace setting. The Agency received several ANPR comments supporting such an approach (Document ID #0034, 0077, 0128, 0145, and 0171). This approach is also consistent with the European Union.

As OSHA noted in the preamble to the NPRM (74 FR 50392–93, Sept. 30, 2009), significant editing was done to the GHS text for this health hazard. The criteria in the GHS lead the evaluator to conduct additional testing when information is not available. While the GHS does not require testing, the criteria imply that it should be done to complete an evaluation. This implication is not acceptable under the HCS, which is based solely on available evidence.

As noted in the NPRM discussion, work had already been initiated in the UN Sub-committee to modify the chapter on skin corrosion/irritation to address inconsistencies and clarify provisions. That work has proceeded since the NPRM, and is on the work program for the next two years as well. OSHA has made modifications to the HCS criteria to reflect discussions in the Sub-committee, and clarify areas of concern. In particular, Chapter A.2 of Appendix A, ''Skin Corrosion/Irritation,'' was reorganized in the final rule so that text and figures are consistent. Paragraph A.2.1's title was changed to ''Definitions and general considerations.'' Paragraph A.2.1.2 was added to introduce a tiered approach to follow when classifying for skin corrosion/irritation. Paragraph A.2.2, ''Classification criteria for substances using test data,'' has been modified to reflect that it covers animal test data. In Paragraph A.2.3, ''Irritation,'' the factors used to determine the corrosion/irritation potential of a substance were deleted, and the text was reorganized to follow the tiered approach to classify substances using other data elements. Figure A.2.1 was updated to make it consistent with the text, and to show the tiered evaluation scheme instead of a testing scheme. Comments had been received that indicated this figure was confusing (Document ID #0344 and 0381). Another commenter noted that the criteria are provided without indicating how they were derived (Document ID #0321). The criteria were developed by a group of experts in the OECD and were derived from the existing criteria of the countries involved. They do not specify a test method because the GHS is test method neutral, but the OECD testing guidelines are generally agreed to provide the type of information needed for classification under the GHS.

There were also several comments that pH criteria are not appropriate to use in some situations (for example, the pH of the ingredients in a mixture may not predict the pH of the mixture) (Document ID #0321, 0335, and 0381). The criteria recognize that test data for these effects provide better information to base a classification on, but pH information can be of assistance when such data are not available.

OSHA believes the edits and changes make the chapter less confusing and clarify that testing is not required to achieve compliance. The basic provisions and approach remain the same as the GHS. The Agency is participating in the continuing work of the UN Sub-committee on this topic, and will revise the HCS if any additional clarifications are made in the criteria for these hazards that will help classifiers follow the provisions.

Serious eye damage/irritation. Proposed Appendix A, Chapter A.3 (''Serious Eye Damage/Eye Irritation''), did not include the criteria for Category 2B of eye irritation, but addressed the label elements for the category in Appendix C. A number of commenters indicated that OSHA should include the criteria for Category 2B (Document IDs #0344, 0351, 0367, 0371, 0381, and 0393), clarify coverage of Category 2B (Document ID #0376 and 0382), or exclude it (Document ID #0405). The omission of the criteria was an oversight, and OSHA has added the criteria for Category 2B to the final rule.

The text for GHS Chapter 3.3, ''Serious Eye Damage/Eye Irritation,'' posed similar issues to those described above for skin corrosion/irritation. The criteria in the GHS implied that testing might be needed to complete classification in the absence of data. This is required by neither the GHS nor the HCS. OSHA made a number of modifications to the parallel text in Appendix A, Chapter A.3, of the HCS proposal to address the perception that testing might be required when it is not. And the UN Sub-committee is also reviewing this chapter for purposes of clarifying the requirements.

As with the skin chapter, in the final rule OSHA has reorganized Chapter A.3 so that the text and figures are consistent, and so that it is clear that what must be followed is a tiered approach. The title of A.3.1 was modified to indicate it covers definitions and general considerations, and paragraph A.3.1.2 was added to introduce the tiered approach for classification. Paragraph A.3.2 (''Classification criteria for substances using animal test data'') was modified to indicate it addresses animal data. Table A.3.1 was modified to indicate that Category 1 corresponds to Serious Eye Damage and not to eye irritants, and Table A.3.2 adds the criteria for Category 2B. In A.3.3 (''Classification criteria for substances using other data elements''), the classification criteria for substances were reorganized using other data elements to make it consistent with Figure A.3.1, and to show the tiered evaluation strategy for classification. Figure A.3.1 was updated to make it consistent with the text. And Table A.3.3 now has a note to indicate that a mixture may be classified as Category 2B in cases when all relevant ingredients are classified as Category 2B. As with skin corrosion/irritation, OSHA will continue to monitor work in the UN Sub-committee to clarify these criteria, and will modify the rule to update the chapter as necessary if changes are made.

One additional issue was raised concerning the coverage of the GHS criteria for eye irritation in comparison to current criteria used by CPSC and EPA. The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) (Document ID #0384) suggests that the GHS criteria are not as protective as the current criteria used by CPSC and EPA. OSHA uses the CPSC criteria in the current HCS, but does not use EPA criteria. NICEATM did an analysis of a group of chemicals to determine what their classifications would be under the different criteria, and concluded that at least 14 of 149 chemicals it reviewed (17%) would not be classified under the GHS criteria, but would have been under current HCS criteria.

OSHA asked a consulting toxicologist familiar with the GHS criteria to review the comment and the analysis, and the results of his review have been entered into the public record (Document ID #0576, 0577, and 0578). The results of this review show that all of the 14 chemicals are differently classified because they present transitory effects that resolve in 72 hours or less; the difference in classification results from the way each method accumulates transitory positive results across test animals. While there may be some differences in conclusions made under the differing criteria, the differences are less pronounced when variance in transient effects is considered (as it is under the criteria as proposed). This is explained as follows in the toxicologist's report:

> In order to compensate for this difference in approaches, OSHA has proposed to also adopt the GHS concept of ''pronounced variability''. Under this concept, for those chemicals where there is pronounced variability among animal responses, such information may be taken into account in determining the classification. As discussed specifically under OSHA's proposed criteria for Classification and Categorization of Skin Corrosion/Irritation, but only mentioned in passing under Serious Eye Damage/Eye Irritation, this notion would allow for classification in cases where there are very definite, positive irritant effects related to chemical exposure in a single animal, but the overall data set does not support classification. In cases where the response is borderline but persistent or severe but transient, the Assessor would likely classify a substance as irritating. It is noted that there are at least two chemicals among those under examination where ''pronounced variability'' would likely cause the Assessor to classify them as irritants (see data for ethyl thioglycolate and glycidyl methacrylate; fomesafen, 2,2-dimethyl-3-pentanol, and cellosolve acetate might also be classified as irritants under this concept).

The final rule retains the pronounced variability language at A.2.2.2.2 and A.3.2.3. The toxicologist also noted that:

> Finally, a quick search of secondary and tertiary sources available on-line indicates that 12 of the 14 chemicals in question would be classified as hazardous materials under both the current and proposed classification criteria. Those that would not be classified are N,N-dimethylguanidine sulfate (sub-EU classification eye and skin irritation responses; not a sensitizer; no other data found); and tetraaminopyrimidine sulfate (not an acute or chronic toxicant; identified as non-irritating by EU Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP)).

Therefore, although the chemical may not be addressed as an eye irritant, it would still be considered a health hazard under the GHS—and the HCS—and thus have information available about its effects on labels and SDSs.

While OSHA appreciates the concerns raised by NICEATM, the criteria are being finalized as proposed, other than the modifications made for clarification purposes. It appears that the pronounced variability considerations will address some of the concerns raised, and that the primary remaining differences involve transient effects of relatively low concern. Both CPSC and EPA were involved in the development of the criteria in the GHS, and were aware of the differences between their existing systems and the agreed harmonized criteria. In harmonizing between the existing systems, the criteria selected were between what currently exists in the U.S. and in the EU. The classification criteria in each existing system is not a bright line determined by science, but rather a scientifically influenced policy determination, and as discussed elsewhere, an inevitable part of adopting harmonized criteria is that a few borderline chemicals might be dropped. No other stakeholders have raised the issue of whether the criteria are protective enough. OSHA is proceeding with the final rule because it believes that in this situation, maintaining harmonization with the GHS is ultimately more important for worker health. This situation will continue to be monitored as implementation takes place to ensure that it is appropriate.

Respiratory or skin sensitization. The final rule makes only minor changes to the proposed text of Appendix A, Chapter A.4, ''Respiratory or Skin Sensitization.'' The footnotes have been re-numbered since they were out of sequence in the NPRM. And the term EC3 has been explained in a footnote to Tables A.4.3 and A.4.4 (estimated concentration of test chemical required to induce a stimulation index of 3 in the local lymph node assay).

The GHS criteria for respiratory and skin sensitizers have one category for each type of sensitization, but also give the option of dividing that one category into two sub-categories, which involves a differentiation in the type of evidence available. In the NPRM, OSHA proposed to adopt the sub-categories for classification. One commenter strongly supported adopting sub-categories for these sensitizers (Document ID #0381), while another did not support it because the EU has not adopted sub-categories (Document ID #0376). OSHA is adopting the sub-categories as proposed. However, the Agency recognizes that there are situations where data are not available to place the chemical into one of the sub-categories. The GHS itself addresses this in 3.4.2.1.1.1 (respiratory sensitization), and 3.4.2.2.1.1 (skin sensitization). Therefore, under the revised HCS, simply classifying the chemical as Category 1 will be sufficient in cases where data are insufficient to assign a subcategory. The American Chemistry Council (Document ID #0393) suggested that more guidance is needed to differentiate potential and severe sensitizers for placement into the sub-categories. OSHA believes that this type of guidance should be developed through the Sub-committee process, rather than by countries independently developing guidance for application. The Agency will consider requesting the Sub-committee to develop such guidance.

Germ cell mutagenicity. The comments on this health hazard centered on whether or not it should be included in Appendix A. Procter & Gamble (Document ID #0381) and the American Chemistry Council (Document ID #0393) argued that it should not be included. The Soap and Detergent Association (Document ID #0344) also argued for exclusion, but said if it is included, only Category 1A should be covered. Ecolab (Document ID #0351) also argued that only Category 1A should be covered. These commenters argued that it is already covered by reproductive toxicity and carcinogenicity, and adding a separate hazard class would create a training burden.

OSHA disagrees. First, while the current HCS does not define mutagenicity as a separate health hazard, it is covered by the reproductive toxin definition. Under the GHS, mutagenicity is not covered by reproductive toxicity, and OSHA's failure to adopt the mutagenicity category would render the final less protective than the current HCS. The hazard class will have to be adopted to maintain coverage. Secondly, though mutagenicity data are used to predict carcinogenicity, the mutagenicity hazard is not covered by the carcinogenicity criteria. Furthermore, little additional burden for training can be claimed for what is already covered under reproductive toxicity in the current HCS.

All of these commenters argue that the HCS should be as consistent with the EU as possible. The EU has already adopted these criteria, so excluding them would not be consistent with the EU. OSHA is maintaining the hazard class as part of the HCS, and including both categories. It is OSHA's understanding that at present there are no chemicals that meet the criteria for Category 1A, so currently this has no burden associated with it—although there may be minimal burdens if new data in the future place chemicals in this category. (*See, e.g.,* Annex VI to the EU's former directive on classification and labeling, which states: ''To place a substance in category 1, positive evidence from human mutation epidemiology studies will be needed. Examples of such substances are not known to date. It is recognized that it is extremely difficult to obtain reliable information from studies on the incidence of mutations in human populations, or on possible increases in their frequencies.'') Chemicals in Category 2 are frequently used already in discussions of potential carcinogenicity, since mutagenicity test results are used to predict carcinogenicity. Thus, there is little burden associated with adopting that category either. Therefore, OSHA has retained Appendix A, Chapter A.5, ''Germ Cell Mutagenicity.''

OSHA included a new heading in A.5.4 entitled ''Examples of scientifically validated test methods.'' In the interest of maintaining current protections, as well as being consistent with implementation in the EU, germ cell mutagenicity is adopted in the final rule as proposed.

Carcinogenicity. The primary change to the carcinogenicity hazard class as proposed in Appendix A, Chapter A.6, ''Carcinogenicity,'' is the addition of A.6.4, ''Classification of carcinogenicity.'' In the current HCS, carcinogenicity was determined in part by consulting the National Toxicology Program's biennial Report on Carcinogens (RoC), or the International Agency for Research on Cancer's monographs. In addition, chemicals that are regulated by OSHA based on their carcinogenicity (*i.e.,* there is a substance-specific standard addressing the chemical, and the chemical poses a risk of carcinogenicity), are always covered by the HCS. The IARC and NTP documents are prepared based on the evaluation of data by experts convened by these organizations. A number of commenters suggested that this should still be permitted under the GHS-aligned criteria. For example, the United Steelworkers argued (Document ID #0403):

> The current Hazard Communication standard includes a reference to several lists of chemicals automatically presumed to be hazardous, such as the lists of carcinogens published by the National Toxicology Program (NTP) and the International Agency for Research on Cancer (IARC). The proposal removes references to such lists, in favor of a more detailed and complicated classification system. While that classification system is required by the GHS, the lists provide useful guidance and should not be removed altogether.
>
> We suggest the following compromise: OSHA should state in the regulatory text that a classifier may presume that the presence of a chemical on one or more of those lists is sufficient to classify the chemical as hazardous with respect to the hazard covered by the list. (OSHA should also state that the inverse is not true: The absence from a list does not indicate the lack of a hazard.) This does not mean that the classifier is required to classify a chemical as hazardous based solely on the list, only that he or she is free to do so. OSHA should also indicate in the preamble that the Agency will use the lists as guidance in enforcement, and that a classifier who ignores the lists should be prepared to show why his or her judgment is better than the judgment of, for example, NTP or IARC.

Similarly, Morganite Industries, Inc. and Morgan Technical Ceramics, stated (Document ID #0321):

> For example, IARC, NTP and other qualified organizations assess carcinogenicity and come to published conclusions. We do not understand why the proposed Hazard Communication Standard establishes procedures for chemical suppliers to conduct such assessments, seemingly asking them to conduct their own evaluations in the manner

of similar to these expert agencies. That makes no sense to us. Why not just refer to the conclusions published by these agencies? That would shorten and simplify the regulation, it would eliminate large parts of the difficult language and it would eliminate regulatory requirements that are in fact infeasible for most preparers of MSDS to comply with.

OSHA agrees with these commenters that allowing evaluators to rely on IARC and NTP could make classification easier for them, as well as lead to greater consistency. Therefore, A.6.4.1 has been added to the criteria in the final rule to indicate that classifiers may treat these sources as establishing that a chemical is a carcinogen without applying the criteria themselves. And A.6.4.2 reiterates that OSHA-regulated carcinogens are covered under the HCS.

In order to facilitate the use of IARC and NTP determinations as sources for purposes of classification, non-mandatory Appendix F has been significantly modified. In the NPRM, Appendix F was simply a verbatim quote of guidance from IARC on determining carcinogenicity. In the final rule, Appendix F has been updated to reflect the latest version of that IARC text, but also includes additional guidance on how to use IARC and NTP to make carcinogenicity classifications. The inclusion of this guidance should make classification easier for chemicals addressed by these sources, and should also provide parameters for the type of weight-of-evidence decisions that are appropriate under the GHS-aligned criteria.

The following table is included in Part D of Appendix F, and may be used to perform hazard classifications for carcinogenicity under the HCS. It relates the approximated GHS hazard categories for carcinogenicity to the classifications provided by IARC and NTP, as described in Parts B and C of Appendix F:

TABLE XIII–2

Approximate equivalences among carcinogen classification schemes

IARC	GHS	NTP RoC
Group 1	Category 1A	Known.
Group 2A	Category 1B	Reasonably Anticipated (See Note 1).
Group 2B	Category 2.	

Note 1:
1. Limited evidence of carcinogenicity from studies in humans (corresponding to IARC 2A/GHS 1B);
2. Sufficient evidence of carcinogenicity from studies in experimental animals (again, essentially corresponding to IARC 2A/GHS 1B);
3. Less than sufficient evidence of carcinogenicity in humans or laboratory animals; however:
a. The agent, substance, or mixture belongs to a well-defined, structurally-related class of substances whose members are listed in a previous RoC as either ''Known'' or ''Reasonably Anticipated'' to be a human carcinogen, or
b. There is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.

While the criteria for carcinogenicity (as well as other health effects) are largely based on weight of evidence evaluations, there are also provisions in the GHS for countries that want to ensure that all potential carcinogens are adequately captured by the criteria. Thus paragraph 3.6.2.6 of the GHS chapter on carcinogenicity states:

> * * * For inclusion into Safety Data Sheets, positive results in any carcinogenicity study performed according to good scientific principles with statistically significant results may be considered.

OSHA chose to include this requirement in Figure A.6.1 of Appendix A in the NPRM under Category 2, suspected human carcinogen. Specifically, the statement read:

> Positive results in any carcinogenicity study performed according to good scientific principles with statistically significant results qualifies for referencing the chemical as, at the least a Category 2 carcinogen.

The Styrene Information and Research Council (SIRC) (Document ID #0361) argues that the ''one positive study'' criterion is inconsistent with the weight of evidence approach. In fact, it is not part of the weight of evidence approach, but rather reflects the Agency's decision to ensure that the current level of protection in terms of identifying potential carcinogens in the workplace is maintained in the HCS as permitted by the GHS provisions.

SIRC also indicated that it is not clear what is meant by ''referencing'' the chemical as, at the least, a Category 2 carcinogen. OSHA agrees that the inclusion of this language in Figure A.6.1 is not as clear as it could be in terms of what is required. In the final rule, OSHA has separated this requirement from Category 2, and added a new heading of ''Other considerations'' to the table. The text for the ''Other considerations'' is: ''Where the weight of evidence for the carcinogenicity of a substance does not meet the above criteria, any positive study conducted in accordance with established scientific principles, and which reports statistically significant findings regarding the carcinogenic potential of the substance, must be noted on the safety data sheet.'' Categories 1 and 2 will remain based on weight of evidence, but the data that meet the definition of ''other considerations'' must also be provided on the SDS for the chemical. This will maintain the protections of the current rule and provide information to downstream users so they can determine the appropriate protective measures to be taken in these situations.

In paragraph A.6.3.2 of the NPRM, OSHA included the mixture approach in GHS paragraph 3.6.3.1 regarding use of test data as a whole to characterize the carcinogenic potential of a 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.

SIRC (Document ID #0361) similarly took issue with this provision:

> Again, the use of the word ''conclusive'' appears to be an inappropriate attempt to apply the European Precautionary Principle to this issue. It is inconsistent with the fundamental principle that hazard communication is to be based on the application of expert judgment to known information and not require chemical testing (either explicitly or as an inevitable practical requirement to avoid unacceptable economic consequences). The word ''conclusive'' should be replaced with the word ''adequate'' or ''persuasive.''

The provision in A.6.3.2 recognizes that it is difficult to accurately characterize the carcinogenicity of a mixture with an ingredient that is clearly carcinogenic. It requires skilled, expert judgment, and test results on the mixture as a whole may be misleading. Therefore, the experts who developed the carcinogenicity criteria believed that given the critical nature of this effect and the known limitations of assessing carcinogenic potential in a mixture, it was appropriate to allow testing of the mixture as a whole to supersede an evaluation based on the carcinogenic potential of a known ingredient only when the data allow a sufficient level of confidence about the mixture's hazards. OSHA agrees with the findings of these experts, and does not believe that the word ''conclusive'' needs to be replaced. This provision remains the same in the final rule. It also does not require or imply that any testing of chemicals be performed. It is actually rather unusual to have mixtures tested for any types of effects, so it is expected that this provision will not be applied frequently. If a test is performed voluntarily with the purpose of avoiding characterization of a mixture as a carcinogen, it is very important that the test provide conclusive evidence before depriving downstream users of information that ingredients in the mixture present a carcinogenicity hazard.

In addition to the technical considerations, SIRC (Document ID #0361) (as well as SPI, Document ID #0392), repeatedly suggests that the precautionary principle, or European approaches, are the genesis of various provisions. First, OSHA does not agree that the precautionary principle had any part in the GHS, or the HCS, provisions. The HCS is an information transmittal standard, not a standard that requires the implementation of controls or other risk management approaches. The precautionary principle generally applies to competent authorities, and allows them to regulate or establish controls in situations where complete information is not available about the situation. That certainly does not apply to this provision in the HCS, which requires definitive data before allowing a chemical manufacturer or importer to designate a mixture as not being carcinogenic, although it contains an ingredient that clearly has a carcinogenic potential. The HCS is a standard that is intended to provide information to users of chemicals so they can make their own determinations as to what controls are needed to prevent adverse health effects or the effects of physical hazards. The better information they have about the chemicals in their workplaces, the more likely they will be able to make their own risk assessments, and choose appropriate risk management measures. The provisions of the HCS—as well as the GHS—are designed to ensure that such information is available to users.

The criteria proposed are adopted in the final standard, with the addition of the paragraphs referring to NTP, IARC, and OSHA-regulated substances, and supplemented by the revised non-mandatory Appendix F.

Reproductive toxicity. This hazard class, described in Appendix A, Chapter A.7, was proposed to have two hazard categories (Category 1, which is subdivided into two sub-categories based on human evidence, and Category 2, which also includes evidence from animal studies). In addition, it requires consideration of effects on or via lactation. Several commenters argued that OSHA should not adopt effects on or via lactation (Document ID #0344, 0351, and 0381). The rationale provided is that there is no standard assessment method. However, the criteria already recognize that there is no standard assessment method, and provide the types of information that can be used to assess whether a chemical poses this effect. While such information may not be available for many chemicals, there are certain types of products that may have such information available, and it is information that needs to be provided to exposed workers. Therefore, OSHA is maintaining effects on or via lactation in the final rule. In addition, this maintains consistency with the EU approach.

The only change OSHA has made in the final rule is to change ''should'' to ''shall'' in A.7.2.5.4, since it is mandatory in the HCS. Otherwise, the criteria are adopted as proposed in the text of the final rule.

Specific target organ toxicity single exposure (STOT–SE). This hazard class, described in Appendix A, Chapter A.8, was proposed to have three categories. The first two categories deal with differences in the type of evidence available to assess the effect, while the third addresses transient target organ effects, such as narcotic effects and respiratory irritation. Several commenters indicated that Category 3 could be adopted without adopting Category 2 (Document ID #0344, 0351, 0381, and 0393). Procter & Gamble (P&G) (Document ID #0381) argues that Category 2 should not be adopted:

> There are also a significant difficulty and potential unintended outcome that weigh against applying Category 2. Animal studies may be done for a variety of purposes, some of which are not relevant to consumer product uses, and the interpretations of animal data from these types of studies often yield conclusions not relevant to consumer products. Using the outcomes from animal studies for classification into Category 2, especially studies at exposures near the point of morbidity, requires an unusual level of expertise that many classifiers would not possess. In addition, classification into Category 2 relies on interpretation of the phrase ''relevant to human health,'' which would involve an additional expertise. Therefore, Category 2 should not be adopted.

There are a number of difficulties with this argument. First, this section addresses protection of workers exposed to chemicals, and not the assessment of consumer products and exposures. Many consumer products are not covered by the HCS, although provisions in the scope and application cover those products where they are used in the workplace in a manner different than consumers would use them, or with a more extensive duration and frequency of use.

In devising the Category 1/Category 2 approach to classifying specific target organ toxicity after single (and repeated) exposure, the framers of the STOT–SE (and STOT–Repeated Exposure) criteria sought to establish a means by which the chemical manufacturers and importers could communicate to the worker information as to both the nature and the severity of adverse systemic and target organ effects. The final rule provides detailed criteria to clarify what would be considered an ''adverse'' effect (*See* A.8.2.1.7.3*),* and it also provides specific examples of effects (''changes'') that might be seen in animal studies, yet would not be considered to be ''adverse'' (A.8.2.1.8).

Using these criteria and examples, classifiers will be able to consider whether a change was, as required by Category 2, ''of *relevance for human health.''* In specific cases when an evaluated change was deemed not to be relevant, the classifier is allowed to discount specific toxicological study findings that are not relevant to human hazard assessment and not classify. OSHA believes that classification under Category 2 will be no more difficult than other hazards under the rule, and that no ''special additional experience'' will be needed to classify for Category 2, as suggested by P&G.

Additionally, the GHS-based STOT criteria proposed for adoption by OSHA sought to introduce the concept of dose response to the communication of specific target organ toxicity hazards. Such a concept has long been part of the assessment of acute toxicity hazards, but has been missing from the communication of many other health hazard endpoints. Adoption of both Categories 1 and 2, as proposed, allows the chemical manufacturer/importer of a chemical to convey to the worker additional information as to the characterization of the specific target organ hazard by providing some general measure of whether an effect (change) might be expected at low (presumably occupationally relevant) exposure, or whether it would be seen only in cases of unusually high exposure (*e.g.,* catastrophic loss of safety controls).

P&G also suggests that Category 2 is inconsistent with paragraph 3.8.1.3 of the GHS in that ''it does not rely primarily on human data * * *.'' However, while GHS 3.8.1.3 (A.8.1.3 in the final rule) does say that human data will be the ''primary source for classification,'' it also specifically states that classification in this hazard class may also be made on reliable evidence ''in experimental animals, toxicologically significant changes * * *.'' Thus, P&G's contention is not accurate. In addition, animal data are used or referred to throughout the criteria in the GHS for health hazards, and the use of such data to predict effects in exposed humans is a standard toxicological approach.

In addition to its appropriateness for protection of workers, Category 2 has been adopted by the EU, and adopting it in the final rule will thus maintain consistency with the EU as well.

Aspiration hazard. OSHA did not propose to adopt Category 2 for aspiration hazards covered by the GHS. This category appeared to be more appropriate for the consumer sector than the workplace. OSHA does not specifically address aspiration hazards in the current HCS although the Agency believes the more relevant and serious Category 1 aspiration hazards are captured under the broad scope of the rule. Several ANPR commenters agreed that Category 2 should not be covered in the HCS (Document ID #0034, 0077, 0128, 0145, and 0171), and the EU does not include it in their requirements. Others suggested that aspiration should not be covered at all since it is not relevant to the occupational setting (Document ID #0102, 0104, and 0163).

Several commenters on the NPRM also argued that aspiration hazard should be completely excluded from the revised HCS (*See, e.g.,* Document ID #0373, 0393, 0398, 0486, and 0528). In addition, one comment suggested that the criteria could be interpreted as applying to drowning, and is overbroad (Document ID #0353).

The primary proponent for complete exclusion of aspiration as a hazard in the revised GHS was the Hydrocarbon Solvents Panel (the Panel) of the American Chemistry Council. In their post-hearing comments, the Panel summarized their position as follows (Document ID #0528):

(1) OSHA should not adopt the Aspiration Toxicity class under the GHS because, as demonstrated by data submitted to the record, aspiration as a route of exposure is not common in the industrial setting, and is not a significant cause of occupationally related severe or fatal poisonings.

(2) Should OSHA include Aspiration Toxicity as one of the Health Hazard classes, the Panel urged that OSHA not require the Health Hazard Symbol be used as part of the pictogram because it does not accurately symbolize the nature of the hazard represented by the aspiration route of entry, and could be potentially misleading.

(3) Should OSHA include Aspiration Toxicity and a symbol, the Exclamation Mark symbol is more appropriate for the Aspiration Hazard Pictogram. Of the existing symbols in the proposed rule, the Exclamation Mark symbol is more representative of an actual aspiration episode. The Exclamation Mark would be a better choice to connote the hazard endpoints and response necessary in an aspiration event, due to the immediate need for intervention in an aspiration episode.

(4) If OSHA is unwilling to adopt the Exclamation Mark symbol for Aspiration Toxicity, we request that OSHA forward the concern to the UNSCEGHS for its consideration.

With regard to the Panel's first point, OSHA agrees that this route of exposure is not frequently found in the occupational setting. But that is different than saying it does not occur, or should not be a concern. NIOSH has submitted a number of studies and reports to the record that document concerns about aspiration (Document ID #0523 and 0524), and address occupational exposures as well (Document ID #0523). For example:

Amoruso et al. [2008] reported that aspiration of mineral spirits into the lungs may produce serious damage leading to bronchopneumonia that may be fatal within 24 h[ours] * * *.

Rodriguez et al. [1991] reported a case incident where deaths in 3 crude oil tanker workers were reported as attributed to pulmonary aspiration as evidenced by histopathology studies. The hypothesized mechanism of deaths included the contributing factors of asphyxia by toxic gases leading to loss of consciousness, traumatic injury and aspiration.

A number of other cases are described in the NIOSH comment. The Panel itself noted two aspiration fatalities in the period from 2003 to 2007, one of which was related to a corrosion inhibitor, and the other to sodium bisulfate (Document ID #0486, 0494 Tr. 212). Moreover, the Panel's chair testified that her company includes aspiration hazard warnings on all of its products (Document ID #494 Tr. 214–15). Therefore, it is clear to OSHA that there are legitimate concerns about aspiration in terms of both occupational injuries and fatalities, and that aspiration hazards need to be included in the scope of the HCS. Thus, OSHA included Chapter A.10, ''Aspiration Hazard,'' in Appendix A in the proposed rule and has retained it in the final rule.

With regard to the symbol, the application of the more severe health hazard symbol to a Category 1 hazard category is consistent with how the symbols are applied to all of the health hazards. Adopting the exclamation mark in the U.S. for aspiration Category 1 would make the HCS inconsistent with other countries' rules regarding aspiration hazard, which would present difficulties for countries exporting to the U.S., and potentially create inconsistencies in what workers see on labels and SDSs. This would not be an effective communication approach to aspiration hazards. Therefore, OSHA does not agree that the exclamation mark should be permitted for Category 1 aspiration hazards. In terms of presenting it to the UN Sub-committee as an issue, OSHA will take that suggestion under advisement. However, industry stakeholders are free to make this suggestion to the Sub-committee themselves through submission of a paper.

With regard to the contention that drowning in water could conceivably be read as being covered by the aspiration hazard criteria, OSHA assures stakeholders that drowning in water is not covered and that the HCS will not be interpreted as addressing drowning in water as an effect covered by the rule.

Aspiration Hazard, Category 1, is included in the final rule as proposed.

Appendix B, Physical Hazards. Appendix B includes the criteria for the physical hazards proposed to be covered by the HCS to be consistent with the GHS. The current HCS covers these hazards, but the definitions, while similar, are not the same as those included in the GHS. The GHS based its physical hazard criteria on those incorporated into the United Nations' Recommendations on the Transport of Dangerous Goods. In the U.S., the Department of Transportation (DOT) has already harmonized its definitions with the UN, and thus, with few exceptions, the GHS. While OSHA's initial physical hazard definitions were consistent with the DOT definitions at the time the current HCS was promulgated, DOT's harmonization with the international requirements resulted in the two agencies having different definitions. Thus the U.S. has not been domestically harmonized for some years. Adopting the same definitions in this rulemaking as DOT has in this rulemaking will have the additional benefit of accomplishing substantial domestic harmonization.

As with Appendix A and the health hazard criteria, OSHA edited Chapter 2 of the GHS (''Physical Hazards'') to shorten the discussions and focus only on the criteria in the proposed revisions. Decision logics and hazard communication information are not included. As with health hazards, OSHA tried to maintain the current scope of the HCS for physical hazards in the proposal, as well as being as consistent as possible with trading partners, particularly the European Union. One exception may be flammable gases, where it appears that more flammable gases will be covered by OSHA adopting Category 2 than are currently covered by the HCS. OSHA is adopting all of the physical hazards in the GHS.

The one deviation from the approach adopted by the European Union is in the proposed adoption of Categories 1 through 4 for flammable liquids. The European system only addresses Categories 1 through 3. The current HCS covers flammable liquids in Category 4, and exclusion of this category would result in reduced protection, which OSHA does not believe is appropriate. Thus Category 4 is included in the revised HCS.

One edit that should be noted occurs in the criteria for explosives. The GHS criteria currently use the term ''article'' in a manner that is inconsistent with that term as used in the workplace in the U.S. OSHA has changed the term to ''item'' in these criteria. This modification was supported by stakeholders (*See, e.g.,* Document ID #0362).

While OSHA believes that harmonizing with DOT provides significant benefits, there were some concerns regarding this approach that arose in reviewing the physical hazard criteria. These concerns involved the test methods referred to in the GHS criteria, which are based on issues related to the packaging and volume in transportation. Packaging is obviously a major concern in transport, and is used to address or mitigate the risk of conveying certain types of chemicals. These chemicals may or may not be present in the workplace in the same size or type of packaging and the relevance of these factors in the test methods are questionable in terms of workplace exposures. OSHA invited comment on these factors, including comments on the appropriateness of the criteria (including the test methods and references to packaging or volume) when applied to the workplace, and any suggestions that interested parties have to address these issues. Of particular interest were criteria for self-reactive chemicals, organic peroxides, self-heating chemicals, and explosives. Commenters indicated that the criteria could be applied to the workplace (*See, e.g.,* Document ID #0330, 0336, 0383, and 0405). Others specifically noted that OSHA should maintain consistency with DOT (*See, e.g.,* Document ID #0338, 0344, 0351, 0376, 0379, 0381, and 0392). For example, the Industry Minerals Association—North America stated (Document ID #0379):

The classification, labeling, handling and storage of chemicals related to transport concerns should remain aligned with the principles of HCS. OSHA should seek where possible to reduce incompatibilities between HCS criteria and US DOT transportation requirements.

Accordingly, OSHA has decided to carry through these requirements to the final rule as proposed. OSHA is satisfied that, in this respect, the criteria proposed are appropriate.

The Society of the Plastics Industry, Inc. (SPI) (Document ID #0392) contends that the requirements will not be possible to implement for organic peroxides:

The GHS would require that the SDS for organic peroxide include:

(1) Recommended use of the chemical and restrictions on use;

(2) Precautions for safe handling;

(3) Conditions for safe storage, including any incompatibilities, and

(4) Appropriate engineering controls.

Compliance with these requirements, which include principles from the EU regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), presents a particular concern for organic peroxide producers following transportation and initial storage in the DOT-regulated transport container. As written, compliance would present unreasonable difficulties and appears to be infeasible for suppliers of these chemicals. Customers are likely to handle and use these materials under significantly different conditions once they remove the organic peroxides from the packages in which they were transported.

SPI further recommends that OSHA require ''that labels and SDSs include a generic statement of fact indicating that changes in risk and hazard can occur when these self-reactive materials are moved from normal transport and storage conditions into process settings, and that they may require assessments by specialists.'' SPI also suggests that OSHA should be harmonizing with DOT in this area.

SPI indicates that these requirements for information on SDSs originate with REACH requirements in Europe. In fact, OSHA has always required such information on SDSs (with the exception of intended use of the chemical, and restrictions on use), and these requirements preceded REACH by many years—as did the negotiated text of the GHS. In § 1910.1200 (g)(2)(viii) and (ix) of the HCS promulgated in 1983, the preparer of the MSDS is required to provide any generally applicable precautions for safe handling and use, and any generally applicable control measures such as engineering controls, which are known to the chemical manufacturer, importer or employer. OSHA also notes that the manual supplied and written by SPI: ''SAFETY AND HANDLING OF ORGANIC PEROXIDES: A Guide'' (dated August 1999), recommends that downstream users consult labels and MSDSs for handling information (Document ID #0392). OSHA does not agree that the SDS requirements in the NPRM, and the final rule, are infeasible or even substantially different than what has been required by OSHA since 1983. The Agency does not agree that the suggested statement should be required by OSHA regarding organic peroxides. Chemical manufacturers and importers of organic peroxides are free to provide whatever advice they deem appropriate in the supplementary information part of the label, or on the SDS, to guide downstream users for appropriate handling, as long as the advice does not conflict with the required hazard communication information.

With regard to harmonizing with DOT, the criteria in the final rule are the criteria that DOT adopted from the UN Transport recommendations. Therefore, OSHA is harmonizing with DOT through this rulemaking.

One commenter indicated that there was concern that criteria based on transport classification may confuse workplace application, and guidance would be needed (Document ID #0339):

Concerns have been expressed that the criteria developed for transport concerns, as stated in the GHS, express very specific constraints, or ''worse case scenarios'', which can be confusing to suppliers and users of chemicals who are reading the Safety Data Sheets (SDSs)/labels, etc., without benefit of the context. PRR believes this is an area in which OSHA could develop informational materials to help chemical suppliers and users understand the rationale behind physical hazard classifications.

OSHA will keep this suggestion in mind as guidance materials are developed.

Only minor editorial revisions have been made to Appendix B after reviewing all of the comments received. While a great number of changes were suggested by one commenter (Document ID #0353), most have not been adopted, consistent with the discussion above on the background for Appendixes A and B. This approach is to maintain consistency with the GHS and DOT, as well as the EU.

The modifications made in the final rule include changing metric references to units used in the U.S., and modifying references to documents incorporated by reference to make them consistent with OSHA's requirements for such references. There are no technical changes to the criteria. Therefore, Appendix B in the final rule is substantially the same as proposed.

Classification Database

One interesting comment that was submitted by a number of respondents to the ANPR involved development of a classification database (Document ID #0047, 0050, 0053, 0054, 0038, 0155, 0160, and 0165). Opinions as to who would develop and maintain such a database varied (OSHA, U.S. industry, and an international body were all mentioned). It appears that the European Union will be making such a database available for compliance with its requirements, as have Japan, Taiwan, South Korea, and New Zealand. Concerns have been raised by stakeholders that classifications in these databases are different for the same chemical. OSHA invited additional comment on this issue in the NPRM (74 FR 50284, Sept. 30, 2009), and received a number of responses.

Many supported the concept of having such a database (Document ID #0328, 0329, 0330, 0335, 0336, 0339, 0341, 0352, 0365, 0366, 0379, 0383, 0389, 0408, 0410, and 0453). There were also various comments about how a database might be done. Some thought OSHA should do the classifications and maintain them online, or that the classifications should be considered ''official'' (Document ID #0330, 0341, and 0453). Others were concerned about the Agency's ability to develop and maintain a database (Document ID #0339), or said it should only be done if resources were provided to maintain it (Document ID #0365). Alternatively, resources could be provided for classifiers to help improve the quality of their classifications (Document ID #0365).

Others suggested that NIOSH could be tasked with developing and maintaining the database (Document ID #0341 and 0408). NIOSH commented that funding is not currently available, and that OSHA may wish to partner with the EU database efforts (Document ID #0412). Additionally, NIOSH and another commenter (Document ID #0383) suggested alternatives to developing a database using existing information such as the Department of Homeland Security's database; using International Chemical Safety Cards that currently cover 1,650 substances and are translated into many languages; or adding GHS classifications to the National Library of Medicine, including its Hazardous Substances Data Bank. NIOSH is also updating its Pocket Guide to include GHS classifications.

Another suggestion was to have the UN develop a database so there is a globally harmonized list, and the Department of Labor could help support it (Document ID #0328 and 0335). The National Fire Protection Association (NFPA) (Document ID #0366) suggested that its database of 2,500 chemicals could be useful in the transition. Other commenters suggested that suppliers can provide classifications to a central repository (Document ID #0352, 0408, and 0410), but one commenter warned that if left to manufacturers, there would be differences that would have to be resolved downstream (Document ID #0328). Another comment raised a concern that, while a common database might be useful, it could also interfere with weight-of-evidence determinations (Document ID #0379). However, such a database could prove useful for substances, which would provide the basis for mixture classifications (Document ID #0335).

Other commenters did not support having a classification database (Document ID #0324, 0344, 0351, 0370, and 0377), or indicated that if OSHA were to develop a classification list, it should be non-binding guidance, and include stakeholder input and global accessibility (Document ID #0344, 0381, 0393, and 0405). Others were concerned that a common database would create another unharmonized list of classifications compared to lists in other countries (Document ID #0344), and that manufacturers should have the responsibility for classification (Document ID #0324 and 0405). Also, a company could have valid data that contradicts a classification assigned in a database, and should be allowed to use its own information (Document ID #0351). There was also a concern that such a list might impede progress by not using the best available data (Document ID #0377). Another commenter argued that the database would need to be internationally developed and maintained to be useful, which would result in the elimination of national or regional lists (Document ID #0376).

OSHA is very interested in whether an international database of classifications could be developed and maintained. It is not likely to be feasible for OSHA to develop and maintain a U.S.-based database, which, as some have noted, would be less useful than an internationally harmonized approach that preempts countries and regions from developing their own approaches. The subject has been raised and discussed in the UN Sub-committee, and a correspondence group has been established to explore the issue further. OSHA has volunteered to lead that group and to help form a consensus position in the Sub-committee on options to address this issue. In the meantime, some of the suggested sources can provide extensive information to assist businesses with GHS classifications, particularly small businesses with fewer technical resources. The International Chemical Safety Cards—which are linked on both OSHA and NIOSH Web pages—are one such resource. The OECD has also established a global chemical portal that includes extensive information on chemicals (*www.oecd.org/ehs/eChemPortal*).

(e) Written hazard communication program. The GHS does not include provisions for a written hazard communication program. Thus the provisions of this paragraph are not directly affected by implementation of the GHS. The only changes proposed align terminology *(i.e.,* the proposal uses the term ''safety data sheet'' rather than ''material safety data sheet'').

The written hazard communication program requirements in paragraph (e) are intended to ensure that hazard communication in a given workplace is coordinated and comprehensive. An employer's program must include a list of the hazardous chemicals known to be present in the workplace (paragraph (e)(1)(i)). This list is basically an inventory of the chemicals the employer must have safety data sheets for, and must be available to employees so they, too, can determine what chemicals should be included under the hazard communication programs in their workplace. The list can be maintained by work area or for the workplace as a whole, and must be kept by an ''identity'' of the chemicals (which will be the ''product identifier'' under the final rule). In other words, the inventory can be common names or product names, rather than individual chemical ingredients of each product by specific chemical identity or chemical name.

The employer's hazard communication program must also include how the standard's requirements for labels, SDSs, and training will be met (paragraph (e)(1)); how the hazards of non-routine tasks will be addressed (paragraph (e)(1)(ii)); and how hazard communication will be handled in a multi-employer workplace situation (paragraph (e)(2)). OSHA has provided guidance over the years on completing a written program, and there are many sample programs in circulation. The program need not be lengthy or complicated, but it should have enough detail to provide the reader with a blueprint of the workplace-specific program.

Several comments to the ANPR were received from the Small Business Administration (SBA) and others that suggested there would be significant burdens associated with revising the written program as a result of implementing the GHS (*See, e.g.,* Document ID #0022, 0027, 0111, and 0164). Revising the chemical inventory was cited by these commenters as one aspect that was likely to be burdensome. Since the chemical inventory is basically a list of the products an employer has in the workplace that are considered hazardous, the only way this list would change as a result of implementing the GHS would be if something that was not hazardous before is now, or vice versa. OSHA believes that this is not a significant concern for three reasons. First, it would be unusual for a chemical to only have one hazardous effect associated with it so that the overall determination of hazard would be affected by a change in classification in one hazard class. Second, because HCS currently covers hazardous chemicals, unless the chemical is new, it is highly probable that it is already covered. Third, as discussed above in relation to paragraph (b) (Scope and application), OSHA does not believe that the scope of hazards covered by the final rule is substantially different than the current HCS.

The most likely differences resulting from re-classification under the final rule are that a chemical would be placed in a category under a hazard class that does not currently include categories. It may also be possible that a chemical may fall into a different category where there are already defined categories (such as flammability). Neither of these differences would necessitate a change in the inventory.

With regard to other changes in an employer's program, it does not appear likely there would be many, if any at all. Written hazard communication programs usually include provisions such as who in the organization is responsible for implementing different parts of the program, or the type of in-plant labeling system used. The final HCS will not affect those provisions. OSHA does not believe that extensive revisions would have to be made to written programs, including the inventory, under the final rule.

OSHA did not propose any substantive modifications to the written hazard communication program, and it does not anticipate any significant new burdens associated with revising the program as a result of other modifications in the final rule.

While the written hazard communication program was mentioned several times in relation to the costs of compliance, or the burdens on small businesses, it was generally not discussed in a substantive way by rulemaking participants. The Building and Construction Trades Department of the AFL–CIO (Document ID #0359) expressed concerns about the challenges associated with implementation of the HCS on multi-employer worksites, a subject that is addressed in the written hazard communication program requirements. They suggested that the controlling employer on a site coordinate hazard communication activities. This is not a subject related to adopting the GHS, and no changes are being made to the rule to address it. The written program must address how the exchange of information will be accomplished, and that will continue under the final rule.

(f) Labels and other forms of warning. The HCS is designed to provide information through three different media: labels or other forms of immediate warning; safety data sheets; and training. Labels are attached to the container of chemicals, and thus provide the information that employees have the most ready access to in the workplace. Given that they are attached to containers, they are by necessity somewhat limited in the amount of information they can present. The labels provide a snapshot or brief summary of the more detailed information provided to employees in training programs, or available to them on safety data sheets. They are not intended to be a complete or detailed source of information on the chemical.

In the current HCS, the requirements for labels are performance-oriented. At the time the standard was promulgated, there were many different types of labels in use. A common label format used by industry was that provided by the ANSI Z129, Hazardous Industrial Chemicals—Precautionary Labeling standard. Employers following this format at the time provided a number of different types of information on the chemicals involved. However, there were two areas where employers were inconsistent or did not necessarily provide what was needed when following the national consensus standard. The first was provision of an identity on the label that could lead a chemical user to the specific chemical identities for the hazardous ingredients. It was common practice to provide a trade name for a product, but not the names of ingredients, on either the label or the safety data sheet. The second was provision of specific information on the hazards involved, such as the target organ affected.

The current HCS label provisions focus on this typically missing information. On shipped containers, chemical manufacturers or importers are required to include an identity, and appropriate hazard warnings, as well as their name and address or that of a responsible party. The term ''identity'' is defined in the current HCS definitions (paragraph (c)) as ''any chemical or common name which is indicated on the material safety data sheet (MSDS) for the chemical. The identity used shall permit cross-references to be made among the required list of hazardous chemicals, the label and the MSDS.'' The hazard warning is to provide specific information about the health or physical hazards posed by the chemical. The term is defined as ''any words, pictures, symbols, or combination thereof appearing on a label or other appropriate form of warning which convey the specific physical and health hazard(s), including target organ effects, of the chemical(s) in the container(s). (*See* the definitions for 'physical hazard' and 'health hazard' to determine the hazards which must be covered.)''

The current HCS similarly requires identity and appropriate hazard warnings for in-plant containers. OSHA has taken a flexible approach to in-plant labeling, allowing a wide variety of systems to be used as long as all of the required information is readily available to employees when they are in their work areas. Thus the current standard allows employers to continue to use systems such as the Hazardous Materials Information System (HMIS) and the National Fire Protection Association (NFPA) labeling systems that use numerical rankings of hazard.

The labeling provisions of the current HCS exemplify the overall performance orientation of the rule. They establish the basic information requirements for chemical manufacturers and importers, but do not specify a format, or any particular label elements to be used. As a result, labels are often quite different when the same chemical is addressed by different suppliers, creating the potential for employee confusion. While many manufacturers follow the ANSI national consensus standard, others do not. Large manufacturers have frequently developed their own libraries or repositories of standard phrases, with decision logics for when to apply them to convey a hazard or a precaution. Therefore, not only does this approach lead to labels that are different, it also results in a large duplication of effort by chemical manufacturers developing their own systems.

This performance-oriented approach also did not lend itself to harmonization. Other countries often use more specific approaches, including assignment of standard phrases to certain hazardous effects, symbols, and other label elements. It was clear that the performance orientation of HCS, with its many acceptable varieties of labels, could not be standardized through agreement on content to achieve harmonization.

Given that a more specified approach would also lead to consistency among manufacturers, as well as helping to ensure the same message is received by all exposed employees, OSHA agreed to negotiate a harmonized approach that was more specific than the current standard. This was also agreed to by stakeholder representatives involved in the negotiations. Thus once a chemical is classified as to its hazard classes and corresponding categories, the GHS specifies exactly what information is to appear on a label for that chemical. As described in Part IV of this preamble, OSHA believes that these specific labeling requirements will be more protective of employee health and safety than the current performance-oriented standard.

The NPRM proposed more modifications for paragraph (f) than most of the other paragraphs of the existing standard. It changed the title of paragraph (f)(1) to indicate it addresses labels on shipped containers. OSHA also proposed adding a number of new types of information to the label: Product identifier, signal word, hazard statement(s), pictogram(s), precautionary statement(s), and the name, address, and telephone number of the chemical manufacturer, importer, or other responsible party. One commenter (Document ID #0520) proposed a different format for the requirements in paragraph (f). While OSHA appreciates the suggestion, the format followed by OSHA is dictated to a large extent by document drafting requirements of the **Federal Register**, and remains the same in the final rule. Commenters suggested that OSHA add the words ''where specified'' to paragraph (f)(1) because there are a few hazard categories that do not require all of the elements listed (for example, there may be no symbol required for the category (Document ID #0344, 0381, 0381, and 0393)). However, this concern is addressed in paragraph (f)(2), which states that the information has to be consistent with Appendix C. Therefore, the change has not been made. There was also a suggestion that the language in (f)(1) conflicts with the definition of label (Document ID #0353). OSHA reviewed both the paragraph language and the definition, and does not agree. Therefore, this change has not been made.

The final rule requires that labels on shipped containers contain much more information than required by the current standard. However, much of this additional information has already been included by manufacturers, particularly when following the ANSI standard for precautionary labeling. In addition, the OSHA requirements are intended to be the minimum information to be provided by manufacturers and importers. Under the GHS, as well as the current HCS and the final rule, chemical manufacturers and importers are free to provide additional information regarding the hazardous chemical and precautions for safe handling and use. The GHS and the final rule refer to this as supplemental information. Several commenters requested that this be permitted (Document ID #0132 and 0145). As has already been discussed above with regard to the definitions for hazard statements and precautionary statements, such additional information is permitted in Appendix C of the rule as long as it is accurate and does not conflict with the required label elements. Paragraph (f)(1) is adopted in the final rule as proposed except to provide clarity in light of OSHA deleting the requirement for labeling for hazards not otherwise classified. OSHA has modified paragraph (f)(1) to explicitly state that hazards not otherwise classified do not have to be addressed on container labels. Paragraph (f)(1) in this final rule now requires that chemical manufacturers, importers, or distributors ensure that each container of hazardous chemical leaving the workplace is labeled, tagged, or marked. Hazards not otherwise classified do not have to be addressed on the container. The paragraph also includes the information that the chemical manufacturer or importer must provide on the label, tag, or mark.

Paragraph (f)(2) of the proposal addressed labeling for unclassified hazards. As noted in the discussion on definitions, this has been changed to Hazards Not Otherwise Classified in the final rule. In addition to the change in the definition, OSHA has removed the proposed requirement for labeling unclassified hazards. Since there are no label elements in the rule to address these hazards, the Agency decided to cover them in a more limited fashion, and removed the requirement for labeling them from the final rule. Hazards not otherwise classified will still be addressed on the SDS.

Paragraph (f)(3) in the proposal elaborated the label requirements by stating that the required information would be taken from new Appendix C of the standard on Allocation of Label Elements, which incorporates the GHS labeling requirements. This Appendix specifies the signal word, hazard statement, pictogram, and precautionary statements for each hazard class and category. It also includes a few basic rules about preparing labels that address precedence of hazards and other topics. Thus once a hazard classification is completed, the chemical manufacturer or importer can refer to Appendix C to determine what information must be included on the label. Since paragraph (f)(2) of the proposal has been deleted from the final standard, paragraph (f)(3) of the proposal is now paragraph (f)(2) in the final rule. Each of the subsequent paragraph numbers have changed accordingly. New paragraph (f)(2) also requires that the label be prominently displayed, and in English (although other languages may also be included).

New paragraph (f)(3) requires the harmonized information to be located together on the label, tag, or mark. This paragraph has been adopted in the final standard as it was proposed.

The rest of paragraph (f) in the current standard remained largely the same in the proposed modified text, although conforming changes to terminology were made throughout the paragraph. The current standard's accommodation for labels associated with solid metal was maintained in the revised text, although OSHA has added a heading of ''Solid materials'' to it. The provision regarding conflicts with the requirements of DOT has also been maintained. In fact, since transport rules have been harmonized with the other sectors under the GHS, the possibility of a conflict in information is less likely when the HCS is consistent with the international approach. Two ANPR commenters specifically noted that OSHA should avoid conflict with DOT (Document ID #0064 and 0066). This is already addressed in paragraph (f)(5) in the final standard. NPRM commenters further noted that the exterior package should be for displaying DOT labels, rather than for OSHA labels (Document ID #0345). In general, this would be true, although there are some cases where the single container serves as both the shipping container and the workplace container, such as drums. In these situations, there are rules in the GHS regarding which pictograms take precedence and the ways in which to display the information. These rules are set forth in Appendix C of the final standard.

The American Trucking Association (ATA) also raised the issue as to whether a GHS-compliant label might lead to a carrier's violation under DOT based on the carrier's ''constructive knowledge'' that a shipment contains a hazardous material (Document ID #0345). ATA suggested that OSHA and DOT need to work together to address this issue. OSHA contacted DOT and was told that this issue is addressed in 49 CFR 172.401, Prohibited Labeling. Specifically, GHS labels are exempted under 49 CFR 172.401(c)(5).

Under proposed paragraph (f)(7) (paragraph (f)(6) in the final rule), OSHA addressed workplace labeling. As noted previously, the current standard provides employers with flexibility regarding the type of system to be used in their workplaces. Some ANPR comments suggested that OSHA maintain this flexibility in the proposed standard (*See, e.g.,* Document ID #0047, 0145, and 0157). OSHA agrees, and the final rule retains the flexibility by indicating that the employer can choose to label workplace containers either with the same label that would be on shipped containers for the chemical under the revised rule, or with label alternatives that meet the requirements for the standard. It should be noted that while alternatives are permitted for workplace containers, the information supplied must be consistent with the revised HCS. Hazard classifications must be revised as necessary to conform with the final rule, and the other information provided must be revised accordingly to ensure the appropriate message is conveyed. Final paragraph (f)(7) remains the same as proposed.

OSHA did not propose to modify the remaining paragraphs on labels in the current HCS, including those that deal with alternatives to affixing labels to stationary containers; labeling of portable containers where the materials are transferred from a labeled container, used within a work shift, and under the control of the employee who performs the transfer; ensuring that all containers in the workplace have a label; a requirement for workplace labels to be in English and prominently displayed, while allowing the information to be in other languages as well; and the requirement for updating label information when there is new and significant information regarding the hazards of a chemical.

The only one of these provisions that received significant comment was the one regarding updating of label information within three months of receiving new and significant information regarding the hazards of a chemical. This provision ((f)(11) in the final rule) has been in the HCS since the 1994 revisions, but an administrative stay was placed on it shortly after it was promulgated in response to manufacturers' concerns. That administrative stay was never reconsidered or removed by OSHA, so the provision was not enforced. OSHA noted in the NPRM (74 FR 50283, Sept. 30, 2009) its intent to lift the stay, and requested comment and input on whether the time frame is appropriate. It should also be noted that an administrative stay is a tool available to OSHA to cease enforcement for reasons the Agency finds appropriate. It is not, as some appeared to assume, something that is adjudicated by an outside body, nor does it involve publication or documentation based on any type of record. It is usually a short-term solution to a problem that can be resolved through discussions with affected parties.

The current HCS requires that SDSs be updated within three months of learning of significant new hazard information, and that requirement has been enforced since the standard first went into effect in 1983. 29 CFR 1910.1200(g)(5). It is important to ensure that labels are similarly updated in a timely fashion, particularly since they provide the most immediate information in the workplace.

It appears that some commenters thought this provision was the effective date for updating the labels with the new GHS-aligned provisions (Document ID #0400, 0502, and 0513). This is not the case. Paragraph (j) of the final rule gives a much longer time period to implement the new GHS label requirements. Paragraph (f)(11), by contrast, addresses situations when a label must be changed because there is new and significant information about the hazards of the chemical. For example, there may be new studies that indicate an ingredient of the product is a potential carcinogen. This happens infrequently, so it is not anticipated that this provision would apply in many cases.

The key concern of commenters is what to do about stockpiles of chemicals that are already labeled. As noted by one commenter (Document ID #0370), new technology is available that links labels and SDSs, making new label generation more efficient. Stockpiles and distribution are now managed through computer programs that were not widely available in 1983. These programs can affect the amount of product kept in stockpiles, as well as the distribution of products in the supply chain, and thus the ability to deal with this updating issue. Consequently, a number of participants agreed that three months was an acceptable time frame (Document ID #0330, 0335, 0336, 0339, 0349, 0351, 0370, 0383, 0408, and 0410). Other commenters suggested that it was reasonable to allow sales to continue of products that are already labeled (Document ID #0313, 0323, 0327, 0328, 0329, 0344, 0351, 0361, 0375, 0377, 0381, 0399, and 0410). For example, Ecolab (Document ID #0351) stated:

> Ecolab agrees that three months for labels to be updated with significant changes to the hazards is acceptable. However, it would also be reasonable to allow the sell-through of product that is already produced and labeled. By three months, we agree new production of that product should occur with the significant new information, as long as existing date-coded inventory can be sold without modification. * * *

Others thought the administrative stay should be continued (Document ID #0353 and 0405). Of those who suggested alternative time frames, a number thought twelve months would be appropriate (Document ID #0328, 0352, 0372, 0376, 0382, 0399, 0402, and 0405). Others indicated three months was not enough (Document ID #0379); updating at some time interval is needed (Document ID #0365); six months would be the minimum (Document ID #0324, 0344, and 0361); or a range of six or seven to twelve months would be appropriate (Document ID #0411).

The North American Insulation Manufacturers Association (NAIMA) detailed some of the factors that influence the ability of a manufacturer to update a label: (1) Identification of the products whose labels need to be changed; (2) drafting new label language, which might require redesign of the packaging; (3) the ability to obtain new label or packing stock for printing; (4) the availability of printers to print the new material within the required time; (5) and transportation time for stock to the printer, from the printer to the manufacturer, and from the manufacturer through the supply chain (Document ID #411). NAIMA argues that many of these factors may be beyond the control of the manufacturer.

OSHA will not maintain the stay. It is necessary that labels be updated to ensure that users have the appropriate information in a timely manner. OSHA is also not convinced that any difficulties in updating labels justify a full year's delay in providing significant new information. However, OSHA is persuaded that, in some cases at least, it may be difficult to update labels within three months. Thus, final paragraph (f)(11) allows six months to begin labeling shipped containers with the new information. As noted above, there are few situations where this provision will come into play. It is not related to every modification of the label, just those that are significant with regard to hazard information. Six months should be long enough to revise labels, and allow for the depletion of already labeled product. While some commenters discussed the need for global compliance associated with different labels (Document ID #0376), OSHA is only requiring domestic compliance within this time frame. Therefore, the provision is adopted in the final rule with a six-month time period for updating product labels when there is new and significant information about the hazards.

One commenter suggested that OSHA add a new requirement that importers, distributors, and employers inform the chemical manufacturer in writing, within three months, when they become aware of significant information about the hazards of a chemical (unless they have already received this information from the chemical manufacturer) (Document ID #0520). The HCS has always been designed on the premise that the chemical manufacturer is in the best position to know what information is available about the chemicals produced. This information is then to be disseminated downstream to distributors and users of the chemical. This suggestion would create a very extensive new burden on parties in the distribution chain who are not responsible for the chemical or the information regarding it as required under the GHS. It is not consistent with the approach in the rule, and is not the most effective and efficient way to identify and distribute information. Therefore, OSHA rejects this suggestion. However, downstream users are free to inform manufacturers of new hazards of which they learn, and OSHA encourages the sharing of such information.

A few commenters on the ANPR also argued that a small package exemption, or some type of prioritization of information on small packages, should be permitted (Document ID #0043, 0046, and 0080). The current HCS does not have such an exemption or limitation, but the Agency has allowed practical accommodations in enforcement policies for those situations where an issue has occurred. (*See, e.g., CPL 02–02–038*'' *Inspection Procedures for the Hazard Communication Standard:* ''CSHOs must consider alternate labeling provisions (for example, tags or markings) for containers which are of unusual shape or proportion and do not easily accommodate a legible label.'')

In Revision 3 of the GHS, some provisions regarding small package labels have been included (1.4.10.5.4.4, Labelling of small packagings). The competent authority is given the discretion to implement changes that allow label preparers to reduce the required information to accommodate a small package size. OSHA did not propose to adopt such a provision, and has retained its current approach regarding small packages in the final rule. Very small packages are less frequent in the workplace than in consumer settings, and it is difficult to argue that employees should get less information just because of the size of the package. The practical accommodation approach OSHA has been utilizing addresses those situations where there is a valid issue, and ensures that workers receive all of the required information.

Following the NPRM, further comments were received on the issue of labeling small packages. Some suggested that OSHA should provide clear guidance for small containers, including perhaps a suggested priority for the label information (Document ID #0313, 0327, and 0339). Others thought the manufacturer should be permitted to pick the most important hazard and precautionary statements to include on small packages (Document ID #0405), or that OSHA should use the GHS guidance on the issue (Document ID #0342). Particular problems were noted, such as labeling small containers for reference standards (Document ID #0342). Phylmar Regulatory Roundtable testified during the hearing, and suggested that OSHA should either establish a priority for information on a small package label, or clarify what is meant by practical accommodations (Document ID #0497 Tr. 113).

The guidance in the GHS (1.4.10.5.4.4) basically allows countries to introduce a consideration of risk by determining that small quantities of the chemical are not a concern, or that information may be omitted because of the small volume. This approach is not consistent with the HCS, or with the concept of right-to-know. It is also unacceptable to OSHA to allow manufacturers to decide which information is the most important. Essentially, all of the suggested solutions result in less information being available to exposed employees than other employees would receive when exposed to the same chemical packaged in a larger container.

The concept of practical accommodations is difficult to define, since it entails a judgment by OSHA staff when confronted with the details of a specific situation. The point, however, is to find a way to provide the required information in every situation, and not to start with the premise that the solution is to omit such information. Ensuring that workers receive the required information may be accomplished in ways other than simply attaching it directly to each small container. OSHA will examine the situation to make sure that the information is associated with the proper containers, and that it is complete. OSHA is not adopting any regulatory requirements for small packages, but will consider whether any additional guidance is needed as the standard is implemented.

While the GHS specifies the information to be placed on a label, it does not provide a specific format for placement, which is similar to current HCS requirements. At least one commenter noted that the GHS does not specify a location or size of core information on a shipment (Document ID #0066). OSHA believes that the performance-oriented approach of paragraphs (f)(3) and (f)(10) is preferable. The Agency will allow accommodations to be made as long as the information is located together, and is prominently displayed as required.

A number of commenters endorsed the overall approach or specific parts of the label requirements. Comments included adopting the GHS labels (Document ID #0324 and 0339), supporting the flexibility of the in-plant labeling (Document ID #0392), and the use of signal words (Document ID #0321). Others wanted to ensure that hazards are conveyed accurately to all levels of education in the work force (Document ID #0331); supported allowing other languages on labels (Document ID #0381); suggested OSHA should allow flexibility of format and placement of required label elements (Document ID #0405); and suggested that OSHA should follow Revision 3 of the GHS for label requirements (Document ID #0382). OSHA believes that the final standard incorporates all of these concepts.

Appendix C details how the specified label elements apply to each hazard class and hazard category. OSHA has made some modifications to the introductory text to Appendix C regarding the combination of hazard and precautionary statements, and these modifications were discussed under paragraph (c), Definitions. Comments received regarding red border frames for pictograms, and making the precautionary statements mandatory, are also discussed above in the explanation of paragraph (c), Definitions. Also, as discussed in the explanation of that paragraph, OSHA has added definitions to the final standard for simple asphyxiant and pyrophoric gas. The Agency has also added a new section to Appendix C to provide the label elements for these hazards (C.4.30, Label Elements for OSHA Defined Hazards).

In C.2.1, ''Precedence of hazard information,'' addressing precedence of symbols, OSHA indicated that where the skull and crossbones is on a label, the exclamation point should not be included for acute toxicity. In the GHS, the statement simply says the exclamation point should not be included where the skull and crossbones is on the label. This is followed in the GHS by two other statements about not using the exclamation point for specific hazards when there is already a symbol for the more severe category of the same hazard. OSHA received a comment that the phrase ''where it is used for acute toxicity'' should be deleted since it is not in the GHS (Document ID #0393). OSHA believes that this phrase is appropriate for clarity and parallel construction with the other provisions of the paragraph. The skull and crossbones symbol only addresses acute toxicity, and does not convey other types of effects.

One commenter indicated that paragraph C.2.3.3 should not be mandatory (Document ID #0335). The paragraph indicates that when there is a DOT pictogram for a hazard on a label, an additional GHS pictogram for the same hazard must not appear. The reason it is mandatory is that having two different pictograms addressing the same hazard may lead to confusion for people handling the chemical.

OSHA also indicated that it was proposing to exclude ammunition and ammunition components under Division 1.4S from having the exploding bomb symbol and precautionary statements normally used for explosives (74 FR 50283, Sept. 30, 2009). This proposed exclusion was based on discussions during OSHA's rulemaking to update the explosives standard, and the issue of ammunition being sold in retail establishments. The Agency asked for input on whether the exclusion of the symbol was sufficiently protective, and whether any adjustments needed to be made. Several people thought the symbol should be included on ammunition and components since they are explosive (Document ID #0313, 0327, and 0328). However, others thought it was appropriate to treat ammunition and components differently, and that the exploding bomb does not represent the hazards of ammunition (Document ID #0330, 0336, 0338, 0370, and 0376). OSHA agrees with these commenters that the exploding bomb does not represent the hazards of ammunition, implying that there is a mass explosion hazard when handling these items, although that is not the case. Therefore, the Agency is maintaining the proposed provisions in the final standard, and will not be requiring a symbol or precautionary statements for ammunition and ammunition components.

A question was raised by the National Propane Gas Association (Document ID #0400) regarding signal words for propane if both simple asphyxiant and flammability hazards are covered since they have different signal words (warning and danger, respectively). Appendix C explains the precedence rules for signal words. Only one is ever required on a label. If one of the hazards warrants a ''danger'' signal word, then that will be the only one required on the label.

A few comments were also received about the interface of the new OSHA label requirements with the requirements of other agencies. For example, it was noted that it would be difficult to use one label to comply with both OSHA and CPSC (Document ID #0405), and that EPA and CPSC should accept GHS labels until they adopt the system themselves (Document ID #0328). OSHA does not have authority to determine the policies of other agencies with regard to accepting the new GHS-aligned labels. Another commenter noted that fireworks are regulated by other agencies, and therefore additional requirements are burdensome (Document ID #0355). The new OSHA requirements will be essentially harmonized with DOT's requirements, which will facilitate compliance with both agencies. Lastly, it was noted that OSHA should coordinate label implementation with Canada's Workplace Hazardous Material Information System (WHMIS) (Document ID #0461). As was noted earlier, OSHA does have bilateral discussions with Canada on implementation issues—however, Canada has not yet adopted the GHS or initiated implementation by regulation.

(g) Safety data sheets. The proposed revisions to this paragraph were confined primarily to paragraph (g)(2), other than conforming terminology regarding classification and SDSs. Paragraph (g)(2) of the current HCS indicates what information must be included on an SDS. It does not specify a format for presentation, or an order of information. Chemical manufacturers and importers have been free to use whatever format they choose, as long as the information is provided.

While this performance orientation was supported by chemical manufacturers when the standard was originally promulgated, it was largely based on the positions of those who were already providing SDSs and did not want to change their format. As the scope of the standard was expanded to cover other industries, it became clear that SDS users preferred a uniform order of information or a format. In particular, stakeholders such as emergency responders were concerned that information not being located in the same place on every SDS could create an increased risk in situations where the information was needed quickly.

Several years after the HCS was adopted, the chemical manufacturers themselves responded to these concerns by developing a national voluntary industry consensus standard that included a 16-section SDS (ANSI Z400, Hazardous Industrial Chemicals—Material Safety Data Sheets—Preparation). This consensus standard establishes the titles of each section and the order of presentation. It addresses concerns raised by also putting information of most use to those exposed in the beginning of the SDS, with the more technical data required by health and safety professionals in later sections. ANSI Z400 also responded to comments indicating that the SDS should be essentially ''one stop shopping'' in terms of information on a chemical, and should include other information such as how it is regulated by other Federal agencies, including transport requirements and environmental information by having sections for each of those categories of information.

In 1990, OSHA published a Request for Information (RFI) that addressed the issues of comprehensibility of labels and SDSs (55 FR 20580, May 17, 1990). Nearly 600 comments were received, and the majority of respondents sought an order of information or format for SDSs. Since the international harmonization process had begun at that point, OSHA thought it would be useful to wait until a globally harmonized SDS was available before changing the requirements. However, through interpretation, OSHA has made clear for many years that the ANSI format is acceptable, as long as the SDS includes the required information (*See* CPL 02–02–038, ''Inspection Procedures for the Hazard Communication Standard'' (Mar. 20, 1998), the compliance directive for the HCS). As explained in Section IV of this preamble, OSHA believes that the implementation of a standardized SDS format will enhance hazard communication and be more protective of employee health than the current performance-oriented standard.

The 16-section format continued to be recognized in different countries and organizations over the years, including an International Labour Organization (ILO) recommendation on chemical safety, the European SDS requirements, and an International Standards Organization standard on SDSs. When the GHS was developed, it was decided that this 16-section format was already a *de facto* international approach, so it was adapted to be part of the GHS. One small change was made to reverse sections 2 and 3 so that hazard information comes before the chemical names of ingredients. This change has subsequently been adopted by ANSI and other groups to be consistent with the GHS.

Since the 16-section SDS was initiated in the U.S. by industry, many companies have been using it. This adoption by industry will reduce the impact of the harmonized GHS requirements. Others who continued to use different formats will need to change their SDSs to conform. There is already software available to assist in developing SDSs in the 16-section format, and it is expected that more tools will be available as the dates for SDS compliance approach.

OSHA proposed to modify paragraph (g)(2) to establish the section numbers and title headings of the sections of the SDS to be consistent with the GHS. Furthermore, a new Appendix D was proposed to be added to the standard to address safety data sheets, and it indicates what information must be included in each section.

As OSHA indicated in the ANPR and the NPRM, sections 12 through 15 of the SDS require information on subjects that are outside the Agency's jurisdiction (*See* the list of sections below). OSHA will not be making these sections mandatory for inclusion, nor will any enforcement activity be directed to these sections. However, inclusion of the sections in an SDS is not precluded, and they have been included in the text of the revised standard so people will be aware that a fully GHS-compliant SDS will have to address those areas in addition to the ones mandated by OSHA.

The revised SDS would require the following sections:

Section 1. Identification.
Section 2. Hazard(s) identification.
Section 3. Composition/Information on ingredients.
Section 4. First-aid measures.
Section 5. Fire-fighting measures.
Section 6. Accidental release measures.
Section 7. Handling and storage.
Section 8. Exposure controls/personal protection.
Section 9. Physical and chemical properties.
Section 10. Stability and reactivity.
Section 11. Toxicological information.
Section 16. Other information, including date of preparation of the last revision.

A note in the revised text addresses the other sections that are not mandatory for OSHA:

Section 12. Ecological information.
Section 13. Disposal considerations.
Section 14. Transport information.
Section 15. Regulatory information.

The remainder of the paragraph on SDSs remains the same as the current HCS. The final rule, like the proposal, retains the current HCS design, ensuring the downstream flow of information from the chemical manufacturer or importer to the distributor and ultimately the employer. Other provisions (completion of all sections of the SDS; provisions for complex mixtures; the requirement for information to be accurate and reflect the scientific evidence; the need to update the SDS when new and significant information is available; maintenance of SDSs so they are accessible to employees; accommodations for situations where employees travel between workplaces during a work shift; and access for OSHA and NIOSH) remain in this final standard as they are in the current standard, although they have been renumbered.

As was the case with labels, relatively few comments were submitted in response to the ANPR or the NPRM on the specific provisions for SDSs. The final provisions are generally consistent with the current HCS, with the exception of the standardized approach described above that OSHA proposed and adopted in the final rule.

The only text changes that were made to the provisions that follow (g)(2) in the standard were to revise the terminology to be consistent with the new approach. However, there were some editorial suggestions for other changes (Document ID #0353). Consistent with OSHA's stated intent to not change anything that does not require change to align with the GHS, these suggestions have not been implemented in the final rule.

A number of rulemaking participants stated that they support the standardization of SDSs, and some noted that standardization would facilitate training (Document ID #0307, 0321, 0322, 0349, 0456, and 0463). It was suggested that OSHA update (g)(8) to (g)(10) to indicate that electronic distribution is acceptable (Document ID #0376 and 0395). It is already stated in (g)(8) that electronic access is acceptable for employees (although OSHA has removed ''microfiche'' from this provision since that technology is outdated and rarely used and in any event is captured under the broader term ''other alternatives,'' which is retained in the final rule). Electronic distribution is not precluded, although the employer on the receiving end of the information must be able to access it in that form. The general issue of electronic distribution and access is addressed in the compliance directive for the standard (CPL 02–02.038), and is based on recommendations made by the National Advisory Committee on Occupational Safety and Health (NACOSH). As explained in the directive, electronic distribution is permitted, but the appropriateness of its implementation will be judged as follows:

MSDSs must be readily accessible and there must be no barriers to employee access during the work shift. The Agency interprets the term ''readily accessible'' to mean immediate access to MSDSs. The employer has flexibility to determine how this will be accomplished. The use of electronic means such as computers with printers, microfiche machines, the Internet, CD–ROMS, fax machines, etc., is acceptable. Employers using electronic means to supply MSDSs to their employees must ensure that reliable devices are readily accessible in the workplace at all times; that workers are trained in the use of these devices, including specific software; that there is an adequate back-up system for rapid access to MSDSs in the event of an emergency, including power outages, equipment, and on-line access delays; and that the system is part of the overall hazard communication program of the workplace. Additionally, employees must be able to access hard copies of the MSDSs, and in the event of medical emergencies, employers must be able to immediately provide copies of MSDSs to medical personnel. Mere transmission of the requested information orally via telephone is not acceptable.

Employers may use off-site MSDS management services to meet the requirements of the HCS only if MSDSs are readily available to employees, either as hard copies in the workplace or through electronic means and as long as the provisions outlined in the previous paragraph are ensured. Despite the use of an MSDS management service, the employer maintains primary responsibility for the hazard communication program, including receipt and use of the information to develop and implement a site-specific hazard communication program under paragraph (e) of the HCS.

When immediate access to paper or hard copy MSDSs does not exist, CSHOs should evaluate the performance of the employer's system by requesting a specific MSDS. Ultimately, the evaluation of an adequate system will rely on the professional judgment of the CSHO. Factors that may be appropriate to consider when determining if MSDSs are readily accessible include:

(1) Are the sheets or alternative methods maintained at a location and under conditions where employees can access them during each work shift, when they are in their work areas?

(2) If an electronic system is used for MSDS access (computer, fax, etc.) do employees know how to operate and obtain information from the system? (CSHOs should request an employee to retrieve MSDSs using the electronic system.)

(3) Was there an emergency/accident where immediate access was critical?

(4) How quickly did the employer respond to the employee's request?

Employees must have immediate access to MSDSs and be able to get information when they need it in order for an employer to be in compliance.

On multi-employer job sites, employers who produce, use or store hazardous chemicals in such a way that other employers' employees are exposed or potentially exposed, must communicate to other employers how the means of access to MSDSs will be accomplished.

Various suggestions were made for improvements to SDSs. For example, it was suggested that the SDS be limited to five pages (Document ID #0415); that a one-page, eighth-grade reading level summary of its contents should be provided (Document ID #0306); and that SDSs be written in plain and simple language (Document ID #0347). OSHA agrees that SDS preparers should try to ensure the SDSs are written clearly, and preparers should consider the audience in determining how the information may be best communicated. As originally designed by ANSI, the sections in the beginning of the SDS are intended to be written in plain language, with fewer technical terms where possible. This information should be of immediate use in emergency situations, and addresses information that exposed workers are most likely to need (summary of hazards for example). But many of the remaining sections of the SDS require technical information, and they are intended to be of use primarily to professionals designing protective measures or providing services such as medical surveillance to exposed employees. These sections need to retain their technical terminology in order to be useful to the professionals for these purposes. It is difficult to regulate those aspects of preparing documents that are intended to convey technical information, and no specific requirements of this type have been included in the final standard.

There was also a comment that the Superfund Amendments and Reauthorization Act (SARA) refers to material safety data sheets (*See 42 U.S.C. 11022),* and that changing the name to safety data sheets would violate the Paperwork Reduction Act (PRA)(Document ID #0350). Changing the references to the data sheet does not violate PRA or SARA. As is clear from the foregoing discussion, MSDSs under the current standard and SDSs under the final rule both serve the same function and communicate the same types of information. OSHA believes that an SDS under the final rule should be treated as an MSDS under SARA, but if the regulated community needs additional clarity, it can ask EPA to issue an interpretation to ensure there are no compliance issues. Similarly, because the change of the regulatory term from material safety data sheet to safety data sheet does not, by itself, create a paperwork burden, there are no PRA implications.

One commenter suggested that OSHA add to the SDS the date the chemical was produced, where chemical testing occurred to determine SDS data, and the manufacturer's Web site (Document ID #0346). OSHA rejects this suggestion, noting that the final rule does not require adding information to the SDS that would make it significantly different from the GHS harmonized information requirements. Furthermore, it would not be practical to require either the date the chemical was produced (which would result in a costly requirement to revise SDSs for every day the chemical was produced), or where chemical testing occurred (which may not be known, given that such information is obtained from many different sources, and studies do not frequently indicate where the testing occurred). However, suppliers are free to provide this information on their Web sites, and often do.

In the NPRM, OSHA noted that mixture safety data sheets could no longer be prepared by attaching multiple SDSs for the ingredients, but rather would have to be an SDS for the mixture as a whole (74 FR 50392, Sept. 30, 2009). One commenter (Document ID #0334) thought the multiple SDSs practice should continue to be allowed, particularly to minimize burdens for small businesses. OSHA believes that this approach is not in compliance with the GHS-aligned requirements. It also does not provide the best information for those downstream, including small business users.

New mandatory Appendix D, ''Safety Data Sheets,'' provides additional requirements for the information to be included under each section heading. The sub-headings used to indicate the additional information were lettered (*e.g.,* (a) product identifier used on the label, (b) Other means of identification, and so forth). Questions were raised as to whether the letters identifying each subheading were considered mandatory (Document ID #0382, 0376, and 0393). Apparently, the EU requires the subheadings to be numbered. OSHA does not consider the letters to be mandatory, but the information each subheading identifies is required to be included. A similar comment indicated that the format of Section 9, Physical and chemical properties should be clarified (Document ID #0339). No particular format is required. Appendix D simply requires that information responsive to that heading and its subheadings must be included. If applicable information is not available, the SDS must state so.

Another commenter indicated concern that Appendix D does not refer to ANSI Z400.1 or Annex 4 of the GHS (Document ID #0336). OSHA does not believe that reference to either of these documents is necessary since Appendix D is self-contained. As Appendix D is mandatory, those documents would have to be incorporated by reference to be referred to, and that is not necessary for purposes of compliance with the standard. However, both ANSI Z400.1 and Annex 4 would be useful references for SDS preparers since they provide additional guidance for completing an SDS.

In the final rule, a small modification has been made to the introduction to Appendix D to indicate that a subheading ''within a section'' needs to be marked when no relevant information is available. Also, OSHA has added column identifiers of ''heading'' and ''sub-heading'' to clarify what is being referred to by that terminology.

Additional comments were received on specific sections of the SDS. For example, in section 1, ''Identification,'' the American Chemistry Council wanted clarification of subheading (c), ''Recommended use of the chemical and restrictions on use'' (Document ID #0393). As explained in Annex 4 of the GHS, A4.3.1.3, the SDS preparer should ''provide the recommended or intended use of the substance or mixture, including a brief description of what it actually does, *e.g.,* flame retardant, anti-oxidant, etc. Restrictions on use should, as far as possible, be stated including non-statutory recommendations by the supplier.'' Section 1 is adopted in the final rule as proposed.

On Section 2 of the SDS, ''Hazard identification,'' the Soap and Detergent Association argued that the requirement for precautionary statements in subheading (b) should not be included because they are not mandatory in the GHS (Document ID #0344). However, the GHS requires that precautionary statements appear on a label (1.4.10.5.2(c)), and Annex 4 (A.4.3.2.2) indicates that the GHS label elements, including precautionary statements, should be included in Section 2 of the SDS. As has already been discussed, OSHA is adopting the GHS precautionary statements, so they are mandatory for purposes of complying with this standard.

Other commenters questioned what was meant by ''unknown toxicity'' in Section 2, subheading (d) (Document ID #0367 and 0371). This term refers to the criteria for determining the acute toxicity of a mixture where there are ingredients that have no available acute toxicity data. In this case, the percentage of ingredients that have no data to consider in the calculations must be indicated in Section 2. In the final rule, OSHA has slightly modified sub-heading (d) to clarify this reference.

In addition to this clarification, two other changes have been made in Section 2. First, references to paragraphs (d) and (f) said ''paragraph (d)[(f)] of this section,'' which is the normal regulatory reference since the entire standard is called a ''section'' of the Code of Federal Regulations. However, since parts of the SDS under the ''Headings'' column are also referred to as sections, it was confusing. Section 2 now refers to the section number of the standard, 1910.1200. This change is tracked in other parts of Appendix D as well. Second, subheading (c) has been revised to refer to hazards not otherwise classified, rather than unclassified hazards, consistent with modifications to the regulatory text.

In Section 3, ''Composition/information on ingredients,'' commenters indicated that OSHA had left out a phrase that appears in the GHS with regard to identification of ingredients in a mixture (Document ID #0344 and 0393). This was an oversight, and OSHA has added the language ''and are present above their concentration limits/cut-off levels'' into Section 3. To ensure consistency with the classification criteria, OSHA has also clarified that ingredients that present a health risk below the cut-off/concentration limits would also need to be disclosed in section 3 of the SDS. It was also suggested that where the SDS discloses only the range of concentrations, the narrowest range possible should be permitted (Document ID #0395). Neither the GHS provisions for information on SDSs, nor the guidance for completing them, address specific limits for concentration limits. Under the current rule, concentrations of chemicals in a mixture are not required to be disclosed at all. OSHA agrees with the commenter that when SDS preparers use ranges rather than a specific percentage composition, the range must be limited in terms of the percentage concentration variation, and the variation in concentration must have no effect on the hazard of the mixture.

In order to help ensure that use of concentration ranges is understood, OSHA has added the term ''concentration'' in parentheses after the ''exact percentage'' terminology used in paragraph (i)(1) regarding trade secret protection. Similarly, the term ''exact percentage'' has been added in parentheses after ''concentration'' in Section 3 requirements for the SDS. These terms refer to situations where the mixture has a set formula, and the amount of a substance in the mixture is consistent from batch-to-batch. OSHA recognizes that there are some very small variances in this situation that have no impact on the hazard of the overall mixture. ''Exact percentage'' is the terminology used in the GHS guidance for preparation of SDSs, but these small variations or tolerances are expected and acceptable when reporting the anticipated percentage based on the formula.

Concentration ranges, rather than concentrations, may be used in other situations. For example, the final standard includes the longstanding provision that addresses the use of a single SDS for complex mixtures in paragraph (g)(4). Under this provision, where complex mixtures have similar hazards and contents (the ingredients are essentially the same, but the specific composition varies from mixture to mixture), one SDS may be used for all of these similar mixtures. Petroleum streams would be an example of a type of complex mixture to which this provision applies. In this situation, concentration ranges may be used for the ingredients that vary from stream to stream.

A chemical manufacturer or importer may also have a line of products that are very similar, but can be varied slightly in composition to meet the needs of customers. For example, toner colors may be changed by varying the amount of pigment. The variances are small, and the hazard remains the same. In these situations, concentration ranges may be used for multiple, similar products.

Trade secret status may be claimed for exact percentage composition but not for concentration ranges. Where a trade secret claim is made for exact percentage, the chemical manufacturer or importer may choose to provide a concentration range to assist downstream users in providing appropriate protections and, at the same time, potentially eliminating requests from users for disclosure of the trade secret in accordance with § 1910.1200. However, Section 3 must indicate that a trade secret claim is being made and information has been withheld.

Section 8 addresses exposure controls and personal protection. Some commenters noted that the information provided should have more detail than what was proposed in Appendix D, such as requiring information on specific PPE materials that provide protection (Document ID #0359 and 0456). OSHA agrees that SDS preparers should provide the most specific information available for the material so that the appropriate protective measures can be implemented. Annex 4 of the GHS, guidance for preparing the SDS, addresses the specific type of information on personal protective equipment that should be provided in Section 8 of the SDS in paragraph A4.3.8.3. OSHA will be making additional guidance available when the rule is implemented.

Section 8 also addresses inclusion of occupational exposure limits (OELs) on the SDS. Comments were received on inclusion of exposure limits on SDSs in response to the ANPR, and a number of different opinions were expressed, particularly regarding TLVs being required. Many ANPR commenters argued that TLVs should be included on the SDSs, as is currently required under the HCS (*See, e.g.,* Document ID #0042, 0179, 0021, 0038, 0124, and 0149). Others suggested they should not be required (*See, e.g.,* Document ID #0036, 0058, 0064, 0129, 0151, and 0163). A number of commenters suggested other types of occupational exposure limits that should be included on SDSs, such as levels from other countries, those recommended by NIOSH, and those recommended by the American Industrial Hygiene Association (*See, e.g.,* Document ID #0018, 0024, 0109, 0147, and 0171).

In the NPRM, OSHA proposed to maintain the requirement to include its mandatory permissible exposure limits

(PELs) on the SDSs, and to specify, as in the existing HCS, that manufacturers should include ''any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet.'' This would allow inclusion of any of the different types of occupational exposure limits commenters recommended for inclusion where the SDS preparer deems it appropriate. It also helps to minimize differences between the U.S. and other countries by not providing (except for PELs) a list of U.S.-specific occupational exposure limits that must be included, yet provides protection for employees by allowing inclusion of various recommendations that will help employers design appropriate protective measures. OSHA requested comment on this approach, and received many opinions from rulemaking participants.

First, many people agreed that the PEL should be on the SDS (although some acknowledged that they are out-of-date) (*See, e.g.,* Document ID #0328, 0330, 0332, 0336, 0338, 0339, 0340, 0341, 0344, 0349, 0351, 0352, 0354, 0357, 0359, 0375, 0379, 0382, 0399, 0412, and 0414). For example, the American Foundry Society (Document ID #0375) supported including the PEL, but thought other limits should only be included at the discretion of the SDS preparer:

> Our industry generally supports the requirement to include OSHA PELs, but not require the other recommended limits on SDSs. In particular, the American Conference of Industrial Hygienists (ACGIH)_TLVs, while able to provide useful information often lack credibility. As the result of a sometimes flawed development process, the TLVs can be misleading and their use can reduce clarity of communication. For certain materials, some manufacturers may choose to include TLVs on an SDS, or include other non-mandatory exposure values, including their own recommendations, but this should not be mandatory. The relevance of such other non-mandatory guidelines should be determined by the manufacturer who can best explain the meaning, context and limitations of such values.

Others specifically supported the approach proposed (*See, e.g.,* Document ID #0351, 0366, 0370, 0376, 0381, 0383, 0393, 0408, and 0411). Clariant Corporation (Document ID #0383) indicated they would support the proposed text, as well as a non-mandatory appendix listing other exposure limits:

> Clariant supports the recommendation to ''include other occupational exposure limits used or recommended''. Clariant would also support a non-mandatory appendix to the HCS to include reference to the TLVs and other occupational exposure limits such as the AIHA WEELs. Many companies already include other occupational exposure limits on their SDS. In most cases, those other limits are more up-to-date than the OSHA PELs.

The American Industrial Hygiene Association (AIHA) also suggested inclusion of a non-mandatory appendix listing other exposure limits such as the TLVs and WEELs (Document ID #0365).

Many commenters supported mandatory disclosure of applicable TLVs on the SDS in Section 8 (*See, e.g.,* Document ID #0313, 0315, 0317, 0319, 0323, 0327, 0328, 0330, 0332, 0336, 0340, 0347, 0349, 0353, 0354, 0357, 0359, 0401, 0403, 0410, 0412, 0413, 0414, 0463, and 0464). Others argued that inclusion of the TLVs would be inappropriate because such inclusion does not meet the Information (or Data) Quality Act, the development process is flawed, or they are non-governmental (*See, e.g.,* Document ID #0325, 0375, 0379, 0408, and 0409).

For example, the Center for Regulatory Effectiveness argued that OSHA's decision to require the disclosure of ACGIH TLVs on SDSs is inconsistent with the requirements of the Information Quality Act, Public Law 106–554, § 1(a)(3), Title V, § 515, 114 Stat. 2763 (2000). That act required OMB and DOL to issue guidelines ''ensuring and maximizing the quality, objectivity, utility, and integrity of information * * * disseminated by the agency.'' 44 U.S.C. 3516, note, at (b)(2)(A). Both OMB and DOL have issued such guidelines, and in addition OMB issued the ''Peer Review Bulletin,'' citing the authority of the Information Quality Act. OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies,* 67 FR 8452 (Feb. 22, 2002) (hereafter ''OMB Guidelines''); DOL, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Department of Labor* (Oct. 1, 2002), found at *http://www.dol.gov/cio/programs/infoguidelines/informationqualitytext.htm* (hereafter ''DOL Guidelines''); OMB, *Final Information Quality Bulletin for Peer Review,* 70 FR 2664 (Jan. 14, 2005) (hereafter ''Peer Review Bulletin''). Each of these guidelines specifies certain steps an agency should take when engaged in the ''dissemination'' of ''information.'' OSHA does not believe that it is disseminating ''information,'' as defined by these documents, in requiring disclosure of TLVs on SDSs.

All three documents except from the definition of information ''opinions, where the agency's presentation makes it clear that what is being offered is someone's opinion rather than fact or the agency's views.'' (OMB Guidelines V.5; DOL Guidelines at 5, 13–14; Peer Review Bulletin I.5.) OSHA understands this to mean that the guidelines do not apply unless the public could reasonably understand the information being disseminated as the official view of the agency. This understanding is supported by a number of statements by OMB and DOL. In the preamble to the Peer Review Bulletin, for example, OMB states that ''[a]n information product is not covered by the Bulletin unless it represents an official view of one or more departments or agencies of the federal government.'' 70 FR at 2667/2. Likewise, DOL's guidelines do not apply to information ''clearly represented as opinion and not an official agency or Departmental representation.'' DOL Guidelines at 3. Hyperlinks on an agency's Web site to information on non-governmental Web sites are not an agency dissemination of information, nor is a private researcher's publication and communication of the results of a government-funded study, where an appropriate disclaimer appears. OMB Guidelines V.5; 67 FR 8454/1; DOL Guidelines at 5, 13–14.

Users of hazardous chemicals could not reasonably think that ACGIH TLVs listed on an SDS are OSHA's dissemination of information as to the correct or feasible level of exposure to the chemical. As explained on the ACGIH Web site, TLVs are the ACGIH's statements of ''scientific opinion'' (Document ID #0529). The SDS is prepared by the manufacturer and represents the manufacturer's understanding of the hazards of the chemical, the appropriate conditions of use, and the necessary protective measures to be employed. It is hard to see, in that context, how a user of the SDS could understand that the TLVs listed on the SDS represent information disseminated by OSHA. The TLV will be identified as such on the SDS. Indeed, in the many cases where there is an applicable OSHA PEL, the PEL will also be listed in addition to the TLV.

Further, if TLVs are ''information'' for purposes of the IQA, then so too is everything in the SDS. If that were true, it would render the approach of the HCS unworkable because it would require OSHA to review and approve every manufacturer's label and SDS. OSHA does not believe Congress intended such a result in enacting the IQA.

The Center for Regulatory Effectiveness and the AFL–CIO's Building and Construction Trades Department suggested that OSHA could require SDS preparers to add a statement to the SDS saying that the TLV does not represent OSHA's view of a safe level (Document ID #0325 and 0644). OSHA has decided against such an approach. First, as explained above, OSHA does not believe that a reasonable SDS user would understand the TLV to be OSHA's official representation. Second, such a disclaimer could cause confusion, creating the incorrect impression that the remainder of the information on the SDS does represent OSHA's official representation about the hazards of the chemical in question.

There are other reasons the IQA guidelines do not apply here. The OMB and DOL guidelines only apply to information ''first disseminated after October 1, 2002'' (OMB Guidelines III.4; DOL Guidelines at 2), and OSHA has required TLVs to be disclosed on MSDSs since 1983. Moreover, the guidelines are ''not intended to impose any binding requirements on DOL or the public or * * * to provide any right to judicial review'' (DOL Guidelines at 2). Rather, ''information quality [is] an important management objective.'' (*Id.*) Courts have accordingly rejected private attempts to force agency compliance with the data quality guidelines. *See, e.g., Salt Institute* v. *Leavitt,* 440 F.3d 156, 159 (4th Cir. 2006) (IQA ''does not create a legal right to access to information or to correctness''); *Single Stick, Inc.* v. *Johanns,* 601 F. Supp. 2d 307, 316 (D.D.C. 2009) (same), *aff'd in relevant part on other grounds sub nom Prime Time Int'l Co.* v. *Vilsack,* 599 F.3d 678, 686 (D.C. Cir. 2010). Likewise, the Peer Review Bulletin is ''intended to improve the internal management of the executive branch, and is not intended to, and does not, create any right or benefit, substantive or procedural'' enforceable against the federal government (Peer Review Bulletin XII). OSHA finds that the DOL and OMB Guidelines and the Peer Review Bulletin do not require the Agency to take the additional step of analysis before requiring the disclosure of TLVs on safety data sheets.

At least one commenter suggested that requiring disclosure of the TLV would violate the Administrative Procedure Act's notice and comment requirements, to the extent that the SDSs were required to disclose TLVs that the ACGIH might adopt after the final rule is published (Document ID #0361). That contention was rejected in *National Ass'n of Manufacturers* v. *OSHA,* 485 F.3d 1201, 1204 (D.C. Cir. 2007), where the court held that the hazard communication standard does not prescribe particular chemicals for which hazard communications are required, but rather a system by which manufacturers and the ACGIH evaluate and communicate chemical hazards. This system is not changed when the ACGIH modifies a TLV, and therefore no new notice and comment is required. *Id.* Nor is OSHA impermissibly delegating its authority to the ACGIH by requiring that TLVs be listed, as argued by the National Association of Home Builders (Document ID #0372). The Third Circuit rejected that argument in a challenge to the current standard, which also required that manufacturers and importers perform hazard determinations for all chemicals for which the ACGIH had published TLVs. *Associated Builders and Contractors* v. *Brock,* 862 F.2d 63, 68 (3d Cir. 1988). The final rule's requirement to list nonbinding TLVs is an *a fortiori* case.

Finally, a number of commenters expressed concerns about the procedures ACGIH uses in adopting TLVs (Document ID #0083, 0084, 0361, 0371, 0372, and 0529). Typical of these is the comment from the Independent Lubricant Manufacturers Association:

> TLVs are developed by way of ACGIH committees that operate in secret with *anonymous* authors. Though the opportunity to provide written comments exists, there is no ''appeal'' process to challenge, question or even engage in a professional discourse with the people responsible for developing and finalizing the TLVs. ILMA believes that because the TLV development process is closed, TLVs have compromised scientific value and limited utility in addressing occupational health and safety matters. Indeed, this non-consensus process can generate defective decisions that have the potential to compromise the health and safety of the very workers the TLVs are designed to help. In addition to issues of transparency and fairness, TLVs are developed without any regard to the economic and technical feasibility of its recommendations or the availability of acceptable methods to determine compliance.

(Document ID #0371 (emphasis in original)). Other commenters also objected to the fact that the ACGIH provides no public hearing, that the extent of review ACGIH committees devote to TLV recommendations before adopting them is unclear, and that TLVs are not ''consensus standards'' within the meaning of the OSH Act (Document ID #0372 and 0529).

As explained on its Web site, ACGIH TLVs ''represent conditions under which ACGIH believes that nearly all workers may be repeatedly exposed without adverse health effects. They are not fine lines between safe and dangerous exposures'' (Document ID #0529). TLVs are to be used by industrial hygienists in determining safe exposures in workplace, according to the ACGIH, but ''are only one of multiple factors to be considered in evaluating specific workplace situations and conditions.'' (*Id.*)

The record evidence shows that the ACGIH uses a reliable and open method to develop TLVs with ample opportunity for public input. ACGIH TLVs are set by the Threshold Limit Value Chemical Substances Committee (Document ID #0536). Members of this committee are chosen for their expertise in industrial hygiene, occupational medicine, epidemiology, toxicology, or related fields such as statistics or chemistry, and members are selected to maintain a balance between these specialties. (*Id.*) Membership preference is given, among other things, to those with 10 or more years experience and advanced degrees within their field. (*Id.*) A majority of committee members must be ''Regular'' ACGIH members, that is, those occupational hygiene, occupational health, environmental health, or safety professionals whose primary employment is with a government agency or an educational institution. (*Id.; See also http://www.acgih.org/Members/memdescrip.htm.*)

The ACGIH has a conflict of interest policy, requiring that members disclose, both orally and in writing, ''potential, real, or perceived conflict[s] of interest'' with respect to a substance under consideration (Document ID #0536). The Committee chair is required to conduct a conflict of interest presentation annually, and Sub-committee chairs will typically inquire at the beginning of meetings as to whether members' conflict status has changed. (*Id.*) Where conflicts arise, the steps to be taken—such as recusal, abstention, or disclosure—are decided based on the nature of the conflict involved. (*Id.*)

Once the relevant ACGIH sub-committee decides to consider a new TLV, it is included on an ''Under Study'' list that the ACGIH publishes each February 1. (*Id.*) Each July 31, that list is updated to indicate the substances for which the ACGIH anticipates issuing a ''Notice of Intended Change'' in the coming year. (*Id.*) An author is assigned to prepare a draft ''documentation'' supporting a proposed new TLV; the author or ACGIH staff must conduct a full literature search on the substance; and only published, peer-reviewed data may be relied upon in the documentation. (*Id.*) The ACGIH has detailed guidelines governing the content of documentations and the method of conducting literature searches. (*Id.*) Once the draft documentation is approved by a sub-committee (by consensus) and the full TLV committee, ACGIH issues a public Notice of Intended Change and makes the draft documentation available to the public for at least a year to submit comments. (*Id.*)

The author and the sub-committee review the public comments received, and the draft documentation is amended if necessary. (*Id.*) Once the sub-committee reaches consensus, the draft documentation is forwarded to the full committee with a proposal to (1) retain the current TLV and publish the draft documentation for comment for an additional year; (2) change the TLV but publish the draft documentation for comment for an additional year; (3) adopt the proposed TLV and draft documentation; or (4) withdraw the proposal. (*Id.*) The proposal is then voted on by the full committee, and then the committee's recommendation is sent to the ACGIH board of directors for ''ratification.'' (*Id.*) Generally ACGIH does not hold meetings with interested parties during this process, but its rules allow for public discussion of the evidence on a chemical's hazard at ACGIH-sponsored symposia, and allows for meetings where new evidence has been developed and is ''essential to the Committee's deliberations.'' (*Id.*)

NIOSH, the Kentucky Labor Cabinet, the American Industrial Hygiene Association, the American Society of Safety Engineers, the Alliance of Hazardous Materials Professionals, and several occupational safety and health consulting firms support the TLV requirement, stating that ACGIH TLVs are useful in developing health and safety programs and are widely used in industry (Document ID #0313, 0323, 0327, 0336, 0354, 0365, 0410, 0412, 0496, and 0521). A number of manufacturers and manufacturer associations also support the TLV requirement (Document ID #0328, 0330, 0332, 0353, 0413, and 495). The International Chemical Safety Cards, prepared under the auspices of the UN, list TLVs (Document ID #0497). TLVs are currently required to be disclosed under the HCS, and witnesses testified that failure to include TLVs on SDSs in the final rule would render the standard less protective of worker health because TLVs are more up to date and cover more substances than OSHA's PELs (Document ID #494 Tr. 28–29, 94; Document ID #496 Tr. 368, 382).

Based on this record, OSHA finds that commenters' objections to TLVs are without merit. TLVs are set through an open process with ample opportunity for public input through the comment and symposium process; the fact that the ACGIH does not hold public hearings on proposed TLVs does not undermine the fairness of the process. While OSHA agrees that TLVs do not address feasibility concerns, it finds that TLVs are useful information for employers and employees to use in evaluating the hazards presented by chemicals used in their workplaces. OSHA finds that the record does not support the contention that TLVs have ''compromised scientific value'' because of the process used by the ACGIH. Each TLV is supported by a documentation explaining the evidence and assumptions on which it relies; these documentations are subjected to public comment and approved at several levels within the organization. It is certainly possible that a manufacturer or importer might disagree with the scientific judgments embodied in a TLV, but the final rule allows them to set forth their own recommendations about an appropriate exposure level on the SDS. Based on the ACGIH's procedures and the evidence of TLV use by industry, occupational safety and health professionals, and NIOSH, OSHA reaffirms its position that, in general, TLVs provide useful information that should be disclosed to employers and employees using hazardous chemicals.

Some commenters supported requiring other limits to be on the SDS in addition to the TLVs, such as the NIOSH Recommended Exposure Limits (RELs); the AIHA Workplace Environmental Exposure Limits (WEELs); and the German maximum allowable concentrations (MAKs) (*See, e.g.,* Document ID #0323, 0330, 0336, 0340, 0349, 0354, 0357, 0359, 0401, 0410, 0412, and 0414). NIOSH recommended broad inclusion of available occupational exposure limits (Document ID #0412):

> Providing occupational exposure limits (OELs) helps workers and employers understand the relationship between exposure concentration and adverse health effects. NIOSH supports the requirement of including PELs on the SDSs and further suggests that OSHA consider adding additional exposure limits, whenever available, such as NIOSH recommended exposure limits (RELs), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), American Industrial Hygiene Association (AIHA) Workplace Environmental Exposure Limits (WEELs), and German maximum allowable concentrations (MAKs) * * *.

There were a number of other comments on the issue of exposure limits in Section 8 of the SDSs, such as asking for an explanation of ''any other exposure limit used or recommended'' by the SDS preparer (Document ID #0329, 0351, 0382, 0381, and 0393), including whether this means exposure limits from other countries. There was also a suggestion to delete ''used or'' from the requirement (Document ID #0339). This language is in the current HCS, and is intended to include any exposure limits developed by the producer to protect their own employees, as well as other exposure limits commonly available such as the TLV or REL. It may also include exposure limits from other countries, but there is no intent to require that every known exposure limit in the world be provided. OSHA does not agree that it is appropriate to delete ''used or'' since companies often have exposure limits to protect their own employees, and this information can help their customers to determine what is needed to protect downstream employees as well. Others thought inclusion of exposure limits in addition to the PELs would confuse small businesses (Document ID #0372), or be detrimental to harmonization (Document ID #0464).

The AFL–CIO summarized their view of the record on this issue, as well as that of other worker representatives, in their post-hearing brief (Document ID #0645):

> We believe that OSHA needs to issue a final rule that restores the requirement to list the TLV on the SDS and strong record evidence supports our position. There is broad support for this position, covering a wide range of organizations including NIOSH (Ex. 0412.1) unions (AFL–CIO, Ex. 340.1; Building and Construction Trades Department, Ex. 0359.1; and the Steelworkers, Ex. 0403.2); safety and health professional associations (American Society of Safety Engineers, Ex. 0336.1); employers and their representatives (Dow Chemical Company, Ex. 03353.1); Patton Boggs, Ex. 0413.1); and individual experts (Adam Finkel, Ex. 0401.1; Harry Ettinger, Ex. 0319.1).

In Section 8 of the SDS in the final rule, OSHA has included the language used in the current rule to describe what exposure limits are to be addressed: ''OSHA permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available.''

As noted in the NPRM, OSHA took the reference to TLVs out of Section 8 of the SDS in the interest of limiting country-specific deviations from the GHS. However, based on many comments in the record, OSHA has concluded that the TLVs provide useful information for those designing protection programs for employees exposed to the chemicals involved, and are already widely used and applied for that purpose in American workplaces, as well as around the world. Referencing TLVs on the SDSs does not make them mandatory or establish them as control guidelines. It simply provides additional information that can help employers determine the proper levels of protections in their workplaces.

With regard to the recommendations for other exposure limits to be included on the SDS, OSHA agrees that referring to those exposure limits could also be useful, and would encourage SDS preparers to include them where available. However, the Agency is still concerned about including additional country-specific deviations, especially for limits that are less available than the TLVs. Providing too many different exposure limits may also be confusing to employers. Publication of a non-mandatory appendix would require OSHA to continually update it, as these different lists are prepared by various organizations. Since the Code of Federal Regulations is only updated annually, the Appendix would always be out-of-date. We do not believe this would be helpful in the long term, and that resources would be better put to other purposes than updating a non-mandatory appendix.

In the NPRM, OSHA did not propose to continue to require specific mention of IARC, NTP, and OSHA as sources of determinations regarding carcinogenicity. The requirement to consider these sources definitive in terms of a carcinogen determination was not included in the NPRM since it was not part of the GHS approach. However, as was discussed above, OSHA has modified Appendix F to allow classifiers to use these sources when assessing carcinogenicity, rather than applying the criteria to the data themselves. In order to facilitate this, OSHA has provided a table in Appendix F that aligns the GHS criteria with those of IARC and NTP. In addition, OSHA has decided to retain the requirement to include this information on the SDS in Section 11. This information will be of use to classifiers, as well as to employers and employees, when ascertaining potential hazards and determining appropriate control measures. This was supported by some commenters (*See, e.g.,* Document ID #0321, 0335, and 0403), while others argued that the determinations of such organizations should not be included because of issues with their process of making determinations (*See, e.g.,* Document ID #0379, 0417, and 0529). OSHA believes that this information from organizations that are recognized as expert in the field of carcinogenicity will continue to be helpful to both classifiers and users of chemicals, and does not agree with the commenters who argue about the process followed to make such determinations. The arguments were similar to those discussed above regarding inclusion of TLVs on SDSs, and OSHA's response to such arguments apply here as well. OSHA finds that both IARC and NTP use reliable procedures and criteria in making their determinations.

OSHA indicated in the NPRM that Sections 12 through 15 of the SDS were not going to be mandatory since they involved information that is outside OSHA's jurisdiction. With regard to Section 12 on environmental effects, some commenters expressed concern about the lack of harmonization with trading partners on environmental issues, or suggested that OSHA should work with EPA on this issue (*See, e.g.,* Document ID #0351 and 0377). OSHA and EPA have discussed this issue, and EPA's Office of Chemical Safety and Pollution Prevention will be updating applicable Toxic Substances Control Act (TSCA) regulations consistent with modifications made in this **Federal Register** Notice. Dates will be published in the Unified Regulatory Agenda (*www.reginfo.gov*). As noted previously, OSHA encourages SDS preparers to complete Section 12, as well as Sections 13 through 15, so as to have an SDS that is compatible with other international requirements, as well as ensuring customers have complete information.

Similarly, comment was received suggesting that Section 14 on transport information should be required, and producers should indicate whether the product is, or is not, covered by DOT's Hazardous Material Regulations (Document ID #0345). While OSHA does not have authority to require this to be included in Section 14, we certainly agree that it would be useful information for users of the chemical, and encourage producers to complete Section 14.

In the final rule, non-mandatory Section 15 of the SDS is intended to provide other regulatory information. OSHA raised as an issue for comment whether this section should be made mandatory by requiring regulatory information on OSHA's substance-specific standards be included in it. Employers can, of course, voluntarily list information about other OSHA standards (Document ID #0376), but voluntarily provided information is not subject to enforcement. Many of the respondents commented that Section 15 should not be made mandatory (*See, e.g.,* Document ID #0324, 0335, 0344, 0352, 0353, 0355, 0370, 0372, 0376, 0377, 0379, 0381, 0385, 0393, 0399, 0402, 0405, and 0408). Some questioned whether information about substance-specific standards would be useful to users of the SDS (*See, e.g.,* Document ID #0329, 0335, 0372, and 0405). Others thought that OSHA should require the substance-specific standards to be indicated, and that Section 15 should thus be mandatory (*See, e.g.,* Document ID #0328, 0330, 0336, 0338, 0339, 0340, 0347, 0349, 0351, 0354, 0357, 0365, 0383, 0389, 0403, 0410, 0414, and 0453).

While OSHA agrees that there is merit in including the substance-specific standards in Section 15 to inform chemical users of their existence and applicability, it is difficult to make completion of Section 15 mandatory since there is likely to be considerable other information in the section that would not be enforceable by OSHA. Having a section that includes both mandatory and non-mandatory information is potentially confusing to the regulated community. Additionally, the PELs will already be indicated in Section 8, and will thus inform the user when there is a substance-specific standard of concern. Therefore, while OSHA encourages additional information in Section 15, it remains non-mandatory in the final rule.

One suggestion received for Section 16 indicated that the preparer should identify the exact changes made to the SDS when revising it so the user can determine if re-training is needed (Document ID #0469). Presumably, the user would review the changes to decide whether re-training is needed. However, the success of such an approach would depend on how often the chemical is purchased, and a new SDS is received. If the chemical has not been purchased for a while, and a new SDS only indicates what changes have been made since the last update, the user could have missed versions of the SDS in the interim, and thus would not know all of the changes that had been made since the last SDS was received. In addition, adding such a requirement would make the OSHA provisions internationally inconsistent.

(h) Employee information and training. The GHS does not include harmonized training requirements, but does recognize the important role that training plays in hazard communication. For example, 1.1.3.1.3 of the GHS states:

> In the workplace, it is expected that all of the GHS elements will be adopted, including labels that have the harmonized core information under the GHS, and safety data

sheets. It is also anticipated that this will be supplemented by employee training to help ensure effective communication.

OSHA agrees that training is key to ensuring effective hazard communication. Under the current HCS, training is used to explain the label and SDS systems used in a workplace, and to address the hazards of chemicals and protective measures. While the written information provided is clearly important, training is an opportunity to explain the data and helps to ensure that the messages are being received accurately so they can be acted on appropriately. (*See* Section IV of this preamble.)

The training provisions in the HCS do not need to be modified to be consistent with the GHS since it does not include such requirements. However, OSHA proposed small revisions to track terminology used in other paragraphs, as well as to clarify the requirement to train on the details of the hazard communication program in (h)(3)(iv). While training on the program has always been required in the HCS, OSHA believed that modifying the text slightly would convey the need to address both the labels that will arrive on shipped containers, as well as any workplace-specific system that the employer uses. In addition, the training on SDSs must include the order of information. The final rule requires that training include the details of the hazard communication program developed by the employer, including an explanation of the labels received on shipped containers and the workplace labeling system used by their employer; the safety data sheets, including the order of information and how employees can obtain and use the appropriate hazard information.

OSHA proposed that employers train or re-train employees regarding the new labels and safety data sheets within two years after the rule is promulgated. The Agency believes that the training needs to be completed by the time employees begin to see labels and safety data sheets with the new information on them, rather than waiting until after the transition has been completed.

Some commenters to the ANPR noted that training would be required to ensure employees understand, in particular, the symbols and pictograms that will be used on labels. Some argued that the burden would be substantial given that all training would have to be revised, and the time and resources required would be significant (*See, e.g.,* Document ID #0153 and 0178). However, many agreed that having a standardized approach to labels and SDSs will make training easier in the future than training under the current rule where chemical manufacturers and importers can use whatever formats they choose (*See, e.g.,* Document ID #0030, 0042, 0072, and 0077).

Marshfield Clinic (Document ID #0028) noted that communication of information about chemicals and other hazardous substances:

> * * * is one of the more difficult to get across to workers. It is very appreciated that OSHA is revisiting this. Standardization will greatly assist in giving workers a better understanding of the hazards they may encounter when working with chemicals and other hazardous substances.

Similarly, Alcoa (Document ID #0042) suggested: ‘‘A standardized format will simplify hazard communication training and the use of pictograms will alleviate some of the problems presented by poor language skills.’’

There were a few commenters who argued that the standardized approach either would not simplify training, or they did not know if it would (*See, e.g.,* Document ID #0065 and 0078). Another noted that the current approach is fine for companies that are domestic only (Document ID #0026).

The majority of the comments made on the training provisions suggested additions to the existing requirements to further specify what is expected, and to improve the training. These comments were submitted primarily by worker representatives, or by the National Institute of Environmental Health Sciences (NIEHS) (*See, e.g.,* Document ID #0340, 0347, 0349, 0357, and 0403). For example, the Communication Workers of America (CWA) (Document ID #0349) suggested:

> * * * Given the significance of education and training, OSHA should develop a mandatory appendix to the Proposed Rule that sets forth the elements (including an evaluative component) of an acceptable education and training program.

As noted above, OSHA agrees with these commenters that effective training is a key part of hazard communication. While the GHS does not include such requirements, the developers also recognized the importance of including training in national programs, and encouraged countries to do that. In addition, the United Nations Institute for Training and Research (UNITAR), which is the international focal point for capacity building on the GHS, is developing training courses to be made available to developing countries, in particular to assist them in adopting the GHS.

As described, OSHA proposed a slight modification to ensure that employers are aware that they need to train specifically on the new label elements and SDS format. This modification is in the final rule, and the training on these aspects is to be completed prior to other provisions going into full effect. OSHA does not agree that other changes should be made to the training provisions of the HCS at this time. As also indicated in this document, the changes to the HCS being promulgated are focused on what is necessary to comply with the GHS. Since the GHS does not have any training requirements, the modification proposed and adopted by OSHA is what is necessary to ensure appropriate compliance with the revised standard, and does not introduce any new approaches or requirements.

OSHA is planning to provide additional guidance to help ensure appropriate training is conducted when complying with the revised HCS. A draft Model Training Program was posted for comment on OSHA's Web page some years ago. It includes many of the concepts addressed in the comments received, but was never finalized. While it was designed to provide an array of tools from which employers could choose what they needed based on their workplaces (lesson plans and slides), there were comments received at the time that it was too long for small employers. OSHA believes that the model program includes important information about conducting appropriate training (which was also the view of other commenters on the program). It is being revised and updated to be consistent with the revised rule, and will be made available on OSHA's Web page. A shorter guidance document for small employers is also being developed.

In addition to these training-specific tools, OSHA has other tools under development that could be used in training (*e.g.,* a quick card with the new symbols). These too will help to address some of the issues that have been raised.

Based on the above reasons, the final rule adopts the training provisions in the proposal. OSHA will address other comments provided through guidance and compliance assistance materials, rather than through further revisions to the rule.

OSHA has made minor changes to the training provisions to reflect the new definition of hazardous chemical in the final rule. In (h)(1), OSHA is replacing the phrase ‘‘new physical or health hazard’’ with the broader term ‘‘chemical hazard.’’ Final paragraph (h)(1) requires that employers provide employees with effective information and training on hazardous chemicals in their work area at the time of their initial assignment, and whenever a new chemical hazard the employees have not previously been trained about is introduced into their work area. Information and training may be designed to cover categories of hazards (e.g., flammability, carcinogenicity) or specific chemicals. Chemical-specific information must always be available through labels and safety data sheets.

Similarly in paragraph (h)(3)(ii), OSHA is replacing the phrase ''The physical and health hazards'' with all of the hazards identified as well as the hazards not otherwise classified. Final paragraph (h)(3)(ii) requires that the training include the physical, health, simple asphyxiation, combustible dust, and pyrophoric gas hazards, as well as hazards not otherwise classified, of the chemicals in the work area. This change was necessary because the final rule covers simple asphyxiants, pyrophoric gas, combustible dust, and hazards not otherwise classified, in addition to what falls under the new definitions for physical and health hazards. The modification to paragraph (h)(3)(ii) requires employers to train employees on all of the chemical hazards in the workplace, rather than only physical and health hazards as defined in the final rule.

(i) Trade secrets. The current HCS includes provisions that define what can be considered trade secret information under the rule, as well as delineate the conditions under which this information must be disclosed to ensure the safety and health of exposed employees. These provisions were a significant focus of the original rulemaking on the HCS, and reflect the common law of the United States on this topic. In the years since the rule has been in effect, however, this issue has not been as important. Overall, since these provisions were promulgated, it appears that fewer claims of trade secrecy have been made, and fewer requests for trade secret disclosure have been received, than were anticipated during the original rulemaking process.

The negotiations for development of the GHS recognized at the outset that trade secrets—generally referred to internationally as confidential business information—would be an issue of concern. Guiding principles included the following (*See* 1.1.1.6(j) of the GHS):

> In relation to chemical hazard communication, the safety and health of workers, consumers and the public in general, as well as the protection of the environment, should be ensured while protecting confidential business information, as prescribed by the competent authorities.

As the issue was considered further, it was recognized that laws regarding confidential business information were very much country-specific, and had a broader context than rules for classification and labeling. Such laws could not be modified or harmonized through the process of harmonizing classification and labeling. Thus it was determined that the GHS would recognize the importance of trade secrets, and provide principles for countries to follow when adopting the GHS. These principles are consistent with the approach already incorporated into the HCS.

The type of information that can be considered confidential or trade secret is limited to the names of chemicals and their concentrations in mixtures. Under the current HCS, OSHA did not require that concentrations in mixtures be disclosed, and thus limited trade secret claims to specific chemical identities. This was the primary difference between the current rule and the proposed revisions to the HCS. To be consistent with GHS, OSHA proposed to add percentage composition information to the SDS. This introduces the possibility that trade secret claims will be made for this type of information, as well as specific chemical identities. Thus the proposal revised the text of the current rule to add consideration of percentage composition everywhere specific chemical identity is addressed in the provisions.

The GHS further suggests that SDSs indicate when information has been withheld as confidential; that the information be disclosed to the competent authority upon request and under condition of confidentiality; that the information must be disclosed in a medical emergency, with mechanisms to protect it while ensuring timely disclosure; that the information be disclosed in non-emergency situations, also under conditions of protecting confidentiality; and that the competent authority have procedures to deal with challenges to this process. All of these principles have already been included in the trade secret provisions of the HCS, and are maintained in the final rule as previously promulgated. The proposed revisions simply conformed terminology, and added text regarding percentage composition being subject to the same provisions as specific chemical identity.

Very few comments on trade secrets or confidential business information were received in response to the ANPR. It was suggested that protection of confidential business information should be an implementation principle for the GHS modifications to HCS (Document ID #0072 and 0179), and that the current trade secret position should be retained (Document ID #0049). There was also a comment that indicated that full disclosure of all ingredients should be required on the SDS unless the employer provides a justification to the Agency showing that a particular ingredient is a trade secret, and demonstrating that the economic damage of disclosure exceeds the damage associated with the potential health effects to exposed employees (Document ID #0044). In addition, the National Paints and Coatings Association (NPCA) argued that the approaches to protection of confidential business information need to be harmonized (Document ID #0050). As NPCA stated, different approaches may lead to development of different SDSs for various authorities.

As noted above, laws regarding confidential business information are generally not specific to classification and labeling requirements, but rather reflect an overall approach of a country. It was not possible to change such laws through the harmonization of classification and labeling, and thus the limit of the agreement was to establish the principles already described. Those principles are consistent with law in the United States, and do not require any modifications to the current HCS approach to be consistent with the GHS.

There were a few comments on the trade secret provisions proposed. Some expressed their support for maintaining the current approach, with the small revisions to conform to the GHS (Document ID #0353, 0367, and 0371). Several indicated that the trade secret provisions should be extended to labels because the name of unclassified hazards was proposed to be included on labels, and when there is an ingredient of unknown toxicity, this must be indicated as well. For example, the American Petroleum Institute (Document ID #0376) indicated:

> Under certain conditions both the SDS and label can require text such as: *x percent of the mixture consists of ingredient(s) of unknown toxicity.* This statement may apply to an ingredient of a mixture whose percentage of composition is a trade secret. In such a case the trade secret provisions only apply when this statement is on the SDS. The current trade secret provisions do not apply to labels. Since the percentage composition of an ingredient can be required on labels as well as SDSs, the trade secret provisions should also apply to labels.

(Footnote omitted; *See also* Document ID #0344, 0381, 0382, and 0393.)

With regard to the inclusion of the name of unclassified hazards on a label, this requirement has been deleted from the final rule. Therefore, listing unclassified hazards on the label no longer raises a trade secret concern. It should be noted that there was never a requirement proposed for the ''specific chemical identity'' to be on the label for unclassified hazards, so even if the provision had been included in the final rule, it still would not have been analogous to the specific chemical identity required on an SDS.

With regard to the statement regarding unknown toxicity, OSHA does not find that this statement merits a change to allow the trade secret provisions to apply to labels. It is noted in paragraph A.1.3.6.2.3 that, where there is one or more ingredient of unknown toxicity in a mixture of other ingredients known to be acutely toxic, the calculation for predicting the acute toxicity cannot be completely accurate. Therefore, as suggested in the GHS, OSHA has indicated that a statement must be on the label and SDS indicating that a percentage of the mixture has unknown acute toxicity. There is no requirement to relate that general statement to specific ingredients, and specific chemical identities are not required on the label. Therefore, no trade secret information is required to be disclosed, and protection of the information under the trade secret provisions is not necessary.

There were also comments that OSHA should allow for flexibility in terms for indicating information is being withheld as a trade secret, such as ''confidential,'' ''confidential business information,'' or ''proprietary'' (Document ID #0376 and 0393). OSHA has never indicated specific terminology for claiming that information is subject to the trade secret provisions of the HCS, and would accept language such as ''confidential,'' ''confidential business information,'' or ''proprietary'' when indicating on an SDS that information is being withheld. This has never been an issue in OSHA enforcement of the HCS.

As implementation moves forward in different countries and regions, conformance to the GHS principles should lead to increased harmonization of approaches. This is an area that should be monitored to determine if further action can be defined and implemented. OSHA does not believe it would be prudent to implement changes in the approach to trade secret protection and disclosure before that time. Therefore, the final maintains the proposed language for the trade secret provisions.

(j) Effective dates. OSHA proposed to require training on the new labels and SDSs two years after publication, and all other provisions within three years. During the three-year transition period, employers would be required to be in compliance with either the existing HCS or the modified GHS, or both. OSHA recognized that hazard communication programs will go through a period of time where labels and safety data sheets under both standards will be present in the workplace. It was indicated that this would be considered acceptable, and employers would not be required to maintain two sets of labels or safety data sheets for compliance purposes. However, given the longstanding requirements for a hazard communication program, there must be no time during the transition period when hazard communication is not in effect in the workplace, and information is not available under either the existing requirements or the new final standard for exposed employees.

It should be noted that due to requirements of the **Federal Register**, a revision date of October 1, 2009, was entered into the proposed language to indicate the version to be used as the existing HCS standard. This confused some commenters (*See, e.g.,* Document ID #0376). There were no actual revisions introduced as of that date, and it is irrelevant to this final rule.

Many comments were received in response to the ANPR on the issue of phasing in the requirements of the GHS, as well as on current practices and time frames required for various activities. There was a wide variety of opinions, as well as a number of factors that commenters suggested should be considered in establishing effective dates.

OSHA specifically requested input on the possibility of phasing in requirements based on the size of the business. While a few commenters supported this approach (*See, e.g.,* Document ID #0022, 0144, 0146, and 0151), many more indicated that this would not be appropriate (*See, e.g.,* Document ID #0018, 0033, 0107, 0116, 0123, 0147, 0154, and 0171). One reason given was that the supply chain may involve large businesses purchasing from small businesses, and thus the large businesses would need information from the small businesses in order to comply themselves (Document ID #0080 and 0123).

There were also those who thought the phasing should be coordinated with other trading partners, particularly the European Union (Document ID #0024, 0072, 0080, 0081, 0163, 0171, and 0179). The European phasing is taking place over a long period of time because of the REACH requirements for chemicals that are going into effect and not necessarily because of the amount of time needed just for compliance with GHS. Another suggestion that had support from commenters was to phase in substances first, and then cover mixtures, or to have a three-step phase-in that includes intermediates before mixtures (*See, e.g.,* Document ID #0021, 0024, 0034, 0036, 0122, 0141, and 0154).

There were also suggestions for a specific number of years, or a range of years, for phase-in. Some of these suggested less than 3 years (*See, e.g.,* Document ID #0019, 0028, and 0064). A number suggested 3 to 5 years, or in some cases, 6 years (*See, e.g.,* Document ID #0015, 0032, 0038, 0111, 0125, and 0163). And there were some commenters who suggested anywhere from 7 to 13 years for full compliance (*See, e.g.,* Document ID #0018, 0050, 0077, 0078, 0116, 0129, 0141, and 0164).

OSHA decided on the three-year proposal based on a consideration of the widely diverse viewpoints expressed, as well as information provided by commenters about stockpiles and other issues. It is clear that activities have already begun by a number of vendors of software programs for hazard classification and labeling to convert to the GHS, and make programs available for companies to use to comply with requirements around the world as countries adopt the GHS.

Stakeholders provided many comments, as well as testimony, on the proposed effective dates. As with the record submitted in response to the ANPR described above, the opinions ranged over a wide variety of effective date options.

As noted, OSHA proposed that employers provide training regarding the new labels and safety data sheets two years after publication of the final rule. The intent of this training is to ensure that when employees begin to see such labels and SDSs in their workplaces, they understand how to use them and access the information effectively. Given the number of chemicals imported into American workplaces, as well as the number of employers who are already beginning to change over to the new formats, OSHA believes it is important to have this introductory training done before all of the labels and SDSs will be changed. It is not possible to pick a time frame that would ensure that such training is done before employees see any of these documents, but two years is a reasonable period of time and helps to ensure that employees will be trained before the new formats become the standard practice.

This training is not required to address the specific hazards of the chemicals, or the protective measures. Employees will have already been trained on hazards and protective measures under the existing hazard communication requirements, but they will not have had training on the new label elements (*e.g.,* pictograms and signal words) and SDS format, nor have learned how this information is to be used in their workplaces. Completion of such training in two years will help to ensure they can use the new documents effectively when they begin to arrive in their workplaces.

Some commenters thought two years would not be enough time, or who appeared to misunderstand what training was to be done by this date (*See, e.g.,* Document ID #0330, 0344, 0351, 0361, 0390, 0397, and 0399). For example, the American Society of Safety Engineers and Industrial Health and Safety consultants indicated that the training should be completed within one year of the final rule (Document ID #0336 and 0410). But the majority of those who commented agreed that two years was an appropriate time period in which to complete the training on the new label and SDS formats (*See, e.g.,* Document ID #0324, 0329, 0335, 0338, 0346, 0370, and 0405).

The three-year time frame for compliance with all other requirements generated significant comment. Many commenters supported this time frame as being appropriate and feasible (*See, e.g.,* Document ID #0313, 0322, 0324, 0327, 0329, 0335, 0339, 0376, 0390, 0395, and 0405). Others indicated that three years would not be adequate (*See, e.g.,* Document ID #0342, 0371, 0399, and 0402). There were also comments that suggested additional time should be provided to distributors to ensure they have the information from suppliers to provide it downstream. For example, the National Association of Chemical Distributors (Document ID #0341) stated:

OSHA should consider an additional 18-month phase in period for chemical distributors after the 3-year implementation date expires. This would allow for a more effective GHS while reducing any potential negative economic impact on small chemical distributors. NACD members have expressed concern that a three-year transition time for the entire value chain (suppliers, distributors, customers) presents the possibility of a bottleneck in the supply of chemicals * * *

Many commenters indicated that the time frame should be longer and tiered, with either substances first, and then mixtures, or a three-tiered system with substances, intermediate mixtures, and complex mixtures. The latter approach has been used by the EU. (*See, e.g.,* Document ID #0328, 0341, 0352, 0363, 0367, 0392, 0393, and 0400.) For example, comments on behalf of the Soap and Detergent Association and the Consumer Specialty Products Association indicated (Document ID #0344):

Therefore, SDA and CPSA support either a sequenced approach of substance suppliers first and formulators last, or a longer overall timeframe in order to minimize the impact of undertaking this significant effort to reclassify substances and mixtures, develop revised labeling, while allowing time to deplete inventories of labels and products with a current label. Any consideration of business size for a phase-in approach would be unacceptable as businesses large and small use each other's products in their end-use products; each one may rely on the upstream supplier for information in hazard classification.

While the Agency wants to provide sufficient time for compliance, there is also a concern about the effect on employees of dealing with multiple systems during a transition period. While some time period when the currently required labels and SDSs, and the new GHS labels and SDSs, will co-exist in workplaces is inevitable, hazard communication during this transition period will be confusing and less effective. It is therefore important to minimize the effects of the transition on the effectiveness of hazard communication by ensuring that it is completed in a timely fashion, while allowing adequate time for an orderly changeover.

Requiring the phasing in of substances first, and then mixtures, clearly has some persuasive logic as an approach. However, the supply chain is not always orderly and logical. It cannot be assumed, for example, that no mixtures can be completed until all substances are done. Mixtures that are comprised of substances that are widely available, and their hazards are well known, do not need an extensive time period to complete. Some mixtures are comprised of other mixtures rather than substances, and producers of such mixtures will need information on the component mixtures before they can comply. If manufacturers of mixtures wait until the end of an extensive time period to complete their work, their customers might not meet the compliance dates. These types of issues are generally addressed by the market, and the needs of a manufacturer's customers, and cannot be individually addressed in a phasing-in period.

OSHA is also mindful of the fact that the initial HCS had a two-year phase-in period for completion and distribution of all labels and SDSs, and an additional six months for all other provisions of the rule to be completed. There was no tiered approach to substances and mixtures. In that situation, the requirements for labels and safety data sheets were completely new, and yet timely compliance was achieved by most employers. Where there were situations that needed special consideration (such as an employer not receiving the required information from suppliers), the Agency made adjustments through enforcement policies. It should also be noted that this took place nearly thirty years ago, and pre-dated many of the resources available today that can facilitate compliance—such as access to extensive information online.

As was the case in the comments to the ANPR, a number of NPRM participants referenced the timeline for compliance with European CLP requirements (*See, e.g.,* Document ID #0328, 0361, 0367, 0377, and 0392). When discussing this issue in the NPRM, OSHA noted that the dates selected for CLP compliance were influenced significantly by compliance dates for REACH, rather than providing an indication of how long compliance should take in the absence of such competing responsibilities (74 FR 50403, Sept. 30, 2009).

That being said, however, nearly two years have elapsed since the NPRM was published, and the EU requirements for notifications regarding classification of substances are now in effect. In January 2011, the European Chemicals Agency (ECHA) indicated that it had received over three million such classifications (*See* discussion earlier in the Summary and Explanation). These substance classifications are being made available in a public database. The availability of this information clearly facilitates compliance with this revised HCS. While chemical manufacturers and importers must review the information if they are using classifications performed by someone else, many of the classifications were being submitted by U.S. companies, and thus they are already substantially in compliance with the new U.S. requirements as well.

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 which examines the effects of different compliance dates on the overall costs of compliance, the following effective dates have been included in the final rule. Rather than specifying a time frame related to the publication date of the final rule, OSHA is establishing dates certain for these activities to be completed. The following table summarizes the requirements in the final rule:

TABLE XIII–3—EFFECTIVE DATES AND REQUIREMENTS

Effective completion date	Requirement(s)	Who
December 1, 2013	Train employees on the new label elements and SDS format.	Employers.
June 1, 2015	Compliance with all modified provisions of this final rule, except:	Chemical manufacturers, importers, distributors and employers.
December 1, 2015	The Distributor shall not ship containers labeled by the chemical manufacturer or importer unless it is a GHS label.	
June 1, 2016	Update alternative workplace labeling and hazard communication program as necessary, and provide additional employee training for newly identified physical or health hazards.	Employers.
Transition Period 5/25/12 to the effective completion dates noted above.	May comply with either 29 CFR 1910.1200 (this final standard), or the current standard, or both.	Chemical manufacturers, importers, distributors, and employers.

First, final paragraph (j)(1) requires training regarding the new label and SDS formats to be completed by all covered employers by December 1, 2013. OSHA has concluded that it is necessary and appropriate to complete this training prior to all of the new labels and SDSs being completed and received in workplaces so that employees know how to access and use the information appropriately. Most of those who commented on this issue agreed with that position, and with the timing proposed. Those who didn't may have misunderstood exactly what training is being required, but we have clarified that in this document.

Secondly, OSHA has not found the arguments regarding phasing in based on whether the product is a substance or a mixture to be convincing. There are many variations in the supply chain that impact the logic of this approach. In addition, given the current situation where substance classifications for the GHS have already had to be completed for both the EU countries, as well as other countries such as Japan, many suppliers involved in international trade have already had to complete substance evaluations. For those who have not, there is extensive information available as a result of these classifications having been done for the purpose of compliance with other authorities' requirements. Thus little time should be necessary to complete this part of the work.

Final paragraph (j)(2) requires compliance with all of the provisions for preparation of new labels and safety data sheets by June 1, 2015. This compliance date is consistent with the EU requirements for classification of mixtures. It also provides almost a year more time for compliance than was proposed. Thus it addresses a number of the suggestions received, but is still a reasonable time frame in terms of employee protections. There are two exceptions to this date. First, final paragraph (j)(2)(i) gives distributors an additional six months to distribute containers received from chemical manufacturers and importers with the new labels and SDSs in order to accommodate those they receive very close to the compliance date. Accordingly, by December 1, 2015, all their distributed containers must be appropriately labeled, and have the new SDS. Second, final paragraph (j)(2)(ii) gives employers until June 1, 2016, to make sure that their workplace labels and training programs reflect any new information received as a result of the final rule.

As was proposed, final paragraph (j)(3) states that employers will be considered to be in compliance with the HCS during the transition period as long as they are complying with either the existing HCS as of October 1, 2011, or this revised HCS.

Employers are encouraged to work with their suppliers to ensure they get the information they need by the dates they need it. While the final rule gives distributors and employers extra time to ensure they have the information before they have to be in compliance with all requirements, coordination will still be key to ensure everything is done on time. For example, mixture formulators need to make sure their suppliers are aware of their need to receive substance classifications as soon as possible. Employers would be best served to start evaluating their workplaces long before the year after suppliers must be in compliance to assess what they will need to do to bring their programs in line with the new requirements. As with the original rule, OSHA will handle individual problems through enforcement policies that recognize difficult issues or situations that impede compliance. Nevertheless, given the long time frame involved, and recognition of different players in the supply chain of the needs of others, OSHA expects that these situations will be minimal.

Summary and Explanation of Requirements in OSHA Standards Affected by the GHS Modifications to HCS

General Explanation

In this final standard, OSHA has modified its current standards in General Industry (29 CFR Part 1910), Construction (29 CFR Part 1926), and Maritime (Shipyards, Marine Terminals, and Longshoring (29 CFR Parts 1915, 1917, and 1918, respectively)) that contain hazard classification and communication provisions so that they will be internally consistent and aligned with the GHS modifications to the HCS. OSHA proposed to do so on the basis of the strong support in the record of comments on the ANPR. The majority of commenters who addressed the impact of the GHS on other OSHA standards recommended the Agency review all its standards and update them for consistency with GHS (71 FR 53617, Sept. 12, 2006) (Document ID #0031, 0038, 0046, 0050, 0054, 0072, 0077, 0107, 0116, 0145, 0147, 0154, 0155, 0163, 0165, 0171, and 0179). OSHA did so, and this rule contains the updates to the requirements in OSHA standards affected by the GHS modifications to HCS. Commenters also urged OSHA to complete these revisions in one rulemaking (Document ID #0079, 0123, 0137, 0154, and 0157). The comments on the proposed standard and testimony at the hearing also strongly supported modifying these standards for consistency with the GHS (Document ID #0313, 0327, 0328, 0329, 0336, 0338, 0352, 0359, 0365, 0370, 0372, 0405, 0408, 0410, 0412, and 494 Tr. 91, 162). Of the commenters who specifically addressed adopting GHS provisions on physical hazards, many urged the

Agency to conform the OSHA standards to the GHS in order to minimize discrepancies and ensure consistency (Document ID #0012, 0018, 0050, 0072, 0104, 0105, 0139, 0140, and 0144). One commenter, 3M, noted that adoption of the GHS physical hazard criteria (without changing OSHA standards) would ''create unacceptable inconsistencies between OSHA standards'' (Document ID #0128).

Several other commenters to the ANPR pointed out some of the difficulties with adoption of the GHS physical hazards criteria in OSHA standards (Document ID #0031, 0034, 0038, 0077, 0145, and 0166). BASF was concerned that modifying OSHA standards to conform to the GHS will cause them to deviate from the national consensus standards they were based on (Document ID #077). In addition, some ANPR commenters recommended that OSHA limit changes only to standards that directly refer to the HCS (Document ID #0047, 0064, 0077, 0104, and 0115). OSHA acknowledged these concerns when developing the NPRM.

OSHA's NPRM reflected the advantages of harmonizing OSHA's standards, but also took into account the places where harmonization might be too difficult at this time because it would substantially change the scope of coverage of a current standard or make OSHA's standards incompatible with other widely accepted standards (74 FR 50280, Sept. 30, 2009). OSHA proposed modifying requirements in primarily the substance-specific health standards and in physical hazards definitions and terminology for the purposes of internal consistency and compatibility with the GHS-modified Hazard Communication Standard (HCS).

Building and Trades Construction Department of AFL–CIO (BTCD) and Northrup Grumman Shipbuilding, in response to the NPRM, requested that OSHA again review the standards, and the Agency has done so (Document ID #0359 and 0395). OSHA reviewed all its standards, the comments, and the entire record and has decided to maintain the modifications to the substance-specific standards as proposed, except for some minor changes that are explained below.

Substance-Specific Health Standards

In the NPRM, OSHA updated the substance-specific health standards in General Industry, Construction, and Maritime, whether they specifically referenced HCS or contained their own hazard communication requirements. OSHA proposed to modify these standards as follows:

▪ Revise the provisions covering workplace signs to require warning statements that are consistent with the GHS modifications to HCS;

▪ Revise all standards to reference the modified HCS for labels, safety data sheets, and training, and identify the hazards that need to be addressed;

▪ Maintain the requirement to avoid creating dust currently in some substance-specific health standards for which GHS modifications contain no equivalent statements at this time;

▪ Maintain or specify language for contaminated clothing and debris;

▪ Update definitions in § 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories, to maintain compatibility with the modified HCS; and

▪ Change the name Material Safety Data Sheets to Safety Data Sheets and require information on them to be compliant with GHS in content, format, and order.

Workplace Warning Language on Signs and Labels

OSHA proposed to update the language for workplace signs and labels to incorporate the GHS hazard statement and the applicable precautionary statement(s), where required. Most OSHA substance-specific heath standards require hazard warning signs, usually for regulated areas, and the language required on the signs varies greatly (*e.g.,* Asbestos, 4-Nitrobiphenyl, 13 Carcinogens, Vinyl Chloride, Inorganic Arsenic, Cadmium, Benzene, Coke Oven Emissions, Cotton Dust, DBCP, Acrylonitrile, Formaldehyde, Methylenedianiline, 1,3-Butadiene, Methylene Chloride, and Lead). With the GHS revision, these standards retain the requirements for specific warning language for specific signs; however, OSHA proposed to modify the language to be compatible with GHS and consistent throughout the OSHA standards. Labels for products, mixtures, and raw materials are included in the GHS-modified HCS and are required to be compliant with it. Labels required by the current standards for contaminated clothing, PPE, and waste and debris, which are not addressed in the GHS, are retained, but their language has been changed to be as reflective of GHS terminology as possible.

The vast majority of persons and entities who commented on the issue in response to the NPRM supported OSHA's harmonization of the signage and labeling currently required in its substance-specific standards with the modifications to HCS (Document ID #0313, 0315, 0327, 0328, 0329, 0330, 0336, 0338, 0344, 0365, 0370, 0372, 0376, 0381, 0382, 0383, 0405, 0408, and 0410). NIOSH pointed out that the consistent language on signs, labels, and SDSs would avoid confusion and allow for easy translation into other languages (Document ID #0414). AIHA, in supporting the modification of language for signs and labels, noted that the action was consistent with GHS and the goal of harmonization. They envisioned clearer warnings, improved comprehension, and better self-protection by workers (Document ID #0365). Companies such as Ecolab, Product Safety Solutions, DuPont Company, Phylmar Group, Stericycle, Procter & Gamble, Clariant Corporation, 3M, Industrial Health and Safety Consultants, and Wacker Chemical specifically addressed the issue of affected standards and stressed that aligning the standards with GHS would bring needed consistency and aid employee understanding (Document ID #0313, 0329, 0335, 0338, 0339, 0351, 0381, 0383, 0405, and 0410). Lawrence R. Klein of DuPont (Document ID #0329) commented that:

> * * * hazard communication regardless of whether * * * general chemicals or substance specific chemicals regulated under other OSHA standards, will prove to be beneficial for industry. Through adequate training * * * and consistent, easily comprehensible hazard and precautionary statements, via workplace signs or chemical labels, the safety and protection of employees will be enhanced.

Ameren added that the language proposed for the substance-specific standards accurately conveyed the hazards (Document ID #0330). Associations that addressed this issue also provided strong support. ORC, ASSE, NAHB, API, Alliance of Hazardous Materials Professionals, National Paint and Coatings Association, Soap and Detergent Association, ACC, and AISI agreed with OSHA that modifying the standards will provide consistency and aid in employee understanding (Document ID #0327, 0328, 0336, 0344, 0370, 0376, 0393, and 0408). Many commenters followed up with testimony at the informal public hearings. NIOSH testified that there would be better identification of what was a hazard and the nature of the hazard (Document ID #0494 Tr. 50). BCTD AFL–CIO testified that the specific format and vocabulary for labels would facilitate hazard communication across a range of English literacy, as one in four construction workers speaks a language other than English, and two in three entering workers speak Spanish. They said that the signs, symbols, and phrases will make it easier for employees to work safely with hazardous products

(Document ID #0497 Tr. 7, 16, 33–34, 62, 66). ORC Worldwide testified their companies have significant global operations and so support concurrent harmonization of hazardous communication components (Document ID #0497 Tr. 88, 91, 99). SIRC generally supported the principles of the GHS update (Document ID #0494 Tr. 118). ASSE agreed that it is important for consistency to have the same language on the label, SDS, and regulated area sign (Document ID #0496 Tr. p. 362). In speaking about all labeling requirements, USSW (Document ID #0499 Tr. 136–37) testified:

> It's imperative that the information on the labels is consistent from product to product. Incorporating the GHS labeling system with pictograms and single-word hazard statements will assist workers to quickly recognize hazards.

AIHA summed up the support from commenters and testifiers by declaring that the GHS modifications will improve quality and consistency of hazard communication information (Document ID #0496 Tr. 415).

Several commenters to the NPRM, while supporting the modifications, raised potential problems with warnings for substance-specific health standards' labels and regulated area signs. Northrop Grumman agreed with the wording of the regulated area signs and that it would enhance employee information, although there was concern that this was a change in OSHA's policy of allowing supplemental language on labels and signs that would enhance the information (Document ID #0395). OSHA has not changed its policy on regulated area signs with this rulemaking and will continue to allow supplemental language on labels and signs. ASSE suggested that, under the proposal, the term ''Cancer Agent'' would be retained in the thirteen identified carcinogens standard, though the ASSE did not believe the problems caused by this inconsistency would be significant (Document ID #0336). OSHA notes that all cancer warnings, including ''Cancer Agent'' and ''Cancer Suspect Agent,'' have been changed to ''May Cause Cancer,'' so there is no inconsistency. NAHB addressed the issue of the cancer warning in a comment to the ANPR, positing that the different signal words (''Danger'' versus ''Warning'') and different hazard statements (''May Cause Cancer'' versus ''Suspected of Causing Cancer'') may create confusion (Document ID #0065). Like other commenters, NIEHS supported consistency, but thought ''May Cause Cancer'' may not be strong enough, and recommended ''Causes Cancer'' be retained. The International Chemical Workers Union Council agreed that ''May Cause Cancer'' was not strong enough; they preferred ''Causes Cancer'' because it was a more definite statement about the health hazard. They were concerned that some workers might not see the warning as a clear indication of the material causing cancer and act accordingly (Document ID #0456). Dr. Michelle Sullivan also supported consistency among SDSs, labels, and in-plant warning signs, but cautioned that training would be needed especially on ''May Cause Cancer'' (Document ID #0382). OSHA agrees that training will be needed and that appropriately trained workers who see the phrase ''May Cause Cancer'' will be well warned and benefit from the use of a consistent hazard statement for all carcinogens.

The current substance-specific health standards that are regulated as carcinogens have varying hazard statements on signs and labels, as, for example, from ''Cancer Hazard'' for inorganic arsenic (29 CFR 1910.1018) to ''Cancer-Suspect Agent'' for vinyl chloride (29 CFR 1910.1017) to ''May Cause Cancer'' for methylenedianiline (MDA) (29 CFR 1910.1050). As stated in the preamble to the proposed standard, these warnings appeared to suggest gradations of cancer hazards, but they were not intended that way. The standards were promulgated over many years, and the differences in the warning language reflect the language widely used for each cancer warning at the time of promulgation, not the degree of hazard (74 FR 50405, Sept. 30, 2009). This inconsistency has long been a problem, especially in workplaces where two or more OSHA-regulated carcinogens are used. The final rule's revision to the substance-specific health standards will solve the problem of different warning statements by standardizing the carcinogen warning language to ''May Cause Cancer'' for each standard. This will lead to clearer and more timely recognition of the hazard and, with training, better understanding of the potential for developing cancer.

OSHA understands the points made by commenters who argued for another warning for cancer that might appear stronger, but any other warning would not be consistent with GHS and thus workers would not benefit from the global consistency of a single hazard statement for carcinogenicity. Moreover, OSHA believes that, with training, workers will understand the seriousness of the warning and benefit from seeing only one warning on carcinogens in the workplace. OSHA has concluded that the signal words and hazard statements, including ''May Cause Cancer,'' in its substance-specific health standards will provide better hazard information to employers, and has carried through the changes proposed in the NPRM to the final rule.

See Table XIII–4 for a comparison of the signs' final language to that currently required.

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Table XIII-4. Regulated Area Signs in Substance-Specific Health Standards

Standard	Substance	Original signs	Final Changes
1910.1001 1915.1001	Asbestos Regulated areas	DANGER ASBESTOS CANCER AND LUNG DISEASE HAZARD AUTHORIZED PERSONNEL ONLY	DANGER ASBESTOS MAY CAUSE CANCER CAUSES DAMAGE TO LUNGS AUTHORIZED PERSONNEL ONLY
	Where the use of respirators and protected clothing is required	RESPIRATORS AND PROTECTIVE CLOTHING ARE REQUIRED IN THIS AREA	WEAR RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING IN THIS AREA
1910.1003	4-Nitrobiphenyl: Regulated areas	CANCER-SUSPECT AGENT AUTHORIZED PERSONNEL ONLY	DANGER (CHEMICAL IDENTIFICATION*) MAY CAUSE CANCER AUTHORIZED PERSONNEL ONLY
	Regulated areas covered by paragraph (C) (5)	CANCER-SUSPECT AGENT EXPOSED IN THIS AREA IMPERVIOUS SUIT INCLUDING GLOVES, BOOTS, AND AIR-SUPPLIED HOOD REQUIRED AT ALL TIMES AUTHORIZED PERSONNEL ONLY	DANGER (CHEMICAL IDENTIFICATION) MAY CAUSE CANCER WEAR AIR-SUPPLIED HOODS, IMPERVIOUS SUITS, AND PROTECTIVE EQUIPMENT IN THIS AREA AUTHORIZED PERSONNEL ONLY *(Use this template for all 13 carcinogens)
1910.1004	alpha-Naphthylamine:		See 1910.1003
1910.1005	Methyl chloromethyl ether:		See 1910.1003
1910.1006	3,3'-Dichlorobenzidine (and its salts):		See 1910.1003
1910.1007	bis-Chloromethyl ether:		See 1910.1003
1910.1008	beta-Naphthylamine,:		See 1910.1003
1910.1009	Benzidine:		See 1910.1003

Standard	Substance	Original signs	Final Changes
1910.1010	4-Aminodiphenyl:		See 1910.1003
1910.1011	Ethyleneimine:		See 1910.1003
1910.1012	beta-Propiolactone:		See 1910.1003
1910.1013	2-Acetylaminofluorene:		See 1910.1003
1910.1014	4-Dimethylaminoazo-benzene:		See 1910.1003
1910.1015	N-Nitrosodimethylamine:		See 1910.1003
1910.1017	Vinyl chloride: Regulated Areas	CANCER-SUSPECT AGENT AREA AUTHORIZED PERSONNEL ONLY	DANGER VINYL CHLORIDE MAY CAUSE CANCER AUTHORIZED PERSONNEL ONLY
	Hazardous operations	CANCER-SUSPECT AGENT IN THIS AREA PROTECTIVE EQUIPMENT REQUIRED AUTHORIZED PERSONNEL ONLY	DANGER VINYL CHLORIDE MAY CAUSE CANCER WEAR RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING IN THIS AREA AUTHORIZED PERSONNEL ONLY
1910.1018	Inorganic arsenic	DANGER INORGANIC ARSENIC CANCER HAZARD AUTHORIZED PERSONNEL ONLY NO SMOKING OR EATING RESPIRATOR REQUIRED	DANGER INORGANIC ARSENIC MAY CAUSE CANCER DO NOT EAT, DRINK OR SMOKE WEAR RESPIRATORY PROTECTION IN THIS AREA AUTHORIZED PERSONNEL ONLY
1910.1025	Lead	WARNING LEAD WORK AREA POISON NO SMOKING OR EATING	DANGER LEAD MAY DAMAGE FERTILITY OR THE UNBORN CHILD CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM DO NOT EAT, DRINK OR SMOKE IN THIS AREA

Standard	Substance	Original signs	Final Changes
1910.1027	Cadmium	DANGER CADMIUM CANCER HAZARD CAN CAUSE LUNG AND KIDNEY DISEASE AUTHORIZED PERSONNEL ONLY RESPIRATORS REQUIRED IN THIS AREA	DANGER CADMIUM MAY CAUSE CANCER CAUSES DAMAGE TO LUNGS AND KIDNEYS WEAR RESPIRATORY PROTECTION IN THIS AREA AUTHORIZED PERSONNEL ONLY
1910.1028	Benzene	DANGER BENZENE CANCER HAZARD FLAMMABLE - NO SMOKING AUTHORIZED PERSONNEL ONLY RESPIRATOR REQUIRED	DANGER BENZENE MAY CAUSE CANCER HIGHLY FLAMMABLE LIQUID AND VAPOR DO NOT SMOKE WEAR RESPIRATORY PROTECTION IN THIS AREA AUTHORIZED PERSONNEL ONLY
1910.1029	Coke oven emissions	DANGER CANCER HAZARD AUTHORIZED PERSONNEL ONLY NO SMOKING OR EATING RESPIRATOR REQUIRED	DANGER COKE OVEN EMISSIONS MAY CAUSE CANCER DO NOT EAT, DRINK OR SMOKE WEAR RESPIRATORY PROTECTION IN THIS AREA AUTHORIZED PERSONNEL ONLY
1910.1043	Cotton Dust	WARNING COTTON DUST WORK AREA MAY CAUSE ACUTE OR DELAYED LUNG INJURY (BYSSINOSIS) RESPIRATORS REQUIRED IN THIS AREA	DANGER COTTON DUST CAUSES DAMAGE TO LUNGS (BYSSINOSIS) WEAR RESPIRATORY PROTECTION IN THIS AREA
1910.1044	1,2-Dibromo-3-chloropropane (DBCP)	DANGER 1,2-Dibromo-3-chloropropane (Insert appropriate trade or common names) CANCER HAZARD AUTHORIZED PERSONNEL ONLY RESPIRATOR REQUIRED	DANGER 1,2-DIBROMO-3-CHLOROPROPANE MAY CAUSE CANCER WEAR RESPIRATORY PROTECTION IN THIS AREA AUTHORIZED PERSONNEL ONLY

Standard	Substance	Original signs	Final Changes
1910.1045	Acrylonitrile (AN)	DANGER ACRYLONITRILE (AN) CANCER HAZARD AUTHORIZED PERSONNEL ONLY RESPIRATORS MAY BE REQUIRED	DANGER ACRYLONITRILE (AN) MAY CAUSE CANCER RESPIRATORY PROTECTION MAY BE REQUIRED IN THIS AREA AUTHORIZED PERSONNEL ONLY
1910.1047	Ethylene oxide (EtO)	DANGER ETHYLENE OXIDE CANCER HAZARD AND REPRODUCTIVE HAZARD AUTHORIZED PERSONNEL ONLY RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN THIS AREA	DANGER ETHYLENE OXIDE MAY CAUSE CANCER MAY DAMAGE FERTILITY OR THE UNBORN CHILD RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING MAY BE REQUIRED IN THIS AREA AUTHORIZED PERSONNEL ONLY
1910.1048	Formaldehyde Regulated Areas	DANGER FORMALDEHYDE IRRITANT AND POTENTIAL CANCER HAZARD AUTHORIZED PERSONNEL ONLY	DANGER FORMALDEHYDE MAY CAUSE CANCER CAUSES SKIN, EYE, AND RESPIRATORY IRRITATION AUTHORIZED PERSONNEL ONLY
	Storage Areas for Contaminated Clothing and Equipment	DANGER FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT AVOID INHALATION AND SKIN CONTACT	DANGER FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT DO NOT BREATHE VAPOR DO NOT GET ON SKIN
1910.1050	Methylenedianiline (MDA)	DANGER MDA MAY CAUSE CANCER LIVER TOXIN AUTHORIZED PERSONNEL ONLY RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN THIS AREA	DANGER MDA MAY CAUSE CANCER CAUSES DAMAGE TO THE LIVER RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING MAY BE REQUIRED IN THIS AREA

Standard	Substance	Original signs	Final Changes
			AUTHORIZED PERSONNEL ONLY
1926.60	MDA	DANGER MDA MAY CAUSE CANCER LIVER TOXIN AUTHORIZED PERSONNEL ONLY RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN THIS AREA	DANGER MDA MAY CAUSE CANCER CAUSES DAMAGE TO THE LIVER RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING MAY BE REQUIRED IN THIS AREA AUTHORIZED PERSONNEL ONLY
1926.62	Lead	WARNING LEAD WORK AREA POISON NO SMOKING OR EATING	DANGER LEAD WORK AREA MAY DAMAGE FERTILITY OR THE UNBORN CHILD CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM DO NOT EAT, DRINK OR SMOKE IN THIS AREA
1926.1101	Asbestos Regulated areas	DANGER ASBESTOS CANCER AND LUNG DISEASE HAZARD AUTHORIZED PERSONNEL ONLY	DANGER ASBESTOS MAY CAUSE CANCER CAUSES DAMAGE TO LUNGS AUTHORIZED PERSONNEL ONLY
	Where the use of respirators and protected clothing is required	RESPIRATORS AND PROTECTIVE CLOTHING ARE REQUIRED IN THIS AREA	WEAR RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING IN THIS AREA
1926.1127	Cadmium	DANGER CADMIUM CANCER HAZARD CAN CAUSE LUNG AND KIDNEY DISEASE AUTHORIZED PERSONNEL ONLY RESPIRATORS REQUIRED IN THIS AREA	DANGER CADMIUM MAY CAUSE CANCER CAUSES DAMAGE TO LUNGS AND KIDNEYS WEAR RESPIRATORY PROTECTION IN THIS AREA AUTHORIZED PERSONNEL ONLY

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OSHA's proposal to change the signage requirements in the substance-specific standards was nearly universally supported by commenters. Product Safety Solutions, AHMP, National Paint and Coatings Association, Ameren, Wacker Chemical Corp, ASSE, Stericycle, Phylmar Regulatory Roundtable, Soap and Detergent Association/Consumer Specialty Products Association, Ecolab, Inc., AIHA, ORC Worldwide, National Association of Homebuilders, API, Procter & Gamble Company, Dr. Michelle Sullivan, Clariant Corporation, American Chemical Council, 3M, AISI (American Coke and Coal Chemicals Institute), Industrial Health and Safety Consultants, and NIOSH, in their comments to the NPRM, specifically supported the harmonization of signage required in the substance-specific standards (Document ID #0313, 0327, 0328, 0330, 0335, 0336, 0338, 0339, 0344, 0351, 0365, 0370, 0372, 0376, 0381, 0382, 0383, 0393, 0405, 0408, 0410, and 0412). USSE, agreeing with the commenters above, testified that having the same wording on regulated-areas signs would be helpful to workers as they move around and it is better for them to see the same information they have been trained on (Document ID #0499 Tr. 165).

Commenters raised several signage issues. Dow Chemical advocated the elimination of signs in substance-specific health standards, arguing that there was no need for signs since the chemical will be labeled and workers can also refer to an SDS (Document ID #0353). OSHA disagrees. The substance-specific standards' sign requirements cover regulated areas of facilities that are by definition high-exposure or potentially high-exposure areas. They are among the most dangerous areas in a facility, which is why OSHA requires signs. Moreover, contrary to what Dow assumes, product labels may not always be available in these circumstances. Thus, OSHA disagrees with Dow Chemical and believes the signs convey crucial information about the chemical hazard in a regulated area and that the signs benefit not only the well-trained worker but also other workers who might be near, or inadvertently enter, the regulated area.

The Battery Council International (Document ID #0390) had suggestions for language on regulated area signs for the lead standard, 29 CFR 1910.1025. First, they requested that OSHA change the language from ''Causes Damage to the Central Nervous System'' to ''May Cause Damage to the Central Nervous System,'' since nerve damage may or may not occur depending on whether or not the facility has taken proper precautions. However, as discussed above, OSHA has updated the signs to be consistent with GHS labeling to ensure that the worker is receiving the same message and this would provide better identification of the hazard. Therefore, OSHA has retained the proposed language for lead regulated area signs in the final.

The Battery Council International also requested that OSHA retain the original language § 1910.1025(m)(2) so that it would be clear that other signage may also be used in places where required (Document ID #0390). For example, it reported that California has such a signage requirement under Proposition 65. OSHA agrees that, in some very specific cases, other warnings may be necessary for lead. Thus, the current requirement that, ''The employer may use signs required by other statutes, regulations or ordinances in addition to, or in combination with, signs required by this paragraph,'' has been retained in the final rule for the lead standard at § 1910.1025(m)(2)(iv).

OSHA concludes that the proposed changes, which are as close as possible to the GHS terminology, are essential in order to make the warnings on signs consistent with each other, as well as labels, to the extent possible. These consistent warning signs will provide the best hazard communication in the relevant workplace regulated areas. The proposed changes to the signage requirements of the substance-specific standards have been carried through to the final rule.

Hazard Communication, Classification and Labels

OSHA's current substance-specific standards are inconsistent in that some have their own communication of hazards requirements, while other standards reference the HCS, and still other standards have no requirements for labels and safety data sheets in their sections. Although these latter standards are missing requirements, they still are covered by HCS. Similarly for labels, while most substance-specific standards require labels on containers of raw materials, mixtures, and products, some specify specific language while others reference the HCS. As proposed, and as carried forward in this final rule, OSHA has standardized the language for hazard communication and has removed the requirements for specific language labels from the ''Communications of hazards'' paragraphs of the substance-specific standards. The new paragraph in each substance-specific standard uses the following model format:

Hazard Communication—General.

(i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (29 CFR 1910.1200) for [chemical name].

(ii) In classifying the hazards of [chemical name] at least the following hazards are to be addressed: [hazard information].

(iii) Employers shall include [chemical name] in the hazard communication program established to comply with the HCS. Employers shall ensure that each employee has access to labels on containers of [chemical name] and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph [Training paragraph] of this section.

By adding this paragraph in each substance-specific health standard, OSHA achieves consistency across standards and with GHS principles. Some commenters indicated that the chemicals covered by the substance-specific standards should not be classified any differently than any other chemical in regard to the health hazards included on a label or SDS (*See, e.g.,* Document ID #0365). That was OSHA's intent. OSHA has clarified the regulatory language to minimize confusion. The final rule, like the proposal, requires compliance with the HCS in each substance-specific standard.

OSHA believes that requiring standards to reference HCS will ensure consistency with the GHS revisions and across the standards and consistency when the specific chemical is part of a mixture. Removal of the current specific warning language was essential for adoption of the GHS language. Retention of these provisions in the standards would result in the untenable situation of two potentially conflicting requirements, only one of which (the reference to HCS) would be in accord with the GHS-modified HCS. Moreover, as OSHA noted in the preamble to the proposed standard, the hazard statements specified for the chemical in the standard might not be correct when the chemical is part of a mixture. As for the current standards that simply referenced HCS, employers could choose any language and format that conveyed the necessary information. This approach is no longer allowed because, as OSHA has found in adopting the GHS approach, consistency in labeling is key to effective communication of hazards. The vast majority of commenters agreed. For example, AHMP noted that eliminating language inconsistent with established hazard statements will facilitate hazard communication and should not result in lower protection (Document ID #0327). Others, including NIOSH, DuPont, Ameren, ASSE, Ecolab, Inc., AIHA, ORC Worldwide, NAHB, API, Procter & Gamble, Dr. Michelle Sullivan, ACC, 3M, AISI, Industrial Health and Safety Consultants, and American Coke and Coal Chemicals Institute, agreed (Document ID #0329, 0330, 0336, 0351, 0365, 0370, 0372, 0376, 0381, 0382, 0393, 0405, 0408, 0410, and 0412). Commenters noted that for the benefits of consistency to accrue, harmonization is essential (Document ID #0313, 0315, 0327, 0328, 0329, 0330, 0335, 0336, 0338, 0344, 0365, 0370, 0372, 0376, 0381, 0382, 0383, 0393, 0405, 0408, and 0410). NIEHS Worker Education and Training Program agreed, testifying that consistency of labels and safety data sheets is important to help employees recognize hazards and be able to deal with them effectively (Document ID #0497 Tr. 104). Phylmar Regulatory said that standardized label elements will be more effective in communicating hazard information (Document ID #0497 Tr. 108–109). AIHA testified that standardized labels will make hazard identification easier and the pictograms will be useful in workplaces where English language reading is limited (Document ID #0496 Tr. 415). USSW affirmed that one hazard communication system would be best (Document ID #0499 Tr. 178). OSHA believes all these commenters provide important and compelling reasons for the labels required by the substance-specific standards to be consistent with the GHS modifications to HCS.

For classification purposes, OSHA proposed to provide guidance on the potential health outcomes that must be addressed when classifying a substance by setting forth the health end-points (outcomes) for each substance-specific health standard. The Agency did not attempt to formally classify each substance; rather, OSHA provided a proposed list of health effects to assist the classifier in determining what must be considered for inclusion on the new labels. The GHS classification process for a specific substance dictates the actual hazard warnings and precautionary statements that are required on the new GHS-compliant labels and SDSs. In determining the hazards to include for each substance-specific health standard, the Agency's primary sources on health effects were the information gained in its own rulemakings and subsequent experience, the NIOSH Pocket Guide to Chemical Hazards (2005), and the International Chemical Safety Cards (ICSCs). The ICSCs are an undertaking of the International Programme on Chemical Safety (IPCS) (a joint activity of three cooperating International Organizations, namely, the United Nations Environment Programme (UNEP), the International Labour Office (ILO), and the World Health Organization (WHO)) and are peer reviewed by a group of internationally recognized experts (Document ID #0412.2). As a secondary source, OSHA also considered the European Union's (EU) ''Proposal for a Regulation of the European Parliament and of the Council on Classification, Labeling and Packaging of Substances and Mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006.'' From these sources, OSHA developed hazard endpoints to be considered for hazard classification in the substance-specific health standards based on either of two criteria: (1) The health hazard was the basis for the original rulemaking; or (2) the health hazard was asserted by OSHA, NIOSH, or IPCS, and confirmed by a second source. For example, acrylonitrile (AN) (§ 1910.1045) was regulated by OSHA based on its carcinogenicity. Skin sensitization was acknowledged by OSHA, IPCS, and EU; skin irritation by OSHA, NIOSH, and EU; respiratory tract irritation by IPCS and EU; eye irritation by OSHA, NIOSH, and IPCS; liver effects and central nervous system effects by IPCS and NIOSH; acute toxicity by OSHA, IPCS, and EU; and flammability by IPCS, NIOSH, and EU. Because all these effects met the criteria for inclusion, skin sensitization, skin irritation, respiratory irritation, eye irritation, liver effects, central nervous system effects, acute toxicity, and flammability were listed as potential hazards in the acrylonitrile standard.

OSHA's approach, including its choice of sources for health effects, was generally supported by many commenters to the proposal (Document ID #0329, 0339, 0351, 0370, and 0376). However, some, including NIOSH, AIHA, ASSE, Ameren, Stericycle, Wacker Chemical Corporation, and 3M Corporation, wanted OSHA to add other sources (Document ID #0233, 0330, 0338, 0365, 0405, and 0412). NIOSH suggested OSHA look at OECD SIDS, ESIS, NOAA, NLM, NLM–TOXSEEK, NLM–TOXNET, IPCS, CCOHS, and GESTIS (Document ID #0412). AIHA commented that substance-specific health standards should be classified the same as other chemicals and that other references such as ATSDR Toxicological Profiles, IRIS Toxicological Reviews, WHC Monographs, CICADS, OECD SIDS, and Patty's Toxicology should be used (Document ID #0365). Wacker Chemical Corporation recommended IARC be included and that one recognized body's determination of a hazard should be sufficient (Document ID #0335). ASSE urged inclusion of ACGIH documentation of TLVs and RELs and precautions developed by manufacturers from testing and epidemiological studies. ASSE submitted a long list of sources including NSC's Fundamentals of Industrial Hygiene, The Industrial Environment—Its Evaluation and Control, Patty's Industrial Hygiene and Toxicology, Casarett & Doull's Toxicology, The Dose Makes the Poison, Quick Selection Guide to Chemical Protective Clothing, U.S. DHHS Seventh Annual Report on Carcinogens, AIHA Engineering Field Reference Manual, and 17 others (Document ID #0336). AIHA urged OSHA to have the hazards for the substance-specific standards considered, but not be mandatory. It recommended additional references such as ATSDR Toxicological Profiles, IRIS Toxicological Reviews, EHC Monographs, CICADS, OECD SIDS, and Patty's Toxicology (Document ID #0365). Ameren would have OSHA add ACHIS and AIHA sources (Document ID #0330). Stericycle advocated adding Industrial Chemical Safety Cards, European Commission, and ACGIH as secondary sources (Document ID #0338). Still others, such as ASSE, API, AHMP, Product Safety Solutions, National Paint and Coatings Association, and Industrial Minerals Association—North America, deemed OSHA's choice of sources inadequate (Document ID #0313, 0327, 0328, 0338, 0376, and 0379). USSW (Document ID #0403) found lists such as IARC's and NTP's useful, but wanted OSHA to state in the regulatory text that a chemical on one or more of these lists was sufficient to classify it as hazardous (although the absence of a chemical on a list does not mean it is not hazardous). It also wanted OSHA to use lists in enforcement.

Commenters also raised other issues in this regard. API believed OSHA should just reference the GHS criteria, while ASSE wanted OSHA to use other authoritative references (Document ID #0336 and 0376). Both AHMP and Product Safety Solutions were concerned the NIOSH Pocket Guide and International Chemical Safety Cards had not been subject to rulemaking and could be overly conservative, even though they felt these sources could be used as information, but not as precedent if significant contradictory information is presented (Document ID #0313 and 0327). National Paint and Coatings Association commented that the substance-specific standards' health hazards should remain as published and only new information should be subject to the two-reference rule (Document ID #0328). Still other commenters, including DuPont Company, Soap and Detergent Association and Consumer Specialty Products Association, Procter & Gamble, and Dr. Michelle Sullivan, expressed concern about whether the sources OSHA was using were to be current or updated, as newer editions become available (Document ID #0329, 0344, 0381, and 0382).

OSHA believes these comments reflect a misunderstanding of what OSHA proposed for its substance-specific health standards and how the sources were used to yield health effects to be considered in classifying all health hazards but not to perform a formal classification. (*See* 74 FR at 50411, Sept. 30, 2009, for the preamble explanation). The substance-specific health standards are unique in that they were all the subject of rulemaking, enabling the Agency to collect extensive information on sources and on health effects. That collection of information, coupled with the Agency's own expertise, enabled the Agency to confidently select sources for these regulated chemicals that would provide adequate information to classifiers. OSHA disagrees with commenters who suggested its chosen sources were inadequate. Some commenters recommended other sources. OSHA believes that these other sources can be useful in classifying hazards, and can certainly be used by classifiers in evaluating the hazards related to chemicals regulated by the substance-specific standards. At issue here, though, is the method OSHA has determined to use for selecting a list of hazard endpoints that, at a minimum, must be considered to provide accurate warnings on labels for its substance-specific standards. OSHA has concluded that the method it used in the proposal is scientifically sound and appropriate.

In complying with the HCS, as discussed above, classifiers must take into account available scientific information about the hazards of the chemical being classified, which could include information found in the other sources noted by the commenters. The manufacturer, distributor, or importer must still classify and categorize each regulated chemical (in the substance-specific health standards) in compliance with the GHS-modified HCS and its appendices. The lists of endpoints for each substance-specific standard are the minimum that must be considered. The manufacturer or importer has leeway to use additional primary studies and sources to evaluate the substance-specific chemical and is free to add health effects' endpoints as appropriate according to the studies or sources. As discussed previously in this section, the HCS generally uses a weight-of-evidence approach in classifying health hazards. Therefore, a superior source or significant and compelling contradictory information to a particular source usually must be weighed with the total body of evidence.

IMA–NA suggested that OSHA's methodology for determining the list of health effects to be considered by classifiers does not meet the requirements of the Information Quality Act (Document ID #0233). OSHA disagrees. That statute, and the guidelines published under it (discussed in more detail above), require that agencies take steps to ensure the "quality, objectivity, utility, and integrity" of information they disseminate. Similar to its response to the concern regarding TLVs, discussed above, OSHA does not believe that it is disseminating information for purposes of the IQA when it merely requires that manufacturers and importers consider specific health effects listed for each substance-specific standard in classifying the chemical under the HCS. However, even if it were disseminating information in the final rule, OSHA believes that it has complied with the applicable requirements of the IQA. OSHA has fully described the methods by which it determined the listed health effects for each substance, relied only on respected health compilations prepared by governmental agencies or subject to peer review, and subjected its analysis to notice and comment in this rulemaking. This adequately assures the quality, objectivity, utility, and integrity of any dissemination of information involved in these provisions of the final rule.

OSHA received no comments on the particular hazards proposed for each substance-specific health standard, and retained them in the final rule. The endpoints for each substance-specific standard are listed in Table XIII–5, "Health Effects Determined for the Substance-Specific Standards."

TABLE XIII–5—HEALTH EFFECTS DETERMINED FOR THE SUBSTANCE-SPECIFIC STANDARDS

Standard No.	Substance	Health effects
1910.1001, 1915.1001, 1926.1101.	Asbestos	Cancer and lung effects.
1910.1003	4-Nitrobiphenyl	Cancer.
1910.1003	Alpha-Naphthylamine	Cancer; skin irritation; and acute toxicity effects.
1910.1003	Methyl chloromethyl ether	Cancer; skin, eye, and respiratory effects; acute toxicity effects; and flammability.
1910.1003	3,3′-Dichlorobenzidine (and its salts)	Cancer and skin sensitization.
1910.1003	Bis-Chloromethyl ether	Cancer; skin, eye, and respiratory tract effects; acute toxicity effects; and flammability.
1910.1003	Beta-Naphthylamine	Cancer and acute toxicity effects.
1910.1003	Benzidine	Cancer and acute toxicity effects.
1910.1003	4-Aminodiphenyl	Cancer.
1910.1003	Ethyleneimine	Cancer; mutagenicity; skin and eye effects; liver effects; kidney effects; acute toxicity effects; and flammability.
1910.1003	Beta-Propiolactone	Cancer; skin irritation; eye effects; and acute toxicity effects.
1910.1003	2-Acetylaminofluorene	Cancer.
1910.1003	4-Dimethylaminoazo-benzene	Cancer; skin effects; and respiratory tract irritation.
1910.1003	N-Nitrosodimethylamine	Cancer; liver effects; and acute toxicity effects.
1910.1017	Vinyl chloride	Cancer; central nervous system effects; liver effects; blood effects; and flammability.
1910.1018	Inorganic arsenic	Cancer; liver effects; skin effects; respiratory irritation; nervous system effects; and acute toxicity effects.

TABLE XIII–5—HEALTH EFFECTS DETERMINED FOR THE SUBSTANCE-SPECIFIC STANDARDS—Continued

Standard No.	Substance	Health effects
1910.1025, 1926.62	Lead	Reproductive/developmental toxicity; central nervous system effects; kidney effects; blood effects; and acute toxicity effects.
1910.1026, 1915.1026, 1926.1126.	Chromium VI	Cancer; skin sensitization; and eye irritation.
1910.1027, 1926.1127	Cadmium	Cancer; lung effects; kidney effects; and acute toxicity effects.
1910.1028	Benzene	Cancer; central nervous system effects; blood effects; aspiration; skin, eye, and respiratory tract irritation; and flammability.
1910.1029	Coke oven emissions	Cancer.
1910.1043	Cotton Dust	Lung effects.
1910.1044	1,2-dibromo-3-chloropropane (DBCP)	Cancer; reproductive effects; liver effects; kidney effects; central nervous system effects; skin, eye, and respiratory tract irritation; and acute toxicity effects.
1910.1045	Acrylonitrile (AN)	Cancer; central nervous system effects; liver effects; skin sensitization; skin, respiratory, and eye irritation; acute toxicity effects; and flammability.
1910.1047	Ethylene oxide (EtO)	Cancer; reproductive effects; mutagenicity; central nervous system; skin sensitization; skin, eye, and respiratory tract irritation; acute toxicity effects; and flammability.
1910.1048	Formaldehyde	Cancer; skin and respiratory sensitization; eye, skin, and respiratory track irritation; acute toxicity effects; and flammability.
1910.1050, 1926.62	Methylenedianiline (MDA)	Cancer; liver effects; and skin sensitization.
1910.1051	1,3 Butadiene (BD)	Cancer; eye and respiratory tract irritation; center nervous system effects; and flammability.
1910.1052	Methylene chloride	Cancer; cardiac effects; central nervous system effects; liver effects; and skin and eye irritation.

The NPRM retained specific language for labels in the substance-specific health standards for containers of contaminated clothing or waste and debris to ensure that protection gained from communicating these hazards to the downstream recipients of the materials would not be lessened. The proposal, however, updated the language to be consistent with the GHS. The labeling requirements in these standards are part of broad protections, resulting from PELs and ancillary provisions such as exposure monitoring, personal protective equipment, and medical surveillance. These requirements for labeling containers of contaminated clothing, PPE, and waste and debris have been an integral part of the standards since their promulgation. To simply conform the labeling requirements for these kinds of containers to the GHS-modified HCS rule would not offer the extra protection currently provided in these standards; because of the variation in the quantity of chemicals in the containers of contaminated clothing, PPE, and waste and debris, the chemical concentration may be lower than the specified cut-off values/concentration limits. In such a case, if OSHA only relied on the GHS-modified HCS labeling requirement, labeling for these containers may not be triggered and protections would be lessened.

Commenters agreed that specific language for labels on containers of contaminated clothing and waste and debris should be maintained. For example, Ameren and 3M Corporation commented that maintaining specific language for labels on contaminated clothing and waste/debris containers for the substance-specific health standards will provide adequate warnings to all (Document ID #0330 and 0405). AIHA, in supporting the specific labels, noted that the workplace-contaminated materials are not hazardous chemicals in commerce; thus, these special labels are not inconsistent with GHS. Further, AIHA said that because recipients of these containers are accustomed to specific warnings, a change, such as elimination of the specific warning language because it might not be required by GHS, might be perceived as a change in hazard (Document ID #0365). The Battery Council International urged OSHA not to eliminate the label language requiring the disposal of lead-contaminated waste water in accordance with applicable local, state, or federal regulations in § 1910.1025(m)(2) for contaminated clothing. OSHA agrees that this information is important and is not inconsistent with GHS labeling. Therefore, OSHA has retained this language for the labels for contaminated clothing and equipment in the final rule. AISI and Industrial Health and Safety Consultants urged OSHA to require that the language on containers of contaminated clothing and waste/debris be in accord with the GHS guidelines. Such harmonization would maintain consistency with other labeling and minimize confusion of downstream handlers (Document ID #0408). In addition, Industrial Health and Safety Consultants felt that containers of contaminated clothing and waste/debris should be classified according to the HCS and the specific language on the label should be eliminated (Document ID #0410). As discussed below, OSHA does not agree. Industrial Health and Safety Consultants also suggested that OSHA require HCS classification and labeling of contaminated waste clothing and waste for all chemicals (Document ID #0410). OSHA did not propose such extensive new requirements for containers of chemically contaminated clothing and waste and debris. These requirements were not part of HCS and would be a significant addition to the final rule.

OSHA agrees with the commenters who advocate retaining the warnings and harmonizing these labels for contaminated clothing and waste and debris containers, and did so to the extent possible. (*See* 74 FR 50434–50439, Sept. 30, 2009). However, classifying containers of chemically contaminated clothing and waste and debris consistent with GHS would be an impossible task, as substances found on contaminated clothing and waste and debris often occur in unknown, varying, and frequently small quantities. In order to ensure and maintain protection for employees in workplaces that receive these containers, labeling of the hazards with specific language is essential. The warnings, like all other warnings, are most effective when they are consistent with each other and, to the extent possible, with the GHS language. This consistency was achieved with the proposed language. Therefore, the proposed language for the substance-specific standards remains unchanged and is finalized in this rulemaking.

OSHA is adding two warnings to the Cadmium standard, which were left out of one paragraph of the proposal, through an error. In the NPRM, OSHA proposed that the warning labels for waste, scrap, or debris be required to include ''Danger''; ''Contains Cadmium''; and ''May Cause Cancer'' in paragraph 1910.1027(m)(3)(ii). The warnings ''Causes Damage to Lungs and Kidneys'' and ''Avoid Creating Dust'' were inadvertently left out of this paragraph. (The NPRM properly included these two warnings in paragraph 1910.1027(i)(2)(iv) for bags and containers of contaminated protective clothing and equipment.) OSHA is correcting this error by adding these warnings in this final standard, making the Cadmium standard consistent with the other substance-specific standards and, to the extent possible, with GHS.

In addition, for labels of bags or containers of contaminated clothing and equipment, OSHA has determined precautionary statements that address creating dust in the current substance-specific health standards must be retained even though there is no GHS equivalent. At this time, a work group formed under the UN Sub-Committee of Experts for the GHS (UN Sub-committee) is working to finalize issues related to hazard and precautionary statements. OSHA has recommended to the UN Sub-committee to adopt the phrase ''avoid creating dust'' as a precautionary statement, if this statement is adopted as a precautionary statement, then this statement will be consistent with the GHS. However, if the UN Sub-committee does not adopt such a statement, OSHA intends to continue to require the dust statements in those paragraphs for labels of bags and containers of contaminated clothing and equipment since OSHA has concluded that removing these statements would be a lessening of protection. An example of requirements for those statements can be found in OSHA's Cadmium standard, § 1910.1027(i), (k), and (m). OSHA also inadvertently removed the term ''Avoid Creating Dust'' from the Asbestos labeling requirements in § 1910.1001(j) and § 1926.1101(l) of the proposal. As discussed above, OSHA believes that this is a unique statement and should be retained. OSHA is correcting this error by reinstating this phrase in the asbestos labeling requirements in § 1910.1001(j) and § 1926.1101(l).

Occupational Exposure To Hazardous Chemicals in Laboratories: Definitions

OSHA proposed to modify most of paragraph (b), Definitions, in § 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories (the laboratory standard), in order to maintain compatibility with HCS. In particular, OSHA removed the definitions of Combustible liquid, Compressed gas, Explosive, Flammable, Flashpoint, Organic peroxide, Oxidizer, Unstable (reactive), and Water-reactive from paragraph (b). In addition, in the NPRM, OSHA revised the definitions of Hazardous chemical, Physical hazard, and Reproductive toxins in paragraph (b) and added definitions for Health hazard and Mutagen in paragraph (b). By these modifications to § 1910.1450, the proposal sought to ensure that the definitions to the GHS-modified HCS also apply to the laboratory standard (§ 1910.1450). The modification is consistent with the goal of this rulemaking and the original intent of the laboratory standard. OSHA explained in the preamble to the laboratory standard the importance of having the HCS and the laboratory standard both use the same definitions for hazardous chemicals:

> The term ''hazardous chemical'' used in this final rule relies on the definition of ''health hazard'' found in the OSHA Hazard Communication Standard. As discussed in the scope and application section above, commenters urged OSHA to maintain consistency in terms between the Hazard Communication Standard and this final standard since laboratories are subject to both regulations.

(55 FR 3315, Jan. 31, 1990).

Ameren agreed with OSHA that ''combustible liquid'' should be removed from paragraph (b) (Document ID #0330). However, the company recommended that OSHA replace the term with specific flashpoint criteria. OSHA disagrees that a definition for combustible liquid with specific flashpoint criteria differing from GHS-modified HCS should be contained in the laboratory standard. OSHA's intention is to harmonize the laboratory standard with the GHS-modified HCS. The final HCS rule contains definitions of flammable liquids with flashpoint criteria in Appendix B, and these flashpoint criteria include what are currently the combustible liquid classes. The laboratory standard does not contain specific requirements for physical hazards, including flammable or combustible liquids. Rather, this program standard contains requirements for such things as a chemical hygiene plan, employee exposure determination, training, medical consultation and examinations, and recordkeeping. Thus, OSHA does not see a need for including separate flashpoint criteria for flammable or combustible liquids and believes that reference to the flammable liquid categories in HCS is appropriate for § 1910.1450.

OSHA proposed to maintain the current definition of ''select carcinogens'' in the laboratory standard since the original purpose of the standard was to deviate from the HCS definition and narrow the scope of the standard. As noted in the preamble to the final rule for the laboratory standard, the scope was set for ''select carcinogens'' based on the small, often minute, quantities of substances handled. OSHA stated its reasons for this deviation in that preamble, and those reasons remain persuasive:

> This final rule, however, modifies the carcinogen definition and the obligatory action so that special provisions must be explicitly considered by the employer, but need only be implemented when the employer deems them appropriate on the basis of the specific conditions existing in his/her laboratory. Moreover, the term, ''carcinogen'' has been replaced by ''select carcinogen'' which covers a narrower range of substances * * *

(55 FR 3315, Jan. 31, 1990).

OSHA has thus incorporated in the final rule its proposed changes to the definitions in the laboratory standard.

Appendices

OSHA reviewed the appendices to each of its substance-specific health standards and made the following minor changes necessary to align the appendices with their GHS-harmonized standards.

The language in Appendix B, ''Employee Standard Summary,'' chapter XI, ''Signs,'' in both the general industry and the construction standards for lead (§ 1910.1025 and § 1926.62, respectively) has been made consistent with the language in their regulatory texts.

In Asbestos § 1910.1001, Appendix F, ''Work Practices and Engineering Controls for Automotive Brake and Clutch Inspection, Disassembly, Repair and Assembly (Mandatory),'' a reference to paragraph (j)(4) of the standard has been redesignated as paragraph (j)(5) to be consistent with the changes in the regulatory text for § 1910.1001. No changes were made to the construction Asbestos standard § 1926.1101, as none were needed.

Safety Data Sheets

OSHA has changed the term ''material safety data sheets'' when it appears to ''safety data sheets'' in both the substance-specific health standards and their appendices. As discussed above, this change reflects the GHS terminology.

Compliance Dates for Substance-Specific Health Standards

OSHA proposed to require implementation of all but one of the revisions to the HCS in three years following completion or promulgation of the final rule. Training was proposed to be required in two years. OSHA noted that during the transition period, an employer could be in compliance with either the current HCS or the revised HCS (the final rule), but there could not be a lapse in compliance. For the final standard, OSHA has decided to align implementation of GHS with the final implementation of GHS in the EU for labeling and SDSs. A full explanation of the information and comments and the Agency's reasoning is set out above in this section.

The proposed changes to the substance-specific health standards required compliance with the HCS, thus incorporating the proposed compliance dates for the revised HCS. One commenter suggested that the proposed sign and label updates be done in accordance with the facility's normal replacement schedule (Document ID #0376). OSHA finds that this is too indefinite a period, because it essentially leaves the compliance date in the hands of each employer. OSHA has concluded that the administration of HCS programs by employers and the communication and comprehension of the hazards by employees will be most effective if the requirement for completion of changes for the substance-specific health standards is the same as for all other chemicals. In a sense, this is just another example of the consistency that was approved by so many of the commenters and hearing witnesses.

Thus, the final rule keeps the compliance dates for the new substance-specific health standard requirements in line with those for the revisions to the HCS. Employers must be using new labels for contaminated clothing and waste and debris by June 1, 2015, the date by which manufacturers and importers must comply with the labeling and SDS requirements of the revised HCS. Employers must post the new signs by June 1, 2016, the same date by which employers must also update their hazard communication plans for any new hazard information they receive as a result of the final rule. In the meantime, as with the revised HCS, employers must comply with either the old or new labeling and signage requirements. Provisions to this effect are inserted for each substance-specific standard in this final rule.

Safety Standards

OSHA proposed modifying safety standards that either directly reference the HCS or provide information pertinent to the SDSs, in particular regarding the storage and handling of chemicals. As noted above, many commenters supported standardizing physical hazard criteria across all applicable OSHA standards (Document ID #0034, 0104, 0105, 0155, 0170, 0171, 0313, 0324, 0327, 0328, 0329, 0336, 0338, 0359, 0365, 0376, 0382, 0395, 0405, 0408, 0410, and 0494 Tr. 91, 162). For example, the Compressed Gas Association (CGA) (Document ID #0324) stated:

> CGA agrees with the harmonization to GHS to align the definitions of the physical hazards to the requirements of the GHS categories in safety standards for general industry, construction, and maritime standards, which either directly reference the Hazard Communication Standard * * * or provide information pertinent to the SDS.

However, some other commenters, and even some who supported applying physical hazard criteria across all standards, raised concerns about storage and handling requirements; degree of impact; potential effects on the scope of the Process Safety Management of Highly Hazardous Chemicals (PSM) standard; and potential conflicts with widely accepted consensus standards (Document ID #0038, 0077, 0104, 0163, 0329, 0335, 0336, 0339, 0366, 0370, 0381, 0383, 0393, 0399, 0414, 0500, 0514, 0530, 0643, 0494 Tr. 91, 162, and 0497 Tr. 81–84).

OSHA agrees with the commenters who supported standardizing physical hazard criteria and is doing so except in some standards, such as OSHA's electrical standards, where conflicts with referenced consensus standards make harmonization inappropriate at this time. OSHA proposed to:

- Incorporate the current HCS definitions of flammable liquid and gas into PSM and health hazard into Hazardous Waste Operations and Emergency Response (HAZWOPER) standards;
- Modify the Welding standard (§ 1910.252) requirements on labeling welding consumables to be consistent with GHS modifications to HCS;
- Amend paragraphs on flammable and combustible liquids to conform categories, terminology, flashpoints (FP), and boiling points to the GHS modifications to HCS;
- Incorporate the modified-HCS definition of flammable aerosols into the Flammable and Combustible Liquids standard, § 1910.106. (In § 1910.106, OSHA is also correcting a rounding error in the conversion from 12 feet to meters. The change is from 3.648 meters to 3.658 meters); and
- Update the acceptable methods for determining flashpoints; but
- Leave unchanged electrical standards in Subpart S for general industry and Subpart K for construction, and explosive standards for general industry (§ 1910.109) and for construction (§ 1926.914).

Commenters overwhelmingly supported ensuring consistency in OSHA standards, while maintaining scope of coverage. (Document ID # 0049, 0050, 0077, 0105, 0123, 0145, 0163, 0170, 0313, 0324, 0327, 0328, 0351, 0359, 0365, 0376, and 0494 Tr. 91, 162). Organization Resource Counselors (ORC) (Document ID # 0494 Tr. 91) testified:

> ORC supports concurrent harmonization of hazard definitions in most OSHA standards. ORC agrees with OSHA's proposal to harmonize hazardous communication components across most other OSHA standards in this rulemaking. ORC believes this is the most efficient way to address this necessary step in ensuring consistent hazard information and eliminating conflicting requirements.

Many comments to the ANPR and the NPRM supported OSHA exempting certain standards such as electrical and explosive standards from harmonization at this time (Document ID # 0047, 0075, 0076, 0104, 0113, 0145, 0163, 0328, 0330, 0336, 0370, 0393, and 0408). For example, the standards in Subpart S contain requirements such as internal design criteria that, if changed, would impact their scope. OSHA's reasons for excluding these standards are explained below. In testimony at the hearing, the ACC (Document ID # 0494 Tr. 162) agreed, stating:

We agree with this approach and therefore would expect that there would be no impact on electrical area classification, facility [s]iting, mechanical integrity, electrical classification, storage quantities, unloading and storage location, ventilation requirements, spill protection, grounding and bonding, tank and vessel design, interlocks and safety devices and process hazard analysis.

As discussed in detail below, in the final rule PSM retains its current scope; HAZWOPER's definition of ''health hazard'' is modified; the definitions in the Flammable and Combustible Liquids standards are aligned with the GHS modifications to HCS; Welding, Cutting and Brazing labeling requirements were also modified to be consistent with HCS; and a few technical amendments have been made to other safety standards that currently use the term ''combustible'' in order to keep their scope the same. Also, no changes were made to standards that OSHA proposed to exclude from this rulemaking.

PSM

PSM standards for general industry and construction reference the HCS for their scopes, which are currently set forth in § 1910.119(a)(1)(ii) and § 1926.64(a)(1)(ii) as covering a process which involves a flammable liquid or gas (as defined in § 1910.1200(c) [§ 1926.59(c)] on site in one location, in a quantity of 10,000 pounds (4535.9 kg) or more, followed by the listed exceptions in the paragraph.

If OSHA did not modify this provision in this rulemaking, the scope of PSM would expand since the HCS's definition of flammable liquid changes from liquids with a flashpoint below 100 °F (37.8 °C) to the new GHS definition of liquids with a flashpoint at or below 199.4 °F (93 °C) (though, as discussed above, the scope of the HCS is unaffected). Keeping the reference to the HCS definition would mean that many more processes would have been covered by the PSM standards than when those standards were promulgated. OSHA does not intend to expand the scope of the PSM standards. Therefore, to maintain the scope of those standards, OSHA proposed to modify the language in the scope paragraphs § 1910.119(a)(1)(ii) and § 1926.64(a)(1)(ii) to read:

A process which involves a Category 1 flammable gas (as defined in § 1910.1200(c)) or flammable liquid with a flashpoint below 100 °F (37.8 °C) on site in one location, in a quantity of 10,000 pounds (4535.9 kg) or more * * *

In other words, for PSM, ''flammable gas'' includes Category 1 flammable gases and liquids only if they have flashpoints below 100 °F (37.8 °C) to be consistent with the criteria specified in the current HCS.

Commenters who considered the issue differed on what should be done (Document ID #0324, and 0402). For example, ACC, in responding the NPRM, supported OSHA's approach (Document ID # 0393). ACC noted that OSHA's proposed regulatory language for § 1910.119, the general industry PSM, appropriately reflected the new cut-off without changing the scope of the regulation (Document ID #0393). However, CGA requested that OSHA update paragraph (a)(1)(ii) of § 1910.119 to use GHS Category 1 flammable liquids as a cutoff for PSM coverage, stating, ''This would maintain consistency throughout the OSHA standards and harmonization with the GHS'' (Document ID #0324). The Society of Chemical Manufacturers and Affiliates (SOCMA) (Document ID #0402) was concerned that the change in the flashpoint trigger for flammable liquids from ''the current 100 °F to the new 140 °F * * * would significantly expand the number of products subject to OSHA 1910.106 (flammable liquids), and OSHA 1910.119 (Process Safety Standards).''

While OSHA agrees with CGA that using GHS Category 1 flammable liquids would maintain consistency throughout the OSHA standards, to do so would change the scope of the PSM standard by making it applicable only to flammable liquids with flashpoints below 73 °F (23 °C). This would significantly narrow the scope of PSM and lessen worker protection by eliminating from coverage flammable liquids with flashpoints from 73 °F to below 100 °F. However, to set the coverage of PSM to 140 °F (flammable liquid categories 1, 2 and 3 which require the hazard warning ''flammable'' to appear on labels), as SOCMA noted, would expand the coverage beyond the scope of the original standard.

OSHA has concluded that setting the flashpoint below 100 °F (37.8 °C), the previous HCS level, properly maintains the scope of the PSM standards as they were promulgated. As explained in the proposal, OSHA's approach to the other affected standards is to ''modify provisions of the standards that reference the HCS definitions to maintain coverage or consistency with the modified HCS'' (74 FR 50404, Sept. 30, 2009). It is beyond the scope of this rulemaking to consider whether, as a substantive matter, the scope of the PSM standards should be changed. Thus, OSHA is neither increasing nor decreasing the scope of the PSM standard; consequently, the same products in the same quantities will be covered. The final rule adopts the proposed changes to the PSM standards noted above.

HAZWOPER

In the NPRM, OSHA updated the definition of health hazard in its HAZWOPER standards, § 1910.120(a)(3) for general industry and § 1926.65(a)(3) for construction, so that the terminology is aligned with the GHS health hazards in § 1910.1200, Appendix A. The final rule retains the proposed definition.

In proposing this change, OSHA was concerned that some of the terminology in HAZWOPER, such as neurotoxin and nephrotoxin, which were partly defined by reference to the HCS, would no longer be consistent with the GHS-modified HCS. For consistency, the proposal removed such terms from HAZWOPER and are now subsumed within the HCS specific target organ toxicity category, thus maintaining the same hazard communication requirements in both HAZWOPER and HCS. By updating the definition of ''health hazard'' in the HAZWOPER standards to clearly reference HCS, employers will have the proper reference to HCS and, in there, the proper guidance on how to classify the health hazards. OSHA received no contrary comment, and the final rule adopts the definition of health hazard as proposed.

The ACC requested that OSHA clarify how the HAZWOPER standards would be affected by OSHA's adoption of the GHS flammable and combustible liquid classifications in § 1910.106, § 1926.152, and § 1926.155 (Document ID # 0393 and 0530). ACC seems to be asking why OSHA did not reference the new definitions (GHS categories) of flammable liquids in HAZWOPER. OSHA believes the HAZWOPER standards would not be directly affected by the GHS-harmonized categories of flammable liquids, and therefore ACC's concern is misplaced. The HAZWOPER standards are program standards, and they do not contain any specific references to flammable or combustible liquids. It is true that the HAZWOPER standards state that all requirements of Parts 1910 and 1926 of CFR title 29 apply to hazardous waste and emergency response (§ 1910.120(a)(2) and § 1926.65(a)(2)). Thus, where HAZWOPER-covered employees are responding to an emergency situation where flammable liquids have been stored or need to be temporarily stored during clean-up, the flammable liquid standards might apply. OSHA believes that even in those situations, GHS harmonization of flammable liquids will have little or no effect on the HAZWOPER standards, because the substantive requirements of these standards have not significantly changed.

Welding, Cutting and Brazing—General Requirements

OSHA is harmonizing the requirements in the Welding, Cutting and Brazing standard, § 1910.252, by adding a Hazard Communication paragraph and bringing in line with the GHS and OSHA's substance-specific health standards the terminology in the labeling requirements for filler metals and fusible granular materials, filler metals containing cadmium, and fluxes containing fluorine compounds.

The final rule retains the proposed text of the Hazard Communication paragraph at § 1910.252(c)(1)(iv). Similar to the substance-specific standards, the welding standard's hazard communication paragraph requires employers to include welding contaminants in a program established to comply with the HCS (§ 1910.1200). Also, similar to the substance-specific standards, OSHA has added a date paragraph requiring employers to be using new labels by June 1, 2015, the date by which manufacturers and importers must comply with the labeling and SDS requirements of the revised HCS.

In addition to adding the general Hazard Communication paragraph, OSHA reorganized some of the paragraphs in § 1910.252 so as to place the general reference to HCS in the correct position in the standard, § 1910.252(c)(1)(iv). To accomplish this, OSHA moved the ''Additional considerations for hazard communication in welding, cutting, and brazing,'' including filler and fusible granular materials, materials containing cadmium, and materials containing fluorine compounds, from paragraphs (c)(1)(iv)(A) through (C) to new paragraphs (c)(1)(v)(A) through (D).

The proposal inserted a cross reference to § 1910.1200 in the welding standards hazard determination section. In addition, as with the substance-specific standards, the proposal deleted specific label language requirements for welding materials containing cadmium and fluorine and instead listed specific health endpoints to be considered in the classification.

OSHA received one comment on the proposed changes from the Gases and Welding Distributors Association, Inc. (GAWDA). While GAWDA generally supported OSHA's rulemaking effort, GAWDA requested that OSHA change ''suppliers'' of welding materials to ''manufacturers'' in § 1910.252(c)(1)(v)(A) of the proposal (Document ID # 0388). GAWDA stated the term ''supplier'' is undefined and might include different entities in the supply chain; furthermore, elsewhere OSHA places the responsibility of hazard determination on manufacturers, importers, and distributors. However, OSHA would like to point out that the term ''supplier'' is used in the current standard, which requires suppliers to determine the hazards in § 1910.252(1)(c)(iv): ''The suppliers of welding materials shall determine the hazard, if any, associated with the use of their materials in welding, cutting, etc.'' OSHA assumes that ''suppliers'' will continue to use the same method that they are currently using to determine the hazards of their materials. To change this term could result in a substantive change in the scope of this standard and would be beyond the scope of this rulemaking. Therefore OSHA will retain the word ''suppliers'' as proposed.

In addition, as discussed in the preamble to the proposal, *See* 74 FR 50417 (Sept. 30, 2009), current § 1910.252(c)(iv) does not merely require suppliers to determine the hazards of their products, but also to ensure that labels properly convey those hazards. A requirement that a supplier only determine the hazard of its products is of little value if they do not also convey information about those hazards on to the persons who use it. The final rule provides additional clarity that suppliers of welding products covered by the standard label as well as determine the hazard.

The changes to this standard were predicated on achieving consistency with the GHS modifications to HCS and other OSHA substance-specific standards, and OSHA has concluded that the modifications as proposed and as explained in the previous paragraphs will effectuate harmonizing the standard's terminology with HCS. In addition, this action also contributes to internal consistency by making the Welding, Cutting, and Brazing standard similar to the substance-specific health standards.

Flammable and Combustible Liquids

OSHA proposed to align the definitions of flammable and combustible liquids in both the general industry and construction standards to conform to the GHS modifications to the HCS. In particular, the proposal changed the definitions of flammable liquid categories and deleted the term and definition of combustible liquids (*See* Table XIII–6 for comparison of the GHS-modified HCS definitions and the current flammable and combustible definitions that were contained in 29 CFR 1910.106 and 29 CFR 1926.155). OSHA has concluded that the proposed changes to the § 1910.106 and § 1926.155 definitions are reasonably necessary and appropriate and carried them forward into the final rule. In addition, to essentially maintain the scope of the standards, OSHA proposed, and is maintaining in the final rule, the addition of the flashpoint cut-off value where the GHS flammable liquid categories overlapped with the current HCS classes. The Alliance of Hazardous Materials Professionals and David Levine of Product Safety Solutions agreed, stating: ''The elimination of the term 'combustible' and substitution of actual flash point data provide a more meaningful definition in the affected standards'' (Document ID # 0313 and 0327).

OSHA proposed to drop the current rules' classifications of flammable and combustible liquids in favor of the GHS flammable liquid classifications. This meant that all liquids under the proposal would fall into GHS flammable liquid Categories 1 through 4, and that the term ''Combustible Liquids'' in §§ 1910.106, 1910.107, 1910.123, 1910.125, 1926.152, and 1926.155 was proposed to be deleted since the GHS does not have a hazard class titled ''Combustible liquids.'' However, the GHS does require the hazard statement ''combustible liquid'' on the label for Category 4 Flammable liquids (flashpoint greater than 60 °C (140 °F) but not greater than 93 °C (199.4°F)).

In addition, the current general industry Spray Finishing standard, § 1910.107, relies on the current § 1910.106 definition of Class IIIB liquids (liquids with a flashpoint over 93 °C). Therefore the proposal amends § 1910.107 to replace its use of the term ''combustible liquids,'' which has no corresponding GHS category, with the phrase ''Liquids with a Flashpoint Greater than 93 °C (199.4 °F).'' With the new terminology, the protection provided by the original standards remains the same.

OSHA believed that most of the proposed changes in the definitions were not significant. The move to GHS categories entails nominal changes to the flashpoint values for flammable and combustible liquids from 22.8 °C (73 °F) (current Class IA/B cut-off) to 23 °C (73.4 °F) (GHS Category 1/2 cut-off) and from 93.3 °C (200 °F) (current Class IIIB cut-off) to 93 °C (199.4 °F) (GHS Category 4). OSHA believes these changes in flash point represent simple rounding to the closest significant value and that they would have no significant effect on the scope of its standards or on employee safety. ACC agreed with OSHA, stating that ''the elimination of the term 'combustible liquid' in § 1910.107 does not significantly change the requirements of the standards and should not adversely affect industry's ability to comply with the standard'' (Document ID #0393). OSHA has concluded these new whole numbers are minute changes and that the rounded numbers coincide with GHS, are easier to understand and remember, and therefore will improve communication of hazards.

However, OSHA requested comment in the proposal on one change that was potentially significant. Under the proposal, the boiling points used to define the threshold for the current Flammable Class IA in § 1910.106 shifted from the cut-off value of 37.8 °C (100 °F) to a cut-off value of 35 °C (95 °F) for GHS Category 1. Likewise, the boiling points in the proposed definition of Flammable Class IB (§ 1910.106) shift from equal to or greater than (≥) 37.8 °C (100 °F) to greater than (≥) 35 °C (95 °F) in GHS Category 2 (*See* Table XIII–6). The Agency believed the changes would be necessary to make OSHA standards internally consistent and consistent with the GHS modifications to HCS. However, as discussed in the NPRM, OSHA was concerned that changing the boiling point cut-off for the highly flammable liquids classified as Flammable IA could, under the GHS modifications to HCS, lead to a subset of these chemicals being classified as GHS Category 2 Flammable Liquids. Since some of the storage and handling requirements are based on the hazard category, the proposal would allow a facility to use larger tanks to store liquids with boiling points between 37.8 °C (100 °F) and 35 °C (95 °F). OSHA was concerned that this practice could decrease safety. OSHA reviewed the properties related to the flammability of approximately 900 chemical substances (754 liquids) listed in the *CRC Handbook of Chemistry and Physics* [85th edition]. Approximately 1 percent of this list of flammable liquids would result in a reclassification from the current Flammable and Combustible Liquids Standard Class IA to GHS Category 2. While this is a small percentage of the total flammable liquids, it represents approximately 15 percent of the Flammable and Combustible Liquids Standard Class IA liquids on this list. OSHA was concerned that this was an instance where the benefits of harmonization could have been in conflict with the measure of safety currently provided and therefore requested comments on this issue.

Most agreed with OSHA that resulting reclassifications of liquids with borderline flashpoints from the old Class IA to the GHS Category 2 was not significant (Document ID #0313, 0324, 0327, 0328, 0338, 0352, 0365, 0366, 0370, 0376, 0382, 0383, 0393, 0405, 0408, 0410, and 0494 Tr. 56). National Association of Chemical Distributers (NACD) stated that ''Several NACD members handle flammable liquids under Category 1 and 2. However, the proposed changes would result in few operational changes'' (Document ID # 0341). Several commenters pointed out that aligning the definitions for flammable liquids is consistent with the single worldwide definition for these hazards (Document ID #0313 and 0327). ORC (Document ID #0370) stated:

ORC agrees that the methods OSHA proposes to classify flammable liquids Category 1and 2 and flammable aerosols are similar enough to the current definitions that substances that are currently regulated by OSHA would continue to be regulated and that few, if any, changes would result in a shift in regulatory coverage.

The National Fire Protection Association (NFPA) (Document ID #0366 and 0497 Tr. 56) stated:

NFPA agrees with OSHA's assessment regarding the slight adjustment resulting from the change in criteria for flash point and boiling point for flammable liquid categories when applying the GHS criteria. NFPA believes the overall impact of the changed flash point and boiling point will be negligible.

The American Petroleum Institute (API) urged OSHA to be consistent across all standards (Document ID #0376). Further, the ACC commented that in reference to the boiling point cut-off for Category 1 and 2 flammable liquids, they believe the language (in the NPRM) is sufficient to reflect the cut-off without changing the scope of the regulation (Document ID #0393).

However, some commenters expressed concern that the shift in flammability criteria would require facilities to modify their storage facilities to maintain compliance with § 1910.106, and consequently storage receptacles would have to be smaller, leading to less storage and greater costs (ISSA, Document ID # 0399). That concern is misplaced because the change from OSHA's old flammable and combustible classes to GHS categories involves a *lowering* of the boiling point cut-offs by 2.8 °C (5.04 °F), so that employers will still be able to use current handling and storage practices affected by the change. Likewise, current storage and handling practices for chemicals whose boiling points fall between 37.8 °C and 35 °C would still be allowed under the proposal. SOCMA commented that changing the definition would expand the number of products subject to § 1910.106 (Document ID #0402). That is also not correct. Due to the rounding of GHS flashpoints, cut-offs are slightly less stringent (*See* Table XIII–6) and no new chemicals would be regulated.

TABLE XIII–6—FLAMMABLE LIQUID DEFINITIONS

GHS			Flammable and combustible liquids standard (29 CFR 1910.106)		
Category	Flashpoint °C (°F)	Boiling point °C (°F)	Class	Flashpoint °C (°F)	Boiling point °C (°F)
Flammable 1	<23 (73.4)	≤35 (95)	Flammable Class IA	<22.8 (73)	<37.8 (100)
Flammable 2	<23 (73.4)	>35 (95)	Flammable Class IB	<22.8 (73)	≥37.8 (100)
Flammable 3	≥23 (73.4) and ≤60 (140)		Flammable Class IC	≥22.8 (73) and <37.8 (100).	.
			Combustible Class II.	≥37.8 (100) and <60 (140).	
Flammable 4	>60 (140) and ≤93 (199.4).		Combustible Class IIIA	≥60 (140) and <93.3 (200).	
None			Combustible Class IIIB	≥93.3 (200)	

The American Society of Safety Engineers (ASSE) agreed with OSHA's assessment of the storage issue. ASSE noted that the differences in boiling points from the original § 1910.106 to the GHS Categories could increase the number of gallons allowed to be stored in rooms and cabinets as well as the size of containers for certain liquids. However, in its opinion, the ''slightly'' increased boiling point would be of ''little significance'' (Document ID #0336). Therefore, based on the analysis discussed above and the comments received, OSHA has concluded that the shift in boiling point and the minor changes in temperatures and the re-categorizing of flammable liquids are insignificant and will have a negligible impact on the protection provided by the standards that use these terms.

Most commenters supported OSHA's proposal to incorporate the GHS definitions for flammable liquids into its safety standards (Document ID #0313, 0327, 0328, 0338, 0365, 0376, 0405, 0408, and 0410). Some stressed the ''consistency'' benefits from harmonization (Document ID #0338, 0405, and 0408). ASSE (Document ID #0336) said:

> In response to OSHA's proposal to eliminate the term ''combustible liquid'' in 29 CFR 1910.106, 1910.107, 1910.123, 1910.124, 1910.125, and 1926.155 for liquids with a flashpoint above 100 degrees F., ASSE believes this list of standards is appropriate. * * * However, ASSE urges OSHA to remove the term ''combustible liquid'' for all liquids and use the GHS criteria for all flammable liquids.

The National Paint and Coatings Association (NPCA), in supporting the removal of the term ''combustible liquid,'' noted that it was consistent with DOT (Document ID #0328).

Although there was considerable support for the changes OSHA made in the proposal to the flammable and combustible liquid categories, OSHA also received comments suggesting that the deletion of the ''combustible'' designation and the combining of NFPA Class 1C flammable and Class II combustible liquids into new Category Flammable 3, would lead to confusion among engineers, employers, and employees, which could result in potential accidents (Document ID #0344, 0366, 0381, 0399, 0402, 0498, 0500, 0514, and 0643). In addition, some commenters questioned whether the OSHA standards that address flammable liquids that are not covered by GHS (Combustible Class IIIB) are best handled by replacing the term ''combustible'' with a quantitative definition so as to maintain their coverage (Document ID #0336, 0366, and 0497 Tr. 56–58 and 68).

Some organizations, though they supported the proposed changes in general, had some specific concerns, particularly with how the OSHA GHS harmonization works with other national standards, including consensus standards. Clariant Corporation opined that eliminating the term ''combustible liquid'' will likely cause some confusion since it is still used by NFPA and DOT but urged OSHA to adopt the GHS criteria to maintain global consistency (Document ID #0383). However, OSHA points out that, as mentioned above by NPCA, the GHS criteria are consistent with DOT. The American Federation of State, County and Municipal Employees (AFSCME) favored OSHA's GHS harmonization, but sought clarification or additional guidance on how secondary labeling systems such as NFPA's 704 Diamond or the Hazardous Materials Information System (HMIS) would be used once GHS was in effect (Document ID #0414).

NFPA testified that the GHS categories would conflict with NFPA's established hazard ratings in NFPA 704, which has been in effect since the 1950s. NFPA recommended that the term ''combustible liquid'' not be deleted (Document ID #0497 Tr. 59–64). In addition, NFPA expressed concern that there may be additional confusion since the rating system in NFPA 704 expresses the most hazardous as a ''4'' while the GHS classification criteria expresses the most hazardous as Category ''1''. The International Fire Marshals Association (IFMA), echoing the sentiments of the NFPA, agreed that users have been relying on the NFPA 704 Hazard Rating and the Hazardous Material Information System (HMIS) systems for a long time and would be confused by the change (Document ID #0497 Tr. 80–84).

These commenters were concerned that the proposed realignment of the flammable liquid categories would result in confusion among employees, emergency responders, authorities having jurisdiction, and others who have been used to the distinction between flammable and combustible liquids (Document ID #0344, 0366, 0381, 0399, 0402, 0498, 0500, 0514, 0643, and 0497 Tr. 56–58). NFPA (Document ID #0366) stated:

> NFPA is also concerned with the elimination of the ''combustible liquids'' classification that will occur with the adoption of GHS as we believe there will be considerable confusion among the workers who have been instructed to take specific precautions for various liquids based on whether they were identified as ''flammable or combustible.'' Further, we believe that the elimination of the ''combustible liquid'' classification may cause confusion among emergency responders and authorities having jurisdiction, who have until now understood that ''flammable liquids'' can be expected to be ignitable at ambient temperatures, while ''combustible liquids'' typically require some degree of heating to reach their flash point temperatures. This lack of definition may also be an issue, albeit to a lesser extent, among designers who have been trained to apply certain fire protection measures to ''flammable liquids'', but not to ''combustible liquids.'' The immediate recognition that has existed in the workplace for decades may be removed by the proposed rule; NFPA cautions OSHA that confusion among workers has the potential to be more significant than OSHA has acknowledged. *See* also Document ID #0497 Tr. 56–58.

As an initial matter, OSHA notes liquids with a flashpoint greater than or equal to 60 °C (140 °F) and less than 93.3 °C (200 °F), which are currently classified as ''combustible,'' will be labeled as ''combustible liquids'' under the final rule. Thus this minimizes the potential for the confusion that NFPA suggests for these chemicals.

In any event, OSHA believes that there is currently confusion and inconsistency in this area. For example, OSHA standards have several cutoff values for flammable and combustible liquids. In OSHA's general industry standard at § 1910.106, 100 °F is the cut-off between flammable liquids and combustible liquids, but in construction, § 1926.155, 140 °F is the cut-off between flammable and combustible. Even the NFPA's standards are confusing. In NFPA 30, the hazard levels are structured from Ia/b/c to III b, with Ia being the highest, while in NFPA 704 the hazard levels range from 1 to 4, where the highest hazard category is 4 and the lowest is 1. NFPA classification and rating systems have been in existence since the 1950s and while the NFPA rating system is widely used, it is still not universally used or understood. Testimony from Mr. Frederick of the United Steelworkers indicated that NFPA is a good quick reference although (he believed) it does not cover all hazards, but it is used to alert workers that they must look elsewhere for additional information (Document ID #0499 Tr. 155–169).

In addition, OSHA reviewed randomly chosen SDSs for liquids classified under the current standard to determine how NFPA ratings correlated to hazard warnings. As shown in Table XIII–7, the hazard warnings were inconsistent, while the MSDSs were all technically correct for physical properties. For example, the hazard warning for flammable liquids with a

NFPA rating of 3 ranges from ''Flammable Liquid'' to ''Extremely Flammable'' to ''Severe.'' Notably, cyclohexanone, currently classified as a combustible liquid under § 1910.106, bears the hazard statement ''Flammable.''

TABLE XIII–7—MSDS COMMUNICATIONS OF FLAMMABLE LIQUID HAZARD WARNINGS

Docket #	Chemical name	Flashpoint	NFPA rating listed	Hazard warning
0565	Toluene	40.7 °F	3	Flammable Liquid
0566	Turpentine	95 °F	3	Flammable Liquid
0570	Aliphatic Hydrocarbons	120 °F	None listed	Flammable Liquid
0571	Reagent N Hexane	−22 °F	3	Extremely Flammable
0567	Paint Thinner	104 °F	2	Combustible
0557	Reagent Alcohol	55 °F	3	Severe (flammable)
0599	Cyclohexane	0 °F	3	Extremely Flammable
0560	Cyclohexanone	111 °F	2	Flammable

OSHA believes that this rulemaking will promote greater harmonization of hazard warnings in the future. Now, when a chemical falls in a particular flammable liquid hazard category, the HCS requirements will dictate the appropriate hazard warning. At least one comment alleges this has already happened in the United States. Dr. Michele Sullivan pointed out that the U.S. Department of Transportation (DOT) is already aligned with the GHS physical hazard criteria (the GHS criteria for physical hazard was based on the DOT physical hazard criteria); thus is already aligned with GHS flammable liquid criteria. Therefore, OSHA is aligning with DOT with this rulemaking (49 CFR 173.120 and Document ID #0382).

Neither the proposal nor final rule prohibits the use of NFPA or HMIS rating systems. They do not prohibit the use of NFPA definitions for employers taking preventive measures in designing facilities or implementing fire protection systems such as automatic sprinklers to ensure a safer situation. OSHA's requirements, even with the substitution of the term ''flammable'' for ''combustible,'' do not prohibit safer workplace designs or installations. Furthermore, OSHA expects that engineers and other professionals will use the actual flashpoints and other properties of the liquids themselves in design and installation of controls rather than a designation of a liquid as ''flammable'' or ''combustible.'' IFMA agreed with this premise (Document ID #0497 Tr. 84–85). In any event, even if the engineer, facility designer, or employer is somehow misled by § 1910.106's use of the term ''flammable,'' which has traditionally connoted a higher level of hazard, the result should be an error on the side of safety, rather than of less protection.

During the public hearings, ORC Worldwide commented on OSHA's review of the standards affected by this rulemaking, stating support for the ''concurrent harmonization of hazard definitions in most OSHA standards.'' However, ORC also ''agrees with member concern that changes to definitions in § 1910.106, Flammable and Combustible Liquids, while not increasing the scope of the standard, may cause confusion to workers who are familiar with NFPA nomenclature for these materials'' (Document ID #0494 Tr. 91–92). OSHA asked ORC to elaborate on this concern and provide support for their testimony. In response, ORC (Document ID #0643) provided two hypothetical situations it believes show that confusion over the realignment of flammable and combustible liquid categories could be significant:

Consider an engineer who is designing a new warehouse. (New) Category 3 liquids are to be stored therein, and these are liquids which were previously called ''combustible.'' Engineer does not design an electrical classification for the area. He does not realize that the new category may also include some liquids which are flammable. Because of this design outage, an electrical issue causes a fire and the warehouse burns down.

Consider a dry cleaning business that is using a (new) Category 3 solvent and does not include automatic sprinklers because the team is familiar with this solvent as being ''combustible'' under the previous NFPA definitions. A different, more effective solvent is proposed, also (new) Category 3, and is accepted as being ''similar''—the manufacturer reassures them that the new solvent is in the same flammability category as the previous one. But this one is indeed flammable and would require automatic sprinkler protection under NFPA rules. A fire starts with the new solvent, and because no automatic sprinklers exist onsite, the dry cleaner burns down.

OSHA thanks ORC Worldwide for their testimony and for providing examples of where revisions to standards affected by this rulemaking might cause confusion. With regard to the situations presented by ORC, OSHA understands that the engineer designing the sprinkler system would be required to follow local and state building codes, along with NFPA codes or other building codes, such as NFPA 1 (Fire Code), NFPA 13 (Standard for the Installation of Sprinkler Systems), NFPA 30 (Flammable and Combustible Liquids Code), NFPA 32 (Standard for Dry Cleaning Plants), NFPA 5000 (Building Construction and Safety Code), and the International Building Code (published by the International Code Council) as well as any OSHA standards that would apply.

The design of a system is not predicated on one physical property, and a prudent engineer or sprinkler designer should be aware that there are special requirements for the storage of combustible and flammable liquids. The codes and standards mentioned above all refer to NFPA 30 for requirements related to the storage and use of flammable and combustible liquids. There are restrictions on maximum container size, maximum storage height, and maximum total quantity stored based on flashpoint.

With regard to the change in solvent used at a dry cleaning facility, the argument remains the same as for the design engineer mentioned above. The flashpoint determines the classification of the chemical. The automatic sprinkler system design would be based on the flashpoint and not the class of chemical being used. OSHA concludes that commenters' concerns about confusion are not well founded and has decided to retain the GHS definition for flammable liquids as proposed in the final rule.

Two commenters, Procter & Gamble and ISSA, believed OSHA was adopting the 140 °F flashpoint cut-off as the definition of a flammable liquid and that this would conflict with the current flashpoint cut-off of 100 °F in § 1910.106 (Document ID #0381 and 0399). Procter & Gamble, arguing that the GHS was designed for hazard communications and not intended to regulate design criteria and that aligning the GHS criteria for flammable liquids in OSHA's safety standards would have unintended consequences (Document ID #0381), offered OSHA two options:

Option 1: Leave the current OSHA definition of flammable liquids unchanged. This is easy, clear, and no-cost to U.S. industry. Option 2: In principle, GHS is a labeling and hazard communication system, and was not intended to regulate the design and operation of facilities. OSHA 1910.106, by comparison, is a risk management regulation used in such design and operation. If OSHA adopts the GHS Building Block of 140 °F, leave the parallel definition of 100 °F intact in 1910.106. This dual system will create some confusion, but will minimize the negative effects listed above.

As an initial matter, Procter & Gamble misunderstood how OSHA incorporated the GHS flammable liquid definitions into the safety standards. This change was made only to align terminology. In fact, OSHA agrees that the GHS was not intended to regulate design criteria. Therefore, OSHA proposed to leave the standard's design criteria intact by using the actual measurable flashpoint as the defining criterion. The proposal, adopted by the final rule, is similar to Procter & Gamble's Option 2 and accomplishes both harmonization with GHS and retention of OSHA's long-established and effective risk management practice.

Finally, there were concerns that realigning the flammability criteria could affect contracts. Phylmar Regulatory Roundtable (PRR), which did not oppose OSHA's alignment of definitions of flammable and combustible liquids with the GHS categories, was concerned the reclassification of chemicals may cause conflicts in contracts with customers. PRR stated that the contracts require specifications in products manufactured, engineering controls, personal protective equipment, and specified instructions. PRR claimed that in such a situation the manufacturer by contract is permitted no deviation from the contract or process standards (Document ID #0514). However, as stated above, OSHA has not changed the scope or the requirements of its standards. Therefore, OSHA has concluded there is unlikely to be any interference with contracts. Moreover, where distinctions must be made in the OSHA requirements between the former Class 1C flammable liquids and Class II combustible liquids, the OSHA requirements have specified such distinctions with specific flashpoints. The contents and scopes of the regulatory paragraphs are not affected by GHS reclassifications or terminology changes, nor are OSHA's ventilation, respiratory protection, and personal protective equipment standards. In addition, OSHA did not change standards, like its electrical standards, that address internal design criteria.

OSHA has decided to remain consistent with GHS and not create additional flammable liquid categories. However, § 1910.106(18)(ii)(b) defines Combustible Class IIIB liquids as liquids with flashpoints at or above 200 °F (93.3 °C). While Class IIIB liquids are not included in the scope of § 1910.106, there is no such exemption in the Spray Finishing standard, § 1910.107 (OSHA letter of interpretation, Aug. 15, 2006). In order to preserve coverage in standards such as Spray Finishing, these liquids are now called ''Liquids with a Flashpoint of >93 °C (199.4 °F).'' Similar to § 1910.106, the use of the flashpoint cut-off is the best way to stay as close to the GHS and maintain scope and consistency within the standards. The Soap and Detergent Association (SDA) and the Consumer Specialty Products Association (CSPA) in a joint comment stated that OSHA should ''correct'' § 1910.107(e) and (e)(4) and § 1910.124(c)(2) to read ''Liquids with a Flashpoint at or below 199.4 °F'' to be consistent with the GHS criteria (Document ID #0344). However, if OSHA were to adhere strictly to GHS in this instance and drop the higher flashpoint category, protection from this hazard would be lost and safety compromised.

Several commenters addressed this issue. ASSE stated that their ''members do not see the need for the fifth category of 'Flammable Liquids Over a Flash Point of 93.3 °C.' Specific flash point criteria should be used'' (Document ID #0336). NFPA expressed general concern about the elimination of the Class IIIB liquids by the adoption of the GHS categorization system, though they acknowledged that OSHA had proposed to extend liquids as ''flammable liquid with flash point greater than 93 °C'' (Document ID #0366 and 0497 Tr. 56–58). The point was further clarified upon questioning at the hearing where NFPA agreed that by extending the liquids to flashpoints greater than 199.4 °F, OSHA was providing the coverage for § 1910.107 that had always been there. In addition, NFPA recommended it be further clarified that these liquids with the higher flashpoints belong to § 1910.107 and are not part of GHS Category 4 (Document ID #0497 Tr. 68).

In addition, Intercontinental Chemical Corporation recommended that OSHA create six new categories matching the six classes in the original § 1910.106 (Document ID #0500). The Agency believes that this approach would be inconsistent with GHS, since the GHS classifications and categories, including flammable liquid Categories 1–4, were established by international committees and are in place. OSHA's intent in this rulemaking is to harmonize the HCS with the existing GHS classifications and categories, not to make new categories.

In summary, OSHA views this rulemaking as a step towards eliminating current inconsistencies. OSHA believes the potential confusion with other agency policies, standards, consensus standards, and traditional practices suggested by the commenters are not likely to occur for several reasons. First, the changes in the final rule will bring internal consistency to the OSHA standards covered. OSHA standards currently have several cut-off values for flammable and combustible liquids. In OSHA's general industry standard (§ 1910.106), 100 °F is the cut-off between the flammable and combustible liquids, but in construction, § 1926.155, 140 °F is the cut-off between flammable and combustible. Harmonizing these standards, which have been out of sync for many years, will bring needed consistency to the safety standards. In addition, as noted above, substantive requirements have not changed, and therefore designs are not affected.

Second, the changes to the standards do not require changes in work practices. Rather, what have changed are a few regulatory terms used in the standards. Commenters who thought that such changes in definitions and terminology would result in significant and costly modifications to facility design and operation are incorrect, as the old requirements in the standards remain and no facility design and operation changes are required (Document ID #0344, 0381, and 0399). The requirements for what were known formerly as combustible liquids remain the same even though they are now categorized as flammable liquids.

Third, there is growing awareness of the GHS ''flammable liquids'' definition. Other agencies, such as DOT, are already aligned with the GHS definition for flammable liquids (49 CFR 173.120), and OSHA believes that its ANPR and NPRM have raised awareness of the definition.

Change occurs in every area of employment, and employers and workers get trained and adjust to the change; OSHA believes these minor changes will be accepted and adopted. OSHA's flammable and combustible liquid storage requirements have always been based on the flashpoint and boiling point of the liquid; OSHA does not believe that facility designs rely on whether the liquid is labeled as flammable or combustible. (*See* Document ID #0497 Tr. 84–85) Thus, OSHA has concluded that the allegations of impacts on facility design and operations are perceptual rather than actual. This is especially true in light of the fact that certain OSHA standards were exempted from the terminology changes if these changes were to affect internal design criteria of any area of the workplace. OSHA has therefore concluded that the proposed changes to the § 1910.106 definitions are reasonably necessary and appropriate and has carried them forward into the final rule.

OSHA will be doing outreach to affected parties and working with professional and trade associations to help users become familiar with and competent in applying these modifications. ORC testified that the changes may cause confusion to workers familiar with NFPA nomenclature, and agreed with OSHA that, with training, any confusion resulting from the change from NFPA definitions and terminology to GHS definitions and terminology would be overcome. ORC (Document ID #0494 Tr. 100–101) further stated that potential confusion would not be a reason to delay moving forward with finalizing the standard:

There's a significant problem with lack of harmonization of chemical control approaches in the United States, and we would like to see, as we said in our testimony, some sort of formalization because we think it's the only thing that's going to work here, formalization of regular contacts between the NFPA and OSHA.

Mike Wright, representing the United Steelworkers (Document ID #0494 Tr. 76–77), put it succinctly, stating:

The whole point of harmonization is to reconcile different standards, which may be conflicting. That means something has to change. * * * Ultimately, in the short term will there be some confusion? Yes. Can we minimize that through good training, through good information? Yes, and we ought to, but ultimately I think we have a globally harmonized system that's been adopted on a worldwide level and then we have various national organizations—very important ones like the NFPA—which may deviate in the way they communicate hazards from that globally harmonized system.

With respect to my friends at the NFPA, who I think do wonderful work, I think their job is to harmonize their system to the Globally Harmonized System. We hope that happens as soon as possible, and I'm confident that it will.

You know, ultimately we need to go to one * * * system worldwide. We have that system now. It will take some time and a little bit of confusion to conform every other kind of national voluntary system to that, but that work has to be done.

OSHA agrees and believes users of the new GHS flammable liquid categories will implement its new terminology in their work.

Minor Safety Standard Changes

The note in the PSM construction standard, § 1926.64(d)(1)(vii), has been changed. In the current standard, paragraph (d)(1)(vii), the note states, ''Material Safety Data Sheets meeting the requirements of 29 CFR 1926.59(g) may be used to comply with this requirement to the extent they contain the information required by this subparagraph.'' The note has been changed to ''Safety Data Sheets (SDSs) meeting the requirements of 29 CFR 1910.1200(g) . * * *''

To correct a technical error and to complete alignment across standards, § 1910.106(j), Scope, has been made consistent with § 1910.106(a)(19) and § 1910.1200, Appendix B. Proposed § 1910.106(j) stated that it ''applie[d] to the handling, storage, and use of flammable liquids with a flashpoint *below* 199.4 °F (93 °C) unless otherwise noted.'' (Emphasis added). Final § 1910.106(j) is now consistent with § 1910.106(a)(19) and § 1910.1200 in that it applies to ''* * * flammable liquids with a flashpoint *at or below* 199.4 °F (93 °C) * * *'' (Emphasis added).

In § 1926.155, OSHA proposed to harmonize the definitions of flammable and combustible liquids to be consistent with the GHS categories of flammable liquids (*i.e.,* the updating of the definition of flammable liquids and the removal of the definition for combustible liquids), and this change is carried through to the final rule. The final rule also removes ''or combustible'' in the other standards in Subpart F, to maintain consistency with the ''Definitions'' in § 1926.155. In § 1926.150(c)(vi), which currently states, ''A fire extinguisher, rated not less than 10B, shall be provided within 50 feet of wherever more than 5 gallons of flammable or combustible liquids or 5 pounds of flammable gas are being used on the jobsite,'' the term ''or combustible'' has been removed. Likewise, the Agency is correcting § 1926.151(b)(3) by removing ''or combustible.'' In § 1926.151(a)(4), Portable battery powered lighting, which states that ''the storage, handling, or use of flammable gases or liquids, shall be * * * approved for the hazardous locations,'' the term ''flammable liquids'' has been changed to ''Category 1, 2, or 3 flammable liquids.'' This change maintains the scope set by the flashpoint ranges for the Subpart (as defined by the original § 1926.155 paragraphs (c) and (h)).

The Soap and Detergent Association and Consumer Specialty Products Association, in a joint comment (Document ID #0344), suggested that OSHA change the term ''pilot light'' to ''indicating light.'' As discussed previously, this type of change is outside of the scope of this rulemaking since it does not pertain to hazard communication or GHS harmonization. Therefore, OSHA is not adopting that suggestion at this time.

Methods To Determine Flashpoints

OSHA proposed to update the methods that may be used to determine flashpoints in the NPRM. These methods include updated ASTM methods, ISO methods, and British, French, and German national standards for the testing. The methods are listed in Appendix B.6 of § 1910.1200 and are also referenced in Revision 3 of the GHS (2009), Chapter 2.6.

In the definitions of § 1910.106, the current standard allowed only ASTM D–56–70 and ASTM D–93–71 as testing methods to determine flashpoints. In § 1926.155, which applies to Subpart F of the construction standards (Fire Protection and Prevention), OSHA currently allows only ASTM D–56–69 and ASTM D–93–69 for such determinations. The current HCS allows only ASTM D 56–79, ASTM D 93–79, and ASTM D 3278–78. The methods allowed in § 1910.155 were adopted in the late 1960s, and the methods for § 1910.106 and § 1926.1200 were adopted in the 1970s.

The NPRM updated the methods in § 1910.1200 to conform to the GHS. However, flashpoint methods in § 1910.1200 had always differed from methods in § 1910.106 and § 1926.155. Instead of revamping the older test methods in OSHA's other standards, the proposal allowed a broader test selection. OSHA kept the tests currently permitted in § 1910.106 and § 1926.155 because they were in the original OSHA standards, but allowed methods in the GHS-modified HCS be used as well. The final rule adopts these changes.

Thus, the final rule amends § 1910.106 and § 1926.155 to allow ASTM D–56–70 and ASTM D–93–71 for § 1910.106; ASTM D–56–69 and ASTM D–93–69 for § 1910.155; and the equivalent testing methods permitted in the HCS, § 1910.1200, Appendix B.6, Physical Hazard Criteria. For example, as amended by the final rule, § 1910.106(a)(14)(i) states that for a liquid which has a viscosity of less than 45 SUS at 100 °F (37.8 °C), does not contain suspended solids, and does not have a tendency to form a surface film while under test, the procedure specified in the Standard Method of Test for Flashpoint by Tag Closed Tester (ASTM D–56–70), which is incorporated by reference as specified in § 1910.6, or an equivalent test method as defined in Appendix B to § 1910.1200—Physical Hazard Criteria, must be used.

By equivalent test method, OSHA means employers can select any of the test methods in Appendix B.6 or in Chapter 2.6 of Revision 3 of the GHS (2009).

The only comments on this issue recommended additional methods for determining flashpoints (Document ID #0344 and 0381). The Soap and Detergent Association/Consumer Specialty Products Association (Document ID #0344) and the Procter & Gamble Company (Document ID #0381) recommended OSHA include ASTM D6450 on the list of approved methods for determining the flashpoints of liquids in the ''incorporation by reference'' list in § 1910.106. OSHA is not prepared to adopt this method at this time. The determination of flashpoint test methods for GHS falls under a Sub-committee of the United Nations Economic and Social Council's Committee of Experts on the Transport of Dangerous Goods (UNCEDTG). Commenters who wish the GHS to incorporate ASTM D6450 should direct their requests to that body, and if the method is incorporated into the GHS, OSHA will consider the matter at that time.

Flammable Aerosols

OSHA currently defines the term ''flammable aerosol'' in § 1910.106 and in § 1910.1200 by reference to a definition developed by the Consumer Product Safety Commission under the Federal Hazardous Substances Act. *See* 16 CFR 1500.45; *See also* 15 U.S.C. 1261(l). The current HCS defines flammable aerosol as an aerosol that, when tested by the method described in 16 CFR 1500.45, yields a flame projection exceeding 18 inches at full valve opening, or a flashback (a flame extending back to the valve) at any degree of valve opening.

The current § 1910.106 definitions for ''aerosol'' and ''flammable aerosol'' are provided in (§ 1910.106(a)(1)) and (§ 1910.106(a)(13)) and are different from those in the revised Hazard Communication Standard. In the current § 1910.106, an aerosol is defined as a material which is dispensed from its container as a mist, spray, or foam by a propellant under pressure. However, in the current § 1910.106, a flammable aerosol is defined as an aerosol which is required to be labeled ''Flammable'' under the Federal Hazardous Substances Labeling Act (15 U.S.C. 1261). For the purposes of § 1910.106(d), such aerosols are considered Class IA liquids.

OSHA proposed to remove the definitions of ''aerosol'' and ''flammable aerosol'' from § 1910.106 and instead insert its GHS-consistent definitions along with references to Appendix B.3 of the GHS-modified HCS. In response to OSHA's proposed action, National Paint and Coatings Association and Alliance of Hazardous Materials Professionals both said that, while they were not prepared to offer specific impact information on operations, ''to align OSHA definitions for * * * Flammable Aerosols is fully consistent with the concept of a 'single world-wide' definition for these hazards.'' (Document ID #0313 and 0327).

OSHA agrees with these comments and has included the revised definition of ''flammable aerosols'' in the final rule. The revised definition in the Flammable liquids standard, § 1910.106, duplicates the flammable aerosols definition contained in Appendix B to § 1910.1200—Physical Hazard Criteria. For the purposes of § 1910.106(d), such aerosols are considered Category 1 flammable liquids.

The GHS-modified definition and classification criteria for flammable aerosols can be found in Appendix B.3 of HCS.

OSHA's decision to change the definition of aerosols to be consistent with the GHS-modified HCS is based not only upon harmonizing its own standards with those followed by other countries who have or are considering adopting GHS, but also to harmonize with DOT's definition for flammable aerosols, which is also consistent with the GHS. *See* 49 CFR 173.115(k).

Dr. Michelle Sullivan (Document ID #0382), alluding to flammable aerosols, pointed out that flammable categories will differ among regulatory authorities. She stated:

> [T]he GHS flammable aerosol criteria are linked to the criteria for flammable liquid, flammable solid and flammable gas, the flammable aerosol criteria depend on the hazard categories/building blocks of these other hazards * * * some regulatory authorities will adopt categories 1–4 while others will adopt categories 1–3 * * * [and thus] * * * the flammable aerosol criteria will differ for these regulatory authorities.

Regarding Dr. Sullivan's comment, OSHA acknowledges that other regulatory bodies, when adopting GHS, may choose different building blocks. However, the basis for classification will still be based on the same criteria and will lead to harmonization of similarly covered materials. This does not affect OSHA's decision to strive for both domestic and international harmonization.

Finally, OSHA believes that the GHS classification criteria are similar enough to the current § 1910.106 and § 1910.1200 criteria that all aerosols currently regulated by OSHA would continue to be so, and that few, if any, new aerosols would be subject to OSHA regulation. Indeed, OSHA raised this issue in the NPRM and received no comments to the contrary.

Standards Not Included in This Rulemaking

OSHA did not propose to change standards that incorporate by reference other consensus standards, such as NFPA codes, or are based on consensus standards when those consensus standards are used for internal design criteria only and do not reference the HCS for applicable scope or incorporation into the SDS. These standards include Subpart S—Electrical, in Part 1910 (General Industry), and Subpart K—Electrical, in Part 1926 (Construction). Many commenters on the ANPR were particularly concerned that a change in OSHA's definitions would create an incompatibility with local building codes (Document ID #0047, 0075, 0076, 0104, 0113, 0145 and 0163). They alleged that, in many cases, this would require extensive rewiring to meet the Subpart S requirements on hazardous locations and would lead to conflicts with local electrical codes.

Many commenters on the NPRM supported OSHA's exemption of these standards (Document ID #0328, 0330, 0336, 0370, 0393, and 0408). Ameren expressed concern that if OSHA harmonized the electrical and blasting agents standards (Part 1910 Subpart S, § 1910.109, and Part 1926 Subpart K, § 1926.914) with the GHS, such changes would require training of affected employees on the changes (Document ID #0330). ASSE agreed with OSHA's decision not to propose updates to the electrical standards (general industry 1910 Subpart S and construction 1926 Subpart K) or explosives and blasting agents (general industry § 1910.109 and construction § 1926.914), since these subparts are ''self-contained'' in that they do not rely on other OSHA standards for regulatory scope or definitions but reference external organizations such as the National Fire Protection Association (NFPA) (Document ID #0336). The American Iron and Steel Institute agreed (Document ID #0408). ORC strongly supported OSHA's approach of not updating these standards but waiting until the referenced external organizations adopted the GHS elements (Document ID #0370).

Wacker Chemical Company, PRR, and ACC urged OSHA to update electrical and explosive and blasting agents standards if the consensus organizations could come to agreement, and they expressed their concerns regarding potential conflicts with local codes and regulations (Document ID #0335, 0339, and 0393). Wacker Chemical Corporation encouraged OSHA to work closely with organizations (NFPA and others) that develop fire and electrical codes to ensure there is consistent application of these codes to area classification, building construction, equipment electrical ratings, etc. (Document ID #0335). Wacker Chemical suggested that OSHA could make progress with the consensus organizations (Document ID #0335). PRR recommended harmonization updates of electrical and explosive standards if the updates would enhance safety and the ease of doing business in the global market (Document ID #0339). The ACC agreed with OSHA's decision not to change standards that incorporate consensus standards by reference (*i.e.,* design criteria) (Document ID #0393). ACC requested OSHA clarify in its final rule that harmonization would not affect the International Building Code and the International Fire Code such that users will not be unduly required to upgrade buildings to conform to requirements for hazardous occupancies. By its decision regarding standards not included in this rulemaking, OSHA is making it clear that upgrading buildings is not within the scope of this rulemaking.

OSHA agrees with those comments that expressed the desire to harmonize but also expressed concern over the potential effects of internal codes. OSHA concluded that exempting those standards where conflicts with internal codes could occur at this time was appropriate. OSHA agrees with ACC that impacting electrical area classification, facility siting, and wiring configuration is not appropriate. Therefore, because of these potential conflicts with internal design criteria, OSHA is not harmonizing the electrical and other standards that depend on internal design criteria and local building codes.

Explosives and Blasting Agents

OSHA did not propose to harmonize the Explosive and Blasting Agents standards, § 1910.109 (general industry) and § 1926, Subpart U (construction). At the time of the proposal, a separate rulemaking to revise them was in progress. That rulemaking has since been terminated (75 FR 5545, Feb. 3, 2010). However, the HCS has always covered hazardous chemicals regulated by OSHA's Explosive and Blasting Agents standards. Although the rulemaking on explosives and blasting agents has ceased, the general requirements in the GHS-modified HCS and specific requirements in its appendices still apply to explosives and blasting agents that can be considered hazardous chemicals. Manufacturers and importers must evaluate chemicals to classify their health and physical hazards in accordance with paragraph (d) of the HCS, must affix labels in accordance with paragraph (f) in HCS, and must provide SDSs in accordance with paragraph (g) of the HCS. Appendix B.1 of the GHS-modified HCS contains specific classification criteria for explosives. Furthermore, labels are required by the Department of Transportation (DOT) for the transportation of packages or containment devices that contain hazardous materials meeting one or more of DOT's hazard class definitions. *See* 49 CFR Part 172 Subpart E. In addition, OSHA's general industry standard § 1910.1201, ''Retention of DOT markings, placards, and labels,'' requires that DOT labels, placards, or markings be retained under certain conditions. Thus, explosives and blasting agents are already covered by the GHS-modified HCS and § 1910.1201.

The few commenters who addressed the issue supported OSHA's decision not to include the Explosive and Blasting Agents standards (§ 1910.109 and § 1926.914) in the proposal (Document ID #0328, 0330, 0336, 0362, and 0370).

As to the continuing coverage of HCS, a representative from Institute Makers of Explosives stated that the commercial explosives industry understands the importance of GHS, has been prepared for several years to implement GHS, and would not experience any impacts to explosives operations that were not already anticipated (Document ID #0362).

Galaxy Fireworks noted that § 1910.109(k)(1) excludes the sale and ''use (public display)'' of pyrotechnics (fireworks) from the explosives standard (Document ID #0355). Galaxy Fireworks' concern was the potential for the proposal to create a regulation that overlaps with the existing requirements of the Department of Transportation and the Consumer Product Safety Commission. Galaxy urged OSHA to work with these other agencies in amending the HCS to develop regulations that would apply uniformly to the fireworks industry and with other organizations to further harmonization (Document ID #0335). OSHA agrees and believes its global harmonization efforts embodied in this rulemaking go a long way toward the overall goal of consistency.

Maritime

OSHA received one comment, from Northrop Grumman Shipbuilding, which stated that OSHA had omitted modification of the shipyard Part 1915 safety standards for GHS harmonization (Document ID # 0395). More specifically, Northrop Grumman believed that the maritime standards that contain requirements for flammable and combustible liquids required review and updating to be GHS harmonized, just as the flammable and combustible liquids the General Industry Part 1910 and Construction Part 1926 standards were proposed to be reviewed and updated.

OSHA did not propose to update the maritime standards, other than the substance-specific standards mentioned above, in this rulemaking. Unlike the standards in general industry and construction, the maritime standards (Shipyard Employment, Part 1915; Marine Terminals, Part 1917; and Longshoring, Part 1918) have always addressed flammables and combustibles in their own unique way, reflecting the special conditions of maritime work. These parts do not use flashpoint criteria to distinguish between flammable and combustible liquids. The terminology in the maritime standards that addresses flammable and combustible materials, including liquids, differs from the general industry and construction standards. For example, § 1915.12(b)(1) (Flammable atmospheres) and § 1915.54 (Welding, cutting and heating of hollow metal containers not covered by § 1915.12) require competent-person testing and contain detailed instructions on the specific maritime work covered.

There are a few paragraphs in the maritime standards where flammable and combustible liquids requirements reference flashpoint criteria but in these cases, flashpoints are not used for the purpose of distinguishing flammable from combustible liquids. Examples include Subpart P, Fire Protection, § 1915.501 through § 1915.509, where flammable liquid is defined as liquids with flashpoints below 100 °F (37.8 °C). Combustible liquids are neither defined nor mentioned in this Subpart, although combustible materials are mentioned and not defined. Other maritime standards such as § 1915.14 (Hot work) and § 1915.35 (Painting) specify flashpoints for certain requirements, but these are not distinctions of flashpoints defining flammable or combustible liquids. The final rule does not modify these criteria.

OSHA has issued a maritime compliance tool, ''Tool Bag Directive for the Part 1915 Shipyard Employment Standards,'' that includes specific interpretations of the maritime standards. The Tool Bag Directive references specific general industry standards in order to provide further guidance related to some of the more general maritime requirements. A specific case is how general industry standard § 1910.106 is used. The Tool Bag Directive informs users that if specific Part 1915 shipyard requirements give flashpoint criteria, those requirements take precedence. However, where definitions of flammable and combustible liquids are not specified in the Part 1915 shipyard standards, the definitions of § 1910.106 are to apply. The final rule's changes do not significantly modify the substantive requirements of § 1910.106, and the Tool Bag Directive's interpretive policy will continue after the final rule becomes effective, using the new definitions in § 1910.106.

In a similar manner, OSHA has a compliance tool for Parts 1917 ''Marine Terminals'' and 1918 ''Longshoring'' called the Tool Shed Directive. This Directive notes that the requirements of § 1910.1200 apply to operations covered by Parts 1917 and 1918. *See also* 1917.1(a)(2)(vi); 1918.1(b)(4). Therefore, all the requirements in the GHS-modified HCS (§ 1910.1200), and its appendices will apply to the maritime industry. In addition, part 1910 applies to marine terminal operations that fall within the exception found at § 1917.1(a)(1)(i): ''facilities used solely for the bulk storage, handling, and transfer of flammable, non-flammable, and combustible liquids and gases.'' The final rule's changes to § 1910.106 will therefore apply to facilities handling flammable and combustible liquids that fall within this exclusion, but again, as explained above, the substantive requirements of § 1910.106 have not changed significantly.

Construction

The Building and Construction Trades Department (BCTD) requested that OSHA clarify inconsistencies in the construction standards, particularly by updating the Part 1926 standards to conform to the proposed requirements for and definitions of ''flammable'' and the related deletion of the term ''combustible'' liquids (Document ID # 0359). BCTD gave examples of §§ 1926.152, 1926.155, 1926.66 and Subpart K of Part 1926 and requested that OSHA conduct a thorough review of the Part 1926 construction standards. Though it had done so once in preparing the NPRM, OSHA again conducted a thorough review of Part 1926. OSHA had already proposed to modify § 1926.152 (Flammable and combustible liquids) and § 1926.155 (Definitions) as well as § 1926.64 (Process Safety Management), § 1926.65 (HAZWOPER), and the substance-specific health standards in construction in the NPRM. As explained above, OSHA has made further revisions in the construction regulations regarding process safety management (§ 1926.64(d)(1)(vii)) and fire protection and prevention (§ 1926.150(c)(vi), § 1926.151(a)(4)), and § 1926.151(b)(3)) in this final rule.

Like Subpart S in general industry, § 1926.66 (Criteria for design and construction of spray booths) belongs to the category of construction standards that incorporate other consensus standards by reference, such as NFPA codes, or are based on consensus standards when those consensus standards are used for internal design criteria only and do not reference HCS for applicable scope or incorporation into the SDS. Clearly, there is no reason to change the terminology in § 1926.66. As noted above, Part 1926, Subpart K (Electrical), belongs in this category. Other similar standards are § 1926.351 (Arc Welding and Cutting), and Part 1926, Subpart V (Power Transmission and Distribution). OSHA is not modifying these standards for the same reasons listed above for general industry.

Similar to the discussion regarding the Maritime standards, OSHA did not propose modifications of standards that do not contain definitions that are applicable to standards in the Subpart or explicitly reference standards that contain the definitions. The standards may contain phrases with the terms ''flammable liquid'' or ''combustible liquid,'' but the definitions of the terms are absent. Standards belonging to this category of undefined terms include § 1926.66(c)(9)(i) (Criteria for design and construction of spray booths), § 1926.252(e) (Disposal of waste materials), § 1926.307(p)(2)(ii) (Mechanical power-transmission apparatus), § 1926.352(c) and (h) (Fire prevention), § 1926.803(l)(13) (Compressed air), and § 1926.1101, Appendix B (Sampling and Analysis for Asbestos). In addition, some of these standards' requirements use the term ''flammable liquid'' without the term ''combustible liquid,'' and some of the requirements use the term ''combustible liquid'' without the term ''flammable liquid.'' As with the maritime standards, since OSHA has not changed the actual requirements of § 1910.106 or § 1926.155, OSHA does not anticipate that the final rule will affect the requirements of other OSHA standards that use some of the same terminology.

In addition, OSHA did not modify standards that refer to flammable and combustible materials, storage piles, etc. that are not liquids. Examples are § 1926.550(a)(15)(vii)(C) (Cranes and derricks), which refers to combustible and flammable materials; § 1926.956(b)(3) (Underground lines), which refers to combustible gases; and § 1926.352(c) (Fire prevention), which refers to flammable compounds. In addition, § 1926.154(e)(1) (Temporary heating devices) mentions ''flammable liquids,'' but the term was not the focus of the standard. The requirement mentions flammable liquid-fired heaters, but the focus is on safety controls for the particular piece of equipment. Safety training and education, § 1926.21(b)(5), is another example that contains some of the terminology, but its focus is on safety training. Flammable liquids are treated in a general sense, *i.e.,* grouped with gases or toxic materials.

Miscellaneous

A commenter from the International Chemical Workers Union Council recommended OSHA include a conversion formula for Centigrade and Fahrenheit or, at a minimum, provide the equivalent degrees when addressing flammable and combustible liquids, since in general employers and employees in the U.S. are more familiar with degrees Fahrenheit (Document ID # 456). OSHA proposed to provide temperature equivalents, and in the final standard equivalents are included where there are requirements for flammable and combustible liquids. The formulas for conversion are:

$(9/5)\ {}^\circ C + 32 = {}^\circ F$ or $(5/9)({}^\circ F - 32) = {}^\circ C$

Since the formulas for conversion are standard formulas found in textbooks, and since equivalents have been provided wherever possible for flammable and combustible liquids, OSHA has determined that it is not necessary to state the formulas for conversion in the actual regulations.

XIV. Authority and Signature

This document was prepared under the direction of David Michaels, 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. 1–2012 (77 FR 3912); and 29 CFR Part 1911.

List of Subjects

29 CFR Part 1910

Asbestos, Blood, Chemicals, Diving, Fire prevention, Gases, Hazard communication, Hazardous substances, Health records, Incorporation by reference, Labeling, Labels, Laboratories, Occupational safety and health, Reporting and recordkeeping requirements, Safety data sheets, Signs and symbols, and Training.

29 CFR Part 1915

Hazard communication, Hazardous substances, Labels, Longshore and harbor workers, Occupational safety and health, Reporting and recordkeeping requirements, Safety data sheets, Signs and symbols, Training, and Vessels.

29 CFR Part 1926

Chemicals, Construction industry, Diving, Fire prevention, Gases, Hazard communication, Hazardous substances, Health records, Labels, Lead, Occupational safety and health, Reporting and recordkeeping requirements, Safety data sheets, Signs and symbols, and Training.

Signed at Washington, DC, on February 23, 2012.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Final Amendments

For the reasons discussed in the preamble, the Occupational Safety and Health Administration amends 29 CFR parts 1910, 1915 and 1926 as set forth below:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Subpart A—[Amended]

■ 1. Revise the authority citation for subpart A of part 1910 to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (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 31159), 4–2010 (75 FR 55355) or 1–2012 (77 FR 3912), as applicable.

Section 1910.6 also issued under 5 U.S.C. 553. Sections 1910.6, 1910.7, and 1910.8 also issued under 29 CFR Part 1911. Section 1910.7(f) also issued under 31 U.S.C. 9701, 29 U.S.C. 9a, 5 U.S.C. 553; Pub. L. 106–113 (113 Stat. 1501A–222); Pub. L. 111–8 and 111–317 and OMB Circular A–25 (dated July 8, 1993) (58 FR 38142, July 15, 1993).

■ 2. Amend § 1910.6 by revising paragraphs (a)(4) and (h), the introductory text of paragraph (q), and by adding new paragraphs (q)(37), (y), and (z) to read as follows:

§ 1910.6 Incorporation by reference

(a) * * *

(4) Copies of standards listed in this section and issued by private standards organizations are available for purchase from the issuing organizations at the addresses or through the other contact information listed below for these private standards organizations. 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–2625, Washington, DC 20210; telephone: 202–693–2350 (TTY number: 877–889–5627). They are also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of these standards at NARA, telephone: 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

* * * * *

(h) Copies of the standards listed below in this paragraph (h) are available for purchase from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959; Telephone: 610–832–9585; Fax: 610–832–9555; Email: *seviceastm.org;* Web site: *http://www.astm.org.* Copies of historical standards or standards that ASTM does not have may be purchased from Information Handling Services, Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112; Telephone: 1–800–854–7179; Email: *global@ihs.com;* Web sites: *http://global.ihs.com* or *http://www.store.ihs.com.*

(1) ASTM A 47–68, Malleable Iron Castings, IBR approved for § 1910.111.

(2) ASTM A 53–69, Welded and Seamless Steel Pipe, IBR approved for §§ 1910.110 and 1910.111.

(3) ASTM A 126–66, Gray Iron Casting for Valves, Flanges and Pipe Fitting, IBR approved for § 1910.111.

(4) ASTM A 391–65 (ANSI G61.1–1968), Alloy Steel Chain, IBR approved for § 1910.184.

(5) ASTM A 395–68, Ductile Iron for Use at Elevated Temperatures, IBR approved for § 1910.111.

(6) ASTM B 88–66A, Seamless Copper Water Tube, IBR approved for § 1910.252.

(7) ASTM B 88–69, Seamless Copper Water Tube, IBR approved for § 1910.110.

(8) ASTM B 117–64, Salt Spray (Fog) Test, IBR approved for § 1910.268.

(9) ASTM B 210–68, Aluminum-Alloy Drawn Seamless Tubes, IBR approved for § 1910.110.

(10) ASTM B 241–69, Standard Specifications for Aluminum-Alloy Seamless Pipe and Seamless Extruded Tube, IBR approved for § 1910.110.

(11) ASTM D 5–65, Test for Penetration by Bituminous Materials, IBR approved for § 1910.106.

(12) ASTM D 56–70, Test for Flash Point by Tag Closed Tester, IBR approved for § 1910.106.

(13) ASTM D 56–05, Standard Test Method for Flash Point by Tag Closed Cup Tester, Approved May 1, 2005, IBR approved for Appendix B to § 1910.1200.

(14) ASTM D 86–62, Test for Distillation of Petroleum Products, IBR approved for §§ 1910.106 and 1910.119.

(15) ASTM D 86–07a, Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure, Approved April 1, 2007, IBR approved for Appendix B to § 1910.1200.

(16) ASTM D 88–56, Test for Saybolt Viscosity, IBR approved for § 1910.106.

(17) ASTM D 93–71, Test for Flash Point by Pensky Martens, IBR approved for § 1910.106.

(18) ASTM D 93–08, Standard Test Methods for Flash Point by Pensky-Martens Closed Cup Tester, Approved Oct. 15, 2008, IBR approved for Appendix B to § 1910.1200.

(19) ASTM D 240–02 (Reapproved 2007), Standard Test Method for Heat of Combustion of Liquid Hydrocarbon Fuels by Bomb Calorimeter, Approved May 1, 2007, IBR approved for Appendix B to § 1910.1200.

(20) ASTM D 323–68, Standard Test Method of Test for Vapor Pressure of Petroleum Products (Reid Method), IBR approved for § 1910.106.

(21) ASTM D 445–65, Test for Viscosity of Transparent and Opaque Liquids, IBR approved for § 1910.106.

(22) ASTM D 1078–05, Standard Test Method for Distillation Range of Volatile Organic Liquids, Approved May 15, 2005, IBR approved for Appendix B to § 1910.1200.

(23) ASTM D 1692–68, Test for Flammability of Plastic Sheeting and Cellular Plastics, IBR approved for § 1910.103.

(24) ASTM D 2161–66, Conversion Tables for SUS, IBR approved for § 1910.106.

(25) ASTM D 3278–96 (Reapproved 2004) E1, Standard Test Methods for Flash Point of Liquids by Small Scale Closed-Cup Apparatus, Approved November 1, 2004, IBR approved for Appendix B to § 1910.1200.

(26) ASTM D 3828–07a, Standard Test Methods for Flash Point by Small Scale Closed Cup Tester, Approved July 15, 2007, IBR approved for Appendix B to § 1910.1200.

(27) ASTM F–2412–2005, Standard Test Methods for Foot Protection, IBR approved for § 1910.136.

(28) ASTM F–2413–2005, Standard Specification for Performance Requirements for Protective Footwear, IBR approved for § 1910.136.

* * * * *

(q) The following material is available for purchase from the National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02269; Telephone: 800–344–3555 or 617–770–3000; Fax: 1–800–593–6372 or 1–508–895–8301; Email: *custserv@nfpa.org;* Web site: *http://www.nfpa.org.*

* * * * *

(37) NFPA 30B, Code for the Manufacture and Storage of Aerosol Products, 2007 Edition, Approved August 17, 2006, IBR approved for Appendix B to § 1910.1200.

* * * * *

(y)(1) The following materials are available for purchase from the International Standards Organization (ISO) through ANSI, 25 West 43rd Street, Fourth Floor, New York, NY 10036–7417; Telephone: 212–642–4980; Fax: 212–302–1286; Email: *info@ansi.org;* Web site: *http://www.ansi.org*.

(2) Documents not available in the ANSI store may be purchased from:

(i) Document Center Inc., 111 Industrial Road, Suite 9, Belmont, 94002; Telephone: 650–591–7600; Fax: 650–591–7617; Email: *info@document-center.com; Web site: www.document-center.com.*

(ii) DECO—Document Engineering Co., Inc., 15210 Stagg Street, Van Nuys, CA 91405; Telephone: 800–645–7732 or 818–782–1010; Fax: 818–782–2374; Email: *doceng@doceng.com;* Web site: *www.doceng.com*

(iii) Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112; Telephone: 1–800–854–7179 or 303–397–7956; Fax: 303–397–2740; Email: *global@ihs.com;* Web sites: *http://global.ihs.com* or *http://www.store.ihs.com;*

(iv) ILI Infodisk, Inc., 610 Winters Avenue, Paramus, NJ 07652; Telephone: 201–986–1131; Fax: 201–986–7886; Email: *sales@ili-info.com;* Web site: *www.ili-info.com*.

(v) Techstreet, a business of Thomson Reuters, 3916 Ranchero Drive, Ann Arbor, MI 48108; Telephone: 800–699–9277 or 734–780–8000; Fax: 734–780–2046; Email: *techstreet.service@thomsonreuters.com;* Web site: *www.Techstreet.com.*

(3) 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.

(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 § 1910.1200.

(5) ISO 13943:2000 (E/F), Fire Safety—Vocabulary, First Edition, April, 15, 2000, IBR approved for Appendix B to § 1910.1200.

(z)(1) The following document is available for purchase from United Nations Publications, Customer Service, c/o National Book Network, 15200 NBN Way, PO Box 190, Blue Ridge Summit, PA 17214; telephone: 1–888–254–4286; fax: 1–800–338–4550; email: *unpublications@nbnbooks.com*. Other distributors of United Nations Publications include:

(i) Bernan, 15200 NBN Way, Blue Ridge Summit, PA 17214; telephone: 1–800–865–3457; fax: 1–800–865–3450; email: *customercare@bernan;* Web site: *http://www.bernan.com;* and

(ii) Renouf Publishing Co. Ltd., 812 Proctor Avenue, Ogdensburg, NY 13669–2205; telephone: 1–888–551–7470; Fax: 1–888–551–7471; email: *orders@renoufbooks.com;* Web site: *http://www.renoufbooks.com.*

(2) UN ST/SG/AC.10/Rev.4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003, IBR approved for Appendix B to § 1910.1200.

Subpart H—[Amended]

■ 3. The authority citation for subpart H is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (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), or 5–2007 (72 FR 31159), 4–2010 (75 FR 55355) or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

Sections 1910.103, 1910.106 through 1910.111, and 1910.119, 1910.120, and 1910.122 through 1910.126 also issued under 29 CFR part 1911.

Section 1910.119 also issued under Section 304, Clean Air Act Amendments of 1990 (Pub. L. 101–549), reprinted at 29 U.S.C.A. 655 Note.

Section 1910.120 also issued under Section 126, Superfund Amendments and Reauthorization Act of 1986 as amended (29 U.S.C.A. 655 Note), and 5 U.S.C. 553.

■ 4. Amend § 1910.106 as follows:
■ A. Revise the section heading;
■ B. Revise paragraphs (a)(13), (a)(14)(i) through (a)(14)(iii), and (a)(19);
■ C. Remove the last sentence of paragraph (a)(17);
■ D. Remove and reserve paragraph (a)(18);
■ E. Remove the words ''or combustible'' wherever they appear in § 1910.106.
■ F. Remove the words ''and combustible'' in paragraphs (d)(5)(vi) introductory text, (e)(2) introductory text, (j)(1) and (j)(3);
■ G. Revise paragraphs (b)(2)(iv)(*f*) and (*g*), (b)(2)(vi)(*b*), (b)(2)(viii)(*e*), (b)(3)(i), (b)(3)(iv)(*a*), (b)(3)(iv)(*c*), (b)(3)(v)(*d*), and (b)(4)(iv)(*e*);
■ H. Revise paragraphs (d)(1)(ii)(*b*), (d)(2)(iii) introductory text and (d)(2)(iii)(*a*)(*2*), Table H–12, paragraphs (d)(3)(i), (d)(4)(iii), (d)(4)(iv), Tables H–14 through H–17, and paragraph (d)(7)(i)(*b*);
■ I. Revise paragraphs (e)(2)(ii)(*b*)(*1*), (e)(2)(ii)(*b*)(*2*), (e)(2)(ii)(*b*)(*3*), (e)(2)(iv)(*a*), (e)(2)(iv)(*c*), (e)(3)(v)(*a*), (e)(3)(v)(*b*), (e)(4)(i), (e)(6)(ii), and (e)(7)(i)(*c*);
■ J. Revise paragraphs (f)(1)(i), (f)(1)(ii), (f)(2)(ii), (f)(2)(iii)(*a*), (f)(2)(iii)(*b*), (f)(2)(iii)(*c*), (f)(3)(i), (f)(3)(ii), (f)(3)(iv)(*a*)(*1*), (f)(3)(iv)(*a*)(*2*), (f)(3)(iv)(*d*)(*2*), (f)(3)(v), (f)(3)(vi), (f)(4)(viii)(*e*), (f)(5)(i), (f)(6), and (f)(8);
■ K. Revise paragraphs (g)(1)(i)(*c*), (g)(1)(i)(*e*) introductory text, (g)(1)(i)(*f*), (g)(1)(iii)(*a*), (g)(1)(iii)(*b*), (g)(1)(iii)(*c*), (g)(1)(v), (g)(3)(iv)(*a*), (g)(3)(iv)(*b*),

(g)(3)(iv)(*c*), (g)(3)(v)(*a*), (g)(3)(vi)(*a*), Table H–19, and paragraphs (g)(4)(iii)(*d*), (g)(5)(i), (g)(6)(iv), and (g)(7); and

■ L. Revise paragraphs (h)(3)(i)(*a*), (h)(3)(iii)(*b*), (h)(3)(iv), (h)(5), (h)(7)(i)(*b*), (h)(7)(iii)(*c*), and (j).

The revisions read as follows:

§ 1910.106 Flammable liquids.

* * * * *

(a) * * *

(13) Flammable aerosol shall mean a flammable aerosol as defined by Appendix B to § 1910.1200—Physical Hazard Criteria. For the purposes of paragraph (d) of this section, such aerosols are considered Category 1 flammable liquids.

(14) * * *

(i) For a liquid which has a viscosity of less than 45 SUS at 100 °F (37.8 °C), does not contain suspended solids, and does not have a tendency to form a surface film while under test, the procedure specified in the Standard Method of Test for Flashpoint by Tag Closed Tester (ASTM D–56–70), which is incorporated by reference as specified in § 1910.6, or an equivalent test method as defined in Appendix B to § 1910.1200—Physical Hazard Criteria, shall be used.

(ii) For a liquid which has a viscosity of 45 SUS or more at 100 °F (37.8 °C), or contains suspended solids, or has a tendency to form a surface film while under test, the Standard Method of Test for Flashpoint by Pensky-Martens Closed Tester (ASTM D–93–71) or an equivalent method as defined by Appendix B to § 1910.1200—Physical Hazard Criteria, shall be used except that the methods specified in Note 1 to section 1.1 of ASTM D–93–71 may be used for the respective materials specified in the Note. The preceding ASTM standard is incorporated by reference as specified in § 1910.6.

(iii) For a liquid that is a mixture of compounds that have different volatilities and flashpoints, its flashpoint shall be determined by using the procedure specified in paragraph (a)(14)(i) or (ii) of this section on the liquid in the form it is shipped.

* * * * *

(18) [Reserved]

(19) *Flammable liquid* means any liquid having a flashpoint at or below 199.4 °F (93 °C). Flammable liquids are divided into four categories as follows:

(i) Category 1 shall include liquids having flashpoints below 73.4 °F (23 °C) and having a boiling point at or below 95 °F (35 °C).

(ii) Category 2 shall include liquids having flashpoints below 73.4 °F (23 °C) and having a boiling point above 95 °F (35 °C).

(iii) Category 3 shall include liquids having flashpoints at or above 73.4 °F (23 °C) and at or below 140 °F (60 °C). When a Category 3 liquid with a flashpoint at or above 100 °F (37.8 °C) is heated for use to within 30 °F (16.7 °C) of its flashpoint, it shall be handled in accordance with the requirements for a Category 3 liquid with a flashpoint below 100 °F (37.8 °C).

(iv) Category 4 shall include liquids having flashpoints above 140 °F (60 °C) and at or below 199.4 °F (93 °C). When a Category 4 flammable liquid is heated for use to within 30 °F (16.7 °C) of its flashpoint, it shall be handled in accordance with the requirements for a Category 3 liquid with a flashpoint at or above 100 °F (37.8 °C).

(v) When liquid with a flashpoint greater than 199.4 °F (93 °C) is heated for use to within 30 °F (16.7 °C) of its flashpoint, it shall be handled in accordance with the requirements for a Category 4 flammable liquid.

* * * * *

(b) * * *

(2) * * *

(iv) * * *

(*f*)*(1)* Tanks and pressure vessels storing Category 1 flammable liquids shall be equipped with venting devices which shall be normally closed except when venting to pressure or vacuum conditions. Tanks and pressure vessels storing Category 2 flammable liquids and Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C) shall be equipped with venting devices which shall be normally closed except when venting under pressure or vacuum conditions, or with approved flame arresters.

(2) Exemption: Tanks of 3,000 bbls (barrels). capacity or less containing crude petroleum in crude-producing areas and outside aboveground atmospheric tanks under 1,000 gallons capacity containing other than Category 1 flammable liquids may have open vents. (*See* paragraph (b)(2)(vi)(*b*) of this section.)

(*g*) Flame arresters or venting devices required in paragraph (b)(2)(iv)(*f*) of this section may be omitted for Category 2 flammable liquids and Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C) where conditions are such that their use may, in case of obstruction, result in tank damage.

* * * * *

(vi) * * *

(b) Where vent pipe outlets for tanks storing Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), are adjacent to buildings or public ways, they shall be located so that the vapors are released at a safe point outside of buildings and not less than 12 feet above the adjacent ground level. In order to aid their dispersion, vapors shall be discharged upward or horizontally away from closely adjacent walls. Vent outlets shall be located so that flammable vapors will not be trapped by eaves or other obstructions and shall be at least five feet from building openings.

* * * * *

(viii) * * *

(e) For Category 2 flammable liquids and Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), other than crude oils, gasolines, and asphalts, the fill pipe shall be so designed and installed as to minimize the possibility of generating static electricity. A fill pipe entering the top of a tank shall terminate within 6 inches of the bottom of the tank and shall be installed to avoid excessive vibration.

* * * * *

(3) * * *

(i) *Location.* Excavation for underground storage tanks shall be made with due care to avoid undermining of foundations of existing structures. Underground tanks or tanks under buildings shall be so located with respect to existing building foundations and supports that the loads carried by the latter cannot be transmitted to the tank. The distance from any part of a tank storing Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), to the nearest wall of any basement or pit shall be not less than 1 foot, and to any property line that may be built upon, not less than 3 feet. The distance from any part of a tank storing Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids to the nearest wall of any basement, pit or property line shall be not less than 1 foot.

* * * * *

(iv) * * *

(a) Location and arrangement of vents for Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C). Vent pipes from tanks storing Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall be so located that the discharge point is outside of buildings, higher than the fill pipe opening, and not less than 12 feet above the adjacent ground level. Vent pipes shall discharge only upward in order to disperse vapors. Vent pipes 2 inches or less in nominal inside

diameter shall not be obstructed by devices that will cause excessive back pressure. Vent pipe outlets shall be so located that flammable vapors will not enter building openings, or be trapped under eaves or other obstructions. If the vent pipe is less than 10 feet in length, or greater than 2 inches in nominal inside diameter, the outlet shall be provided with a vacuum and pressure relief device or there shall be an approved flame arrester located in the vent line at the outlet or within the approved distance from the outlet.

* * * * *

(*c*) Location and arrangement of vents for Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids. Vent pipes from tanks storing Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids shall terminate outside of the building and higher than the fill pipe opening. Vent outlets shall be above normal snow level. They may be fitted with return bends, coarse screens or other devices to minimize ingress of foreign material.

* * * * *

(v) * * *

(*d*) For Category 2 flammable liquids and Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), other than crude oils, gasolines, and asphalts, the fill pipe shall be so designed and installed as to minimize the possibility of generating static electricity by terminating within 6 inches of the bottom of the tank.

* * * * *

(4) * * *

(iv) * * *

(*e*) For Category 2 flammable liquids and Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), other than crude oils, gasoline, and asphalts, the fill pipe shall be so designed and installed as to minimize the possibility of generating static electricity by terminating within 6 inches of the bottom of the tank.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(*b*) Category 1, 2, or 3 flammable liquids in the fuel tanks of a motor vehicle, aircraft, boat, or portable or stationary engine;

* * * * *

(2) * * *

(iii) *Size.* Flammable liquid containers shall be in accordance with Table H–12, except that glass or plastic containers of no more than 1-gallon capacity may be used for a Category 1 or 2 flammable liquid if:

(*a*) * * *

(*2*) The user's process either would require more than 1 pint of a Category 1 flammable liquid or more than 1 quart of a Category 2 flammable liquid of a single assay lot to be used at one time, or would require the maintenance of an analytical standard liquid of a quality which is not met by the specified standards of liquids available, and the quantity of the analytical standard liquid required to be used in any one control process exceeds one-sixteenth the capacity of the container allowed under Table H–12 for the category of liquid; or

* * * * *

TABLE H–12—MAXIMUM ALLOWABLE SIZE OF CONTAINERS AND PORTABLE TANKS FOR FLAMMABLE LIQUIDS

Container type	Category 1	Category 2	Category 3	Category 4
Glass or approved plastic	1 pt	1 qt	1 gal	1 gal.
Metal (other than DOT drums)	1 gal	5 gal	5 gal	5 gal.
Safety cans	2 gal	5 gal	5 gal	5 gal.
Metal drums (DOT specifications)	60 gal	60 gal	60 gal	60 gal.
Approved portable tanks	660 gal	660 gal	660 gal	660 gal.

Note: Container exemptions: (a) Medicines, beverages, foodstuffs, cosmetics, and other common consumer items, when packaged according to commonly accepted practices, shall be exempt from the requirements of 1910.106(d)(2)(i) and (ii).

(3) * * *

(i) *Maximum capacity.* Not more than 60 gallons of Category 1, 2, or 3 flammable liquids, nor more than 120 gallons of Category 4 flammable liquids may be stored in a storage cabinet.

* * * * *

(4) * * *

(iii) *Wiring.* Electrical wiring and equipment located in inside storage rooms used for Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall be approved under subpart S of this part for Class I, Division 2 Hazardous Locations; for Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) and Category 4 flammable liquids, shall be approved for general use.

(iv) *Ventilation.* Every inside storage room shall be provided with either a gravity or a mechanical exhaust ventilation system. Such system shall be designed to provide for a complete change of air within the room at least six times per hour. If a mechanical exhaust system is used, it shall be controlled by a switch located outside of the door. The ventilating equipment and any lighting fixtures shall be operated by the same switch. A pilot light shall be installed adjacent to the switch if Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), are dispensed within the room. Where gravity ventilation is provided, the fresh air intake, as well as the exhaust outlet from the room, shall be on the exterior of the building in which the room is located.

* * * * *

BILLING CODE 4510–26–P

TABLE H-14 - INDOOR CONTAINER STORAGE

Category liquid	Storage level	Gallons: Protected storage maximum per pile	Gallons: Unprotected storage maximum per pile
1	Ground and upper floors.....	2,750 (50)	660 (12)
	Basement....................	Not permitted	Not permitted
2	Ground and upper floors.....	5,500 (100)	1,375 (25)
	Basement....................	Not permitted	Not permitted
3 ..... FP<100F	Ground and upper floors.....	16,500 (300)	4,125 (75)
	Basement....................	Not permitted	Not permitted
3 .... FP≥100F	Ground and upper floors.....	16,500 (300)	4,125 (75)
	Basement....................	5,500 (100)	Not permitted
4 ...	Ground and upper floors.....	55,000 (1,000)	13,750 (250)
	Basement....................	8,250 (450)	Not permitted

NOTE 1: When 2 or more categories of materials are stored in a single pile, the maximum gallonage permitted in that pile shall be the smallest of the 2 or more separate maximum gallonages.

NOTE 2: Aisles shall be provided so that no container is more than 12 ft. from an aisle. Main aisles shall be at least 3 ft. wide and side aisles at least 4 ft. wide.

NOTE 3: Each pile shall be separated from each other by at least 4 ft.

NOTE 4: FP means Flashpoint.

(Number in parenthesis indicate corresponding number of 55-gal. drums.)

TABLE H-15 - INDOOR PORTABLE TANK STORAGE

Category	Storage level	Gallons	
		Protected storage maximum per pile	Unprotected storage maximum per pile
1	Ground and upper floors.....	Not permitted	Not permitted
	Basement....................	Not permitted	Not permitted
2	Ground and upper floors.....	20,000	2,000
	Basement....................	Not permitted	Not permitted
3	Ground and upper floors.....	40,000	5,500
FP<100F	Basement....................	Not permitted	Not permitted
3	Ground and upper floors.....	40,000	5,500
FP≥100F	Basement....................	20,000	Not permitted
4	Ground and upper floors.....	60,000	22,000
	Basement....................	20,000	Not permitted

NOTE 1: When 1 or more categories of materials are stored in a single pile, the maximum gallonage permitted in that pile shall be the smallest of the 2 or more separate maximum gallonages.

NOTE 2: Aisles shall be provided so that no portable tank is more than 12 ft. from an aisle. Main aisles shall be at least 8 ft. wide and side aisles at least 4 ft. wide.

NOTE 3: Each pile shall be separated from each other by at least 4 ft.

NOTE 4: FP means Flashpoint.

TABLE H-16 - OUTDOOR CONTAINER STORAGE

1-Category	2-Maximum per pile	3-Distance between piles	4-Distance to property line that can be built upon	5-Distance to street, alley, public way
	gallons	feet	feet	feet
1	1,100	5	20	10
2	2,200	5	20	10
3 FP<100F.	4,400	5	20	10
3 FP≥100F.	8,800	5	10	5
4	22,000	5	10	5

NOTE 1: When 2 or more categories of materials are stored in a single pile, the maximum gallonage in that pile shall be the smallest of the 2 or more separate gallonages.

NOTE 2: Within 200 ft. of each container, there shall be a 12 ft. wide access way to permit approach of fire control apparatus.

NOTE 3: The distances listed apply to properties that have protection for exposures as defined. If there are exposures, and such protection for exposures does not exist, the distances in column 4 shall be doubled.

NOTE 4: When total quantity stored does not exceed 50 percent of maximum per pile, the distances in columns 4 and 5 may be reduced 50 percent, but not less than 3 ft.

NOTE 5: FP means flashpoint.

TABLE H-17 - OUTDOOR PORTABLE TANK STORAGE

1-Category	2-Maximum per pile	3-Distance between piles	4-Distance to property line that can be built upon	5-Distance to street, alley, public way
	gallons	feet	feet	feet
1	2,200	5	20	10
2	4,400	5	20	10
3 FP<100F.	8,800	5	20	10
3 FP≥100F.	17,600	5	10	5
4	44,000	5	10	5

NOTE 1: When 2 or more categories of materials are stored in a single pile, the maximum gallonage in that pile shall be the smallest of the 2 or more separate gallonages.

NOTE 2: Within 200 ft. of each portable tank, there shall be a 12 ft. wide access way to permit approach of fire control apparatus.

NOTE 3: The distances listed apply to properties that have protection for exposures as defined. If there are exposures, and such protection for exposures does not exist, the distances in column 4 shall be doubled.

NOTE 4: When total quantity stored does not exceed 50 percent of maximum per pile, the distances in columns 4 and 5 may be reduced 50 percent, but not less than 3 ft.

NOTE 5: FP means flashpoint.

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(7) * * *

(i) * * *

(*b*) At least one portable fire extinguisher having a rating of not less than 12–B units must be located not less than 10 feet, nor more than 25 feet, from any Category 1, 2, or 3 flammable liquid storage area located outside of a storage room but inside a building.

* * * * *

(e) * * *

(2) * * *

(ii) * * *

(*b*) * * *

(*1*) 25 gallons of Category 1 flammable liquids in containers

(*2*) 120 gallons of Category 2, 3, or 4 flammable liquids in containers

(*3*) 660 gallons of Category 2, 3, or 4 flammable liquids in a single portable tank.

* * * * *

(iv) * * *

(*a*) Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall be kept in covered containers when not actually in use.

* * * * *

(*c*) Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), may be used only where there are no open flames or other sources of ignition within the possible path of vapor travel.

* * * * *

(3) * * *

(v) * * *

(*a*) Areas as defined in paragraph (e)(3)(i) of this section using Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall be ventilated at a rate of not less than 1 cubic foot per minute per square foot of solid floor area. This shall be accomplished by natural or mechanical ventilation with discharge or exhaust to a safe location outside of the building. Provision shall be made for introduction of makeup air in such a manner as not to short circuit the ventilation. Ventilation shall be arranged to include all floor areas or pits where flammable vapors may collect.

(*b*) Equipment used in a building and the ventilation of the building shall be designed so as to limit flammable vapor-air mixtures under normal operating conditions to the interior of equipment, and to not more than 5 feet from equipment which exposes Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), to the air. Examples of such equipment are dispensing stations, open centrifuges, plate and frame filters, open vacuum filters, and surfaces of open equipment.

* * * * *

(4) * * *

(i) Tank vehicle and tank car loading or unloading facilities shall be separated from aboveground tanks, warehouses, other plant buildings or nearest line of adjoining property which may be built upon by a distance of 25 feet for Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), and 15 feet for Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) and Category 4 flammable liquids, measured from the nearest position of any fill stem. Buildings for pumps or shelters for personnel may be a part of the facility. Operations of the facility shall comply with the appropriate portions of paragraph (f)(3) of this section.

* * * * *

(6) * * *

(ii) *Grounding.* Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall not be dispensed into containers unless the nozzle and container are electrically interconnected. Where the metallic floorplate on which the container stands while filling is electrically connected to the fill stem or where the fill stem is bonded to the container during filling operations by means of a bond wire, the provisions of this section shall be deemed to have been complied with.

(7) * * *

(i) * * *

(*c*) Locations where flammable vapor-air mixtures may exist under abnormal conditions and for a distance beyond Division 1 locations shall be classified Division 2 according to the requirements of subpart S of this part. These locations include an area within 20 feet horizontally, 3 feet vertically beyond a Division 1 area, and up to 3 feet above floor or grade level within 25 feet, if indoors, or 10 feet if outdoors, from any pump, bleeder, withdrawal fitting, meter, or similar device handling Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C). Pits provided with adequate mechanical ventilation within a Division 1 or 2 area shall be classified Division 2. If only Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids are handled, then ordinary electrical equipment is satisfactory though care shall be used in locating electrical apparatus to prevent hot metal from falling into open equipment.

* * * * *

(f) * * *

(1) * * *

(i) *Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C).* Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall be stored in closed containers, or in storage tanks above ground outside of buildings, or underground in accordance with paragraph (b) of this section.

(ii) *Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) and Category 4 flammable liquids.* Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) and Category 4 flammable liquids shall be stored in containers, or in tanks within buildings or above ground outside of buildings, or underground in accordance with paragraph (b) of this section.

* * * * *

(2) * * *

(ii) *Heating.* Rooms in which Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), are stored or handled shall be heated only by means not constituting a source of ignition, such as steam or hot water. Rooms containing heating appliances involving sources of ignition shall be located and arranged to prevent entry of flammable vapors.

(iii) * * *

(*a*) Ventilation shall be provided for all rooms, buildings, or enclosures in which Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), are pumped or dispensed. Design of ventilation systems shall take into account the relatively high specific gravity of the vapors. Ventilation may be provided by adequate openings in outside walls at floor level unobstructed except by louvers or coarse screens. Where natural ventilation is inadequate, mechanical ventilation shall be provided.

(*b*) Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall not be stored or handled within a building having a basement or pit into which flammable vapors may travel, unless such area is provided with ventilation designed to prevent the accumulation of flammable vapors therein.

(*c*) Containers of Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall not be drawn from or filled within buildings unless provision is made to prevent the accumulation of flammable vapors in hazardous concentrations. Where mechanical ventilation is required, it shall be kept in operation while flammable liquids with a flashpoint below 100 °F (37.8 °C) are being handled.

(3) * * *

(i) *Separation.* Tank vehicle and tank car loading or unloading facilities shall be separated from aboveground tanks, warehouses, other plant buildings or nearest line of adjoining property that may be built upon by a distance of 25 feet for Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), and 15 feet for Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) and Category 4 flammable liquids measured from the nearest position of any fill spout. Buildings for pumps or shelters for personnel may be a part of the facility.

(ii) *Category restriction.* Equipment such as piping, pumps, and meters used for the transfer of Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), between storage tanks and the fill stem of the loading rack shall not be used for the transfer of Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids.

* * * * *

(iv) * * *

(*a*) * * *

(*1*) Where Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), are loaded, or

(*2*) Where Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids are loaded into vehicles which may contain vapors from previous cargoes of Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C).

* * * * *

(*d*) * * *

(*2*) Where no Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), are handled at the loading facility and the tank vehicles loaded are used exclusively for Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) and Category 4 flammable liquids; and

* * * * *

(v) *Stray currents.* Tank car loading facilities where Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), are loaded through open domes shall be protected against stray currents by bonding the pipe to at least one rail and to the rack structure if of metal. Multiple lines entering the rack area shall be electrically bonded together. In addition, in areas where excessive stray currents are known to exist, all pipe entering the rack area shall be provided with insulating sections to electrically isolate the rack piping from the pipelines. No bonding between the tank car and the rack or piping is required during either loading or unloading of Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids.

(vi) *Container filling facilities.* Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall not be dispensed into containers unless the nozzle and container are electrically interconnected. Where the metallic floorplate on which the container stands while filling is electrically connected to the fill stem or where the fill stem is bonded to the container during filling operations by means of a bond wire, the provisions of this section shall be deemed to have been complied with.

(4) * * *

(viii) * * *

(*e*) In addition to the requirements of paragraph (f)(4)(viii)(*d*) of this section, each line conveying Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), leading to a wharf shall be provided with a readily accessible block valve located on shore near the approach to the wharf and outside of any diked area. Where more than one line is involved, the valves shall be grouped in one location.

* * * * *

(5) * * *

(i) *Application.* This paragraph (f)(5)(i) shall apply to areas where Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), are stored or handled. For areas where only Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids are stored or handled, the electrical equipment may be installed in accordance with the provisions of Subpart S of this part, for ordinary locations.

* * * * *

(6) *Sources of ignition.* Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall not be handled, drawn, or dispensed where flammable vapors may reach a source of ignition. Smoking shall be prohibited except in designated localities. ''No Smoking'' signs shall be conspicuously posted where hazard from flammable liquid vapors is normally present.

* * * * *

(8) *Fire control.* Suitable fire-control devices, such as small hose or portable fire extinguishers, shall be available to locations where fires are likely to occur. Additional fire-control equipment may be required where a tank of more than 50,000 gallons individual capacity contains Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), and where an unusual exposure hazard exists from surrounding property. Such additional fire-control equipment shall be sufficient to extinguish a fire in the largest tank. The design and amount of such equipment shall be in accordance with approved engineering standards.

* * * * *

(g) * * *

(1) * * *

(i) * * *

(*c*) Apparatus dispensing Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), into the fuel tanks of motor vehicles of the public shall not be located at a bulk plant unless separated by a fence or similar barrier from the area in which bulk operations are conducted.

* * * * *

(*e*) The provisions of paragraph (g)(1)(i)(*a*) of this section shall not prohibit the dispensing of flammable liquids with a flashpoint below 100 °F (37.8 °C) in the open from a tank vehicle to a motor vehicle. Such dispensing shall be permitted provided:

* * * * *

(*f*) Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall not be stored or handled within a building having a basement or pit into which flammable vapors may travel, unless such area is provided with ventilation designed to prevent the accumulation of flammable vapors therein.

* * * * *

(iii) * * *

(*a*) Except where stored in tanks as provided in paragraph (g)(1)(ii) of this section, no Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall be stored within any service station building except in closed containers of aggregate capacity not exceeding 60 gallons. One container not exceeding 60 gallons capacity equipped with an approved pump is permitted.

(*b*) Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), may be transferred from one container to another in lubrication or service rooms of a service station building provided the electrical installation complies with Table H–19 and provided that any heating equipment complies with paragraph (g)(6) of this section.

(*c*) Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) and Category 4 flammable liquids may be stored and dispensed inside service station buildings from tanks of not more than 120 gallons capacity each.

* * * * *

(v) *Dispensing into portable containers.* No delivery of any Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall be made into portable containers unless the container is constructed of metal, has a tight closure with screwed or spring cover, and is fitted with a spout or so designed so the contents can be poured without spilling.

* * * * *

(3) * * *

(iv) * * *

(*a*) Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall be transferred from tanks by means of fixed pumps so designed and equipped as to allow control of the flow and to prevent leakage or accidental discharge.

(*b*)(*1*) Only listed devices may be used for dispensing Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C). No such device may be used if it shows evidence of having been dismantled.

(*2*) Every dispensing device for Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), installed after December 31, 1978, shall contain evidence of listing so placed that any attempt to dismantle the device will result in damage to such evidence, visible without disassembly or dismounting of the nozzle.

(*c*) Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall not be dispensed by pressure from drums, barrels, and similar containers. Approved pumps taking suction through the top of the container or approved self-closing faucets shall be used.

* * * * *

(v) * * *

(*a*) This paragraph (g)(3)(v) shall apply to systems for dispensing Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), where such liquids are transferred from storage to individual or multiple dispensing units by pumps located elsewhere than at the dispensing units.

* * * * *

(vi) * * *

(*a*) A listed manual or automatic-closing type hose nozzle valve shall be provided on dispensers used for the dispensing of Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C).

* * * * *

(4) * * *

(iii) * * *

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TABLE H-19 - ELECTRICAL EQUIPMENT HAZARDOUS AREAS - SERVICE STATIONS

Location	Class I Group D division	Extent of classified area
Underground tank:		
Fill opening..........	1	Any pit, box or space below grade level, any part of which is within the Division 1 or 2 classified area.
	2	Up to 18 inches above grade level within a horizontal radius of 10 feet from a loose fill connection and within a horizontal radius of 5 feet from a tight fill connection.
Vent-Discharging Upward.	1	Within 3 feet of open end of vent, extending in all directions.
	2	Area between 3 feet and 5 feet of open end of vent, extending in all directions.
Dispenser:		
Pits	1	Any pit, box or space below grade level, any part of which is within the Division 1 or 2 classified area.
Dispenser enclosure ..	1	The area 4 feet vertically above base within the enclosure and 18 inches horizontally in all directions.
Outdoor	2	Up to 18 inches above grade level within 20 feet horizontally of any edge of enclosure.
Indoor:		
With mechanical ventilation	2	Up to 18 inches above grade or floor level within 20 feet horizontally of any edge of enclosure.
With gravity ventilation	2	Up to 18 inches above grade or floor level within 25 feet horizontally of any edge of enclosure.

Remote pump - Outdoor.	1	Any pit, box or space below grade level if any part is within a horizontal distance of 10 feet from any edge of the pump.
	2	Within 3 feet of any edge of the pump, extending in all directions. Also up to 18 inches above grade level within 10 feet horizontally from any edge of the pump.
Remote pump - Indoor..	1	Entire area within any pit.
	2	Within 5 feet of any edge of pump, extending in all directions. Also up to 3 feet above floor or grade level within 25 feet horizontally from any edge of pump.
Lubrication or service room	1	Entire area within any pit.
	2	Area up to 18 inches above floor or grade level within entire lubrication room.
Dispenser for Liquids with a flashpoint below 100 ^{0}F (37.8 °C)(1).....	2	Within 3 feet of any fill or dispensing point, extending in all directions.
Special enclosure inside building per 1910.106(f)(1)(ii).	1	Entire enclosure.
Sales, storage and rest rooms..........	(2)	If there is any opening to these rooms within the extent of a Division 1 area, the entire room shall be classified as Division 1.

Footnote (1) Category 1 or 2 flammable liquids, or for Category 3 flammable liquids with a flashpoint below 100 ^{0}F (37.8 ^{0}C).
Footnote(2) Ordinary

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(*d*) Piping handling Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall be grounded to control stray currents.

(5) * * *

(i) *Application.* This paragraph (g)(5) shall apply to areas where Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), are stored or handled. For areas where Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids are stored or handled the electrical equipment may be installed in accordance with the provisions of subpart S of this part, for ordinary locations.

* * * * *

(6) * * *

(iv) *Work areas.* Heating equipment using gas or oil fuel may be installed in the lubrication, sales, or service room where there is no dispensing or transferring of Category 1 or 2 flammable liquids or 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), provided the bottom of the combustion chamber is at least 18 inches above the floor and the heating equipment is protected from physical damage by vehicles. Heating equipment using gas or oil fuel listed for use in garages may be installed in the lubrication or service room where Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), are dispensed provided the equipment is installed at least 8 feet above the floor.

* * * * *

(7) *Drainage and waste disposal.* Provision shall be made in the area where Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), are dispensed to prevent spilled liquids from flowing into the interior of service station buildings. Such provision may be by grading driveways, raising door sills, or other equally effective means. Crankcase drainings and flammable liquids shall not be dumped into sewers but shall be stored in tanks or drums

outside of any building until removed from the premises.

* * * * *

(h) * * *

(3) * * *

(i) * * *

(*a*) Processing buildings shall be of fire-resistance or noncombustible construction, except heavy timber construction with load-bearing walls may be permitted for plants utilizing only stable Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids. Except as provided in paragraph (h)(2)(ii) of this section or in the case of explosion resistant walls used in conjunction with explosion relieving facilities, see paragraph (h)(3)(iv) of this section, load-bearing walls are prohibited. Buildings shall be without basements or covered pits.

* * * * *

(iii) * * *

(*b*) Equipment used in a building and the ventilation of the building shall be designed so as to limit flammable vapor-air mixtures under normal operating conditions to the interior of equipment, and to not more than 5 feet from equipment which exposes Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), to the air. Examples of such equipment are dispensing stations, open centrifuges, plate and frame filters, open vacuum filters, and surfaces of open equipment.

(iv) *Explosion relief.* Areas where Category 1 or unstable liquids are processed shall have explosion venting through one or more of the following methods:

* * * * *

(5) *Tank vehicle and tank car loading and unloading.* Tank vehicle and tank car loading or unloading facilities shall be separated from aboveground tanks, warehouses, other plant buildings, or nearest line of adjoining property which may be built upon by a distance of 25 feet for Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), and 15 feet for Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) and Category 4 flammable liquids measured from the nearest position of any fill stem. Buildings for pumps or shelters for personnel may be a part of the facility. Operations of the facility shall comply with the appropriate portions of paragraph (f)(3) of this section.

* * * * *

(7) * * *

(i) * * *

(*b*) Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall not be dispensed into containers unless the nozzle and container are electrically interconnected. Where the metallic floorplate on which the container stands while filling is electrically connected to the fill stem or where the fill stem is bonded to the container during filling operations by means of a bond wire, the provisions of this section shall be deemed to have been complied with.

* * * * *

(iii) * * *

(*c*) Locations where flammable vapor-air mixtures may exist under abnormal conditions and for a distance beyond Division 1 locations shall be classified Division 2 according to the requirements of subpart S of this part. These locations include an area within 20 feet horizontally, 3 feet vertically beyond a Division 1 area, and up to 3 feet above floor or grade level within 25 feet, if indoors, or 10 feet if outdoors, from any pump, bleeder, withdrawal fitting, meter, or similar device handling Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C). Pits provided with adequate mechanical ventilation within a Division 1 or 2 area shall be classified Division 2. If Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids only are handled, then ordinary electrical equipment is satisfactory though care shall be used in locating electrical apparatus to prevent hot metal from falling into open equipment.

* * * * *

(j) *Scope.* This section applies to the handling, storage, and use of flammable liquids with a flashpoint at or below 199.4 °F (93 °C) unless otherwise noted. This section does not apply to:

* * * * *

■ 5. Amend § 1910.107 as follows:

■ A. Amend paragraphs (c)(9)(i), (e)(1), (e)(2), (e)(3), (e)(6)(iv), (e)(8), and (e)(9) by removing the terms ''flammable or combustible liquids'' wherever it appears and adding in its place the phrase ''flammable liquids or liquids with a flashpoint greater than 199.4 °F (93 °C)''; and

■ B. Revise the heading of paragraph (e), and (e)(4) to read as follows:

§ 1910.107 Spray finishing using flammable and combustible materials.

* * * * *

(e) *Flammable liquids and liquids with a flashpoint greater than 199.4 °F (93 °C)*

* * * * *

(4) *Transferring liquids.* Except as provided in paragraph (e)(5) of this section the withdrawal of flammable liquids and liquids with a flashpoint greater than 199.4 °F (93 °C) from containers having a capacity of greater than 60 gallons shall be by approved pumps. The withdrawal of flammable liquids or liquids with a flashpoint greater than 199.4 °F (93 °C) from containers and the filling of containers, including portable mixing tanks, shall be done only in a suitable mixing room or in a spraying area when the ventilating system is in operation. Adequate precautions shall be taken to protect against liquid spillage and sources of ignition.

* * * * *

■ 6. Amend § 1910.119 to revise paragraphs (a)(1)(ii) introductory text, (a)(1)(ii)(B) and the definition of ''Trade secret'' in paragraph (b) to read as follows:

§ 1910.119 Process safety management of highly hazardous chemicals.

* * * * *

(a) * * *

(1) * * *

(ii) A process which involves a Category 1 flammable gas (as defined in 1910.1200(c)) or a flammable liquid with a flashpoint below 100 °F (37.8 °C) on site in one location, in a quantity of 10,000 pounds (4535.9 kg) or more except for:

* * * * *

(B) Flammable liquids with a flashpoint below 100 °F (37.8 °C) stored in atmospheric tanks or transferred which are kept below their normal boiling point without benefit of chilling or refrigeration.

* * * * *

(b) * * *

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. *See* Appendix E to § 1910.1200—Definition of a Trade Secret (which sets out the criteria to be used in evaluating trade secrets).

* * * * *

■ 7. In § 1910.120, revise the definition of the term *Health hazard* in paragraph (a)(3) to read as follows:

§ 1910.120 Hazardous waste operations and emergency response.

(a) * * *

(3) * * *

Health hazard means a chemical or a pathogen where acute or chronic health effects may occur in exposed employees. It also includes stress due to temperature extremes. The term *health hazard* includes chemicals that are classified in accordance with the Hazard Communication Standard, 29 CFR 1910.1200, 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); aspiration toxicity or simple asphyxiant. (*See* Appendix A to § 1910.1200—Health Hazard Criteria (Mandatory) for the criteria for determining whether a chemical is classified as a health hazard.)

* * * * *

■ 8. Amend paragraph (d) of § 1910.123 by removing the definition of ''Combustible liquid'' and revising the definitions of the terms ''Flammable liquid'' and ''Flashpoint'' to read as follows:

§ 1910.123 Dipping and coating operations: Coverage and definitions.

* * * * *

(d) * * *

Flammable liquid means any liquid having a flashpoint at or below 199.4 °F (93 °C).

Flashpoint means the minimum temperature at which a liquid gives off a vapor in sufficient concentration to ignite if tested in accordance with the test methods in Appendix B to § 1910.1200—Physical Hazard Criteria.

* * * * *

■ 9. In § 1910.124, revise paragraph (c)(2) introductory text to read as follows:

§ 1910.124 General requirements for dipping and coating operations.

* * * * *

(c) * * *

(2) You must ensure that any exhaust air re-circulated from a dipping or coating operation using flammable liquids or liquids with flashpoints greater than 199.4 °F (93 °C) is:

* * * * *

■ 10. Amend § 1910.125 by revising the section heading and the introductory text (including the table) to read as follows:

§ 1910.125 Additional requirements for dipping and coating operations that use flammable liquids or liquids with flashpoints greater than 199.4 °F (93 °C).

If you use flammable liquids, you must comply with the requirements of this section as well as the requirements of §§ 1910.123, 1910.124, and 1910.126, as applicable.

You must also comply with this section if:	And:
• The flashpoint of the liquid is 199.4 °F (93 °C) or above	• The liquid is heated as part of the operation; or • A heated object is placed in the liquid.

■ 11. Amend the introductory text of paragraph (c) of § 1910.126 by removing the words ''or combustible''.

Subpart Q—[Amended]

■ 12. The authority citation for subpart Q continues to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); Secretary of Labor's Orders Nos. 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 31159), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

■ 13. Amend § 1910.252 as follows;
■ A. Revise paragraph (c)(1)(iv);
■ B. Add new paragraphs (c)(1)(v) and (c)(1)(vi).

§ 1910.252 General requirements.

* * * * *

(c) * * *

(1) * * *

(iv) *Hazard communication.* The employer shall include the potentially hazardous materials employed in fluxes, coatings, coverings, and filler metals, all of which are potentially used in welding and cutting, or are released to the atmosphere during welding and cutting, in the program established to comply with the Hazard Communication Standard (HCS) (§ 1910.1200). The employer shall ensure that each employee has access to labels on containers of such materials and safety data sheets, and is trained in accordance with the provisions of § 1910.1200. Potentially hazardous materials shall include but not be limited to the materials itemized in paragraphs (c)(5) through (c)(12) of this section.

(v) *Additional considerations for hazard communication in welding, cutting, and brazing.* (A) The suppliers shall determine and shall label in accordance with § 1910.1200 any hazards associated with the use of their materials in welding, cutting, and brazing.

(B) In addition to any requirements imposed by § 1910.1200, all filler metals and fusible granular materials shall carry the following notice, as a minimum, on tags, boxes, or other containers:

Do not use in areas without adequate ventilation. *See* ANSI Z49.1–1967 Safety in Welding, Cutting, and Allied Processes published by the American Welding Society.

(C) Where brazing (welding) filler metals contain cadmium in significant amounts, the labels shall indicate the hazards associated with cadmium including cancer, lung and kidney effects, and acute toxicity effects.

(D) Where brazing and gas welding fluxes contain fluorine compounds, the labels shall indicate the hazards associated with fluorine compounds including eye and respiratory tract effects.

(vi) Prior to June 1, 2015, employers may include the following information on labels in lieu of the labeling requirements in paragraph (c)(1)(v) of this section:

(A) All filler metals and fusible granular materials shall carry the following notice, as a minimum, on tags, boxes, or other containers:

CAUTION

Welding may produce fumes and gases hazardous to health. Avoid breathing these fumes and gases. Use adequate ventilation. *See* ANSI Z49.1–1967 Safety in Welding and Cutting published by the American Welding Society.

(B) Brazing (welding) filler metals containing cadmium in significant amounts shall carry the following notice on tags, boxes, or other containers:

WARNING
CONTAINS CADMIUM—POISONOUS FUMES MAY BE FORMED ON HEATING

Do not breathe fumes. Use only with adequate ventilation such as fume collectors, exhaust ventilators, or air-supplied respirators. *See* ANSI Z49.1–1967. If chest pain, cough, or fever develops after use call physician immediately.

(C) Brazing and gas welding fluxes containing fluorine compounds shall have a cautionary wording to indicate that they contain fluorine compounds. One such cautionary wording recommended by the American Welding

Society for brazing and gas welding fluxes reads as follows:

CAUTION
CONTAINS FLUORIDES

This flux when heated gives off fumes that may irritate eyes, nose and throat.

1. Avoid fumes—use only in well-ventilated spaces.
2. Avoid contact of flux with eyes or skin.
3. Do not take internally.

* * * * *

Subpart Z—[Amended]

■ 14. Revise the authority citation for subpart Z to read as follows:

Authority: Sections 4, 6, 8 of the Occupational Safety and Health Act of 1970 (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 31159), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

All of subpart Z issued under section 6(b) of the Occupational Safety and Health Act of 1970, except those substances that have exposure limits listed in Tables Z–1, Z–2, and Z–3 of 29 CFR 1910.1000. The latter were issued under section 6(a) (29 U.S.C. 655(a)).

Section 1910.1000, Tables Z–1, Z–2 and Z–3 also issued under 5 U.S.C. 553, but not under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, cotton dust, and chromium (VI) listings.

Section 1910.1001 also issued under section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704) and 5 U.S.C. 553.

Section 1910.1002 also issued under 5 U.S.C. 553, but not under 29 U.S.C. 655 or 29 CFR part 1911.

Sections 1910.1018, 1910.1029, and 1910.1200 also issued under 29 U.S.C. 653.

Section 1910.1030 also issued under Pub. L. 106–430, 114 Stat. 1901.

Section 1910.1201 also issued under 49 U.S.C. 1801–1819 and 5 U.S.C. 533.

■ 15. Amend § 1910.1001 as follows:
■ A. Remove paragraph (j)(5);
■ B. Redesignate paragraphs (j)(1) through (j)(4) as paragraphs (j)(2) through (j)(5);
■ C. Revise paragraphs (h)(2)(iv), (h)(3)(vi), the newly redesignated paragraphs (j)(4), (j)(5), and the introductory text of paragraph (j)(6);
■ D. Add new paragraph (j)(1);
■ E. Amend Appendix F, to § 1910.1001, Paragraph [A] (6) by removing ''(j)(4)'' and adding in its place ''(j)(5)''.

The revisions and additions read as follows:

§ 1910.1001 Asbestos.

* * * * *

(h) * * *

(2) * * *

(iv) The employer shall ensure that containers of contaminated protective devices or work clothing, which are to be taken out of change rooms or the workplace for cleaning, maintenance or disposal, bear labels in accordance with paragraph (j) of this section.

(3) * * *

(vi) The employer shall ensure that contaminated clothing is transported in sealed impermeable bags, or other closed, impermeable containers, and labeled in accordance with paragraph (j) of this section.

* * * * *

(j) * * *

(1) *Hazard communication—general.* (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for asbestos.

(ii) In classifying the hazards of asbestos at least the following hazards are to be addressed: Cancer and lung effects.

(iii) Employers shall include asbestos in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of asbestos and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (j)(7) of this section.

* * * * *

(4) *Warning signs*—(i) *Posting.* Warning signs shall be provided and displayed at each regulated area. In addition, warning signs shall be posted at all approaches to regulated areas so that an employee may read the signs and take necessary protective steps before entering the area.

(ii) *Sign specifications:*

(A) The warning signs required by paragraph (j)(4)(i) of this section shall bear the following legend:

DANGER
ASBESTOS
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AUTHORIZED PERSONNEL ONLY

(B) In addition, where the use of respirators and protective clothing is required in the regulated area under this section, the warning signs shall include the following:

WEAR RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING IN THIS AREA

(C) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (j)(4)(ii)(A) of this section:

DANGER
ASBESTOS
CANCER AND LUNG DISEASE HAZARD
AUTHORIZED PERSONNEL ONLY

(D) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (j)(4)(ii)(B) of this section:

RESPIRATORS AND PROTECTIVE CLOTHING ARE REQUIRED IN THIS AREA

(iii) The employer shall ensure that employees working in and contiguous to regulated areas comprehend the warning signs required to be posted by paragraph (j)(4)(i) of this section. Means to ensure employee comprehension may include the use of foreign languages, pictographs and graphics.

(iv) At the entrance to mechanical rooms/areas in which employees reasonably can be expected to enter and which contain ACM and/or PACM, the building owner shall post signs which identify the material which is present, its location, and appropriate work practices which, if followed, will ensure that ACM and/or PACM will not be disturbed. The employer shall ensure, to the extent feasible, that employees who come in contact with these signs can comprehend them. Means to ensure employee comprehension may include the use of foreign languages, pictographs, graphics, and awareness training.

(5) *Warning labels*—(i) *Labeling.* Labels shall be affixed to all raw materials, mixtures, scrap, waste, debris, and other products containing asbestos fibers, or to their containers. When a building owner or employer identifies previously installed ACM and/or PACM, labels or signs shall be affixed or posted so that employees will be notified of what materials contain ACM and/or PACM. The employer shall attach such labels in areas where they will clearly be noticed by employees who are likely to be exposed, such as at the entrance to mechanical room/areas. Signs required by paragraph (j) of this section may be posted in lieu of labels so long as they contain the information required for labeling.

(ii) *Label specifications.* In addition to the requirements of paragraph (j)(1), the employer shall ensure that labels of bags or containers of protective clothing and equipment, scrap, waste, and debris containing asbestos fibers include the following information:

DANGER
CONTAINS ASBESTOS FIBERS
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
DO NOT BREATHE DUST
AVOID CREATING DUST

(iii) Prior to June 1, 2015, employers may include the following information on raw materials, mixtures or labels of bags or containers of protective clothing and equipment, scrap, waste, and debris containing asbestos fibers in lieu of the labeling requirements in paragraphs (j)(1)(i) and (j)(5)(ii) of this section:

DANGER
CONTAINS ASBESTOS FIBERS
AVOID CREATING DUST
CANCER AND LUNG DISEASE HAZARD

(6) The provisions for labels and for safety data sheets required by paragraph (j) of this section do not apply where:

* * * * *

■ 16. Amend § 1910.1003 as follows:
■ A. In the last sentence in paragraph (c)(4)(v) remove the words ''paragraphs (e)(2), (3), and (4)'' and add the words ''paragraph (e)'' in their place;
■ B. Revise the heading of paragraph (e);
■ C. Revise paragraphs (e)(1) and (e)(2).
■ D. Remove paragraph (e)(3); and
■ E. Redesignate paragraphs (e)(4) and (e)(5) as (e)(3) and (e)(4).

The revisions read as follows:

§ 1910.1003 13 Carcinogens (4-nitrobiphenyl, etc.).

* * * * *

(e) *Communication of hazards*—(1) *Hazard communication.* (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for each carcinogen listed in paragraph (e)(1)(iv) of this section.

(ii) In classifying the hazards of carcinogens listed in paragraph (e)(1)(iv) of this section, at least the hazards listed in paragraph (e)(1)(iv) are to be addressed.

(iii) Employers shall include the carcinogens listed in paragraph (e)(1)(iv) of this section in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of the carcinogens listed in paragraph (e)(1)(iv) and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (e)(4) of this section.

(iv) List of Carcinogens:

(A) 4-Nitrobiphenyl: Cancer.

(B) alpha-Naphthylamine: Cancer; skin irritation; and acute toxicity effects.

(C) Methyl chloromethyl ether: Cancer; skin, eye and respiratory effects; acute toxicity effects; and flammability.

(D) 3,3′-Dichlorobenzidine (and its salts): Cancer and skin sensitization.

(E) bis-Chloromethyl ether: Cancer; skin, eye, and respiratory tract effects; acute toxicity effects; and flammability.

(F) beta-Naphthylamine: Cancer and acute toxicity effects.

(G) Benzidine: Cancer and acute toxicity effects.

(H) 4-Aminodiphenyl: Cancer.

(I) Ethyleneimine: Cancer; mutagenicity; skin and eye effects; liver effects; kidney effects; acute toxicity effects; and flammability.

(J) beta-Propiolactone: Cancer; skin irritation; eye effects; and acute toxicity effects.

(K) 2-Acetylaminofluorene: Cancer.

(L) 4-Dimethylaminoazo-benzene: Cancer; skin effects; and respiratory tract irritation.

(M) N-Nitrosodimethylamine: Cancer; liver effects; and acute toxicity effects.

(2) *Signs.* (i) The employer shall post entrances to regulated areas with signs bearing the legend:

DANGER
(CHEMICAL IDENTIFICATION)
MAY CAUSE CANCER
AUTHORIZED PERSONNEL ONLY

(ii) The employer shall post signs at entrances to regulated areas containing operations covered in paragraph (c)(5) of this section. The signs shall bear the legend:

DANGER
(CHEMICAL IDENTIFICATION)
MAY CAUSE CANCER
WEAR AIR-SUPPLIED HOODS, IMPERVIOUS SUITS, AND PROTECTIVE EQUIPMENT IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(iii) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (e)(2)(i) of this section:

CANCER-SUSPECT AGENT
AUTHORIZED PERSONNEL ONLY

(iv) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (e)(2)(ii) of this section:

CANCER-SUSPECT AGENT EXPOSED IN THIS AREA
IMPERVIOUS SUIT INCLUDING GLOVES, BOOTS, AND AIR-SUPPLIED HOOD REQUIRED AT ALL TIMES
AUTHORIZED PERSONNEL ONLY

(v) Appropriate signs and instructions shall be posted at the entrance to, and exit from, regulated areas, informing employees of the procedures that must be followed in entering and leaving a regulated area.

* * * * *

■ 17. Revise § 1910.1017 paragraph (l) to read as follows:

§ 1910.1017 Vinyl chloride.

* * * * *

(l) *Communication of hazards*—(1) *Hazard communication—general.* (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for vinyl chloride and polyvinyl chloride.

(ii) In classifying the hazards of vinyl chloride at least the following hazards are to be addressed: Cancer; central nervous system effects; liver effects; blood effects; and flammability.

(iii) Employers shall include vinyl chloride in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of vinyl chloride and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (j) of this section.

(2) *Signs.* (i) The employer shall post entrances to regulated areas with legible signs bearing the legend:

DANGER
VINYL CHLORIDE
MAY CAUSE CANCER
AUTHORIZED PERSONNEL ONLY

(ii) The employer shall post signs at areas containing hazardous operations or where emergencies currently exist. The signs shall be legible and bear the legend:

DANGER
VINYL CHLORIDE
MAY CAUSE CANCER
WEAR RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(iii) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (l)(2)(i) of this section:

CANCER-SUSPECT AGENT AREA
AUTHORIZED PERSONNEL ONLY

(iv) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (l)(2)(ii) of this section:

CANCER-SUSPECT AGENT IN THIS AREA
PROTECTIVE EQUIPMENT REQUIRED
AUTHORIZED PERSONNEL ONLY

(3) *Labels.* (i) In addition to the other requirements in this paragraph (l), the employer shall ensure that labels for containers of polyvinyl chloride resin waste from reactors or other waste contaminated with vinyl chloride are legible and include the following information:

CONTAMINATED WITH VINYL CHLORIDE
MAY CAUSE CANCER

(ii) Prior to June 1, 2015, employers may include the following information on labels of containers of polyvinyl chloride resin waste from reactors or other waste contaminated with vinyl chloride in lieu of the labeling requirements in paragraphs (l)(3)(i) of this section:

CONTAMINATED WITH VINYL CHLORIDE
CANCER-SUSPECT AGENT

(4) Prior to June 1, 2015, employers may include the following information for containers of polyvinyl chloride in lieu of the labeling requirements in paragraphs (l)(1)(i) of this section:

POLYVINYL CHLORIDE (OR TRADE NAME) Contains
VINYL CHLORIDE
VINYL CHLORIDE IS A CANCER-SUSPECT AGENT

(5)(i) Prior to June 1, 2015, employers may include either the following information in either paragraph (l)(5)(i) or (l)(5)(ii) of this section on containers of vinyl chloride in lieu of the labeling requirements in paragraph (l)(1)(i) of this section:

VINYL CHLORIDE
EXTREMELY FLAMMABLE GAS UNDER PRESSURE
CANCER-SUSPECT AGENT

(ii) In accordance with 49 CFR Parts 170–189, with the additional legend applied near the label or placard:

CANCER-SUSPECT AGENT

(6) No statement shall appear on or near any required sign, label, or instruction which contradicts or detracts from the effect of any required warning, information, or instruction.

* * * * *

■ 18. Revise § 1910.1018 paragraphs (j)(2)(vii) and (p) to read as follows:

§ 1910.1018 Inorganic arsenic.

* * * * *

(j) * * *

(2) * * *

(vii) Labels on contaminated protective clothing and equipment.

(A) The employer shall ensure that the containers of contaminated protective clothing and equipment in the workplace or which are to be removed from the workplace are labeled and that the labels include the following information:

DANGER: CONTAMINATED WITH INORGANIC ARSENIC. MAY CAUSE CANCER. DO NOT REMOVE DUST BY BLOWING OR SHAKING. DISPOSE OF INORGANIC ARSENIC CONTAMINATED WASH WATER IN ACCORDANCE WITH APPLICABLE LOCAL, STATE OR FEDERAL REGULATIONS.

(B) Prior to June 1, 2015, employers may include the following information on containers of protective clothing and equipment in lieu of the labeling requirements in paragraphs (j)(2)(vii) of this section:

CAUTION: Clothing contaminated with inorganic arsenic; do not remove dust by blowing or shaking. Dispose of inorganic arsenic contaminated wash water in accordance with applicable local, State or Federal regulations.

* * * * *

(p) *Communication of hazards*—(1) *Hazard communication—General.* (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for inorganic arsenic.

(ii) In classifying the hazards of inorganic arsenic at least the following hazards are to be addressed: Cancer; liver effects; skin effects; respiratory irritation; nervous system effects; and acute toxicity effects.

(iii) Employers shall include inorganic arsenic in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of inorganic arsenic and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (o) of this section.

(iv) The employer shall ensure that no statement appears on or near any sign or label required by this paragraph (p) which contradicts or detracts from the meaning of the required sign or label.

(2) *Signs.* (i) The employer shall post signs demarcating regulated areas bearing the legend:

DANGER
INORGANIC ARSENIC
MAY CAUSE CANCER
DO NOT EAT, DRINK OR SMOKE
WEAR RESPIRATORY PROTECTION IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(ii) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (p)(2)(i) of this section:

DANGER
INORGANIC ARSENIC
CANCER HAZARD
AUTHORIZED PERSONNEL ONLY
NO SMOKING OR EATING
RESPIRATOR REQUIRED

(iii) The employer shall ensure that signs required by this paragraph (p) are illuminated and cleaned as necessary so that the legend is readily visible.

(3)(i) Prior to June 1, 2015, in lieu of the labeling requirements in paragraphs (p)(1)(i) of this section, employers may apply precautionary labels to all shipping and storage containers of inorganic arsenic, and to all products containing inorganic arsenic, bearing the following legend:

DANGER
CONTAINS INORGANIC ARSENIC
CANCER HAZARD
HARMFUL IF INHALED OR SWALLOWED
USE ONLY WITH ADEQUATE VENTILATION OR RESPIRATORY PROTECTION

(ii) Labels are not required when the inorganic arsenic in the product is bound in such a manner so as to make unlikely the possibility of airborne exposure to inorganic arsenic. (Possible examples of products not requiring labels are semiconductors, light emitting diodes and glass.)

* * * * *

■ 19. Amend § 1910.1025 as follows:

■ A. Revise paragraph (g)(2)(vii) and paragraph (m);

■ B. Revise Appendix B to § 1910.1025, paragraph xi.

The revisions read as follows:

§ 1910.1025 Lead.

* * * * *

(g) * * *

(2) * * *

(vii) Labeling of contaminated protective clothing and equipment.

(A) The employer shall ensure that labels of bags or containers of contaminated protective clothing and equipment include the following information:

DANGER: CLOTHING AND EQUIPMENT CONTAMINATED WITH LEAD. MAY DAMAGE FERTILITY OR THE UNBORN CHILD. CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM. DO NOT EAT, DRINK OR SMOKE WHEN HANDLING. DO NOT REMOVE DUST BY BLOWING OR SHAKING. DISPOSE OF LEAD CONTAMINATED WASH WATER IN ACCORDANCE WITH APPLICABLE LOCAL, STATE, OR FEDERAL REGULATIONS.

(B) Prior to June 1, 2015, employers may include the following information on bags or containers of contaminated protective clothing and equipment in lieu of the labeling requirements in paragraphs (g)(2)(vii)(A) of this section:

CAUTION: CLOTHING CONTAMINATED WITH LEAD. DO NOT REMOVE DUST BY BLOWING OR SHAKING. DISPOSE OF LEAD CONTAMINATED WASH WATER IN ACCORDANCE WITH APPLICABLE LOCAL, STATE, OR FEDERAL REGULATIONS.

* * * * *

(m) *Communication of hazards*—(1) *Hazard communication—general.* (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for lead.

(ii) In classifying the hazards of lead at least the following hazards are to be addressed: Reproductive/developmental toxicity; central nervous system effects; kidney effects; blood effects; and acute toxicity effects.

(iii) Employers shall include lead in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of lead and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (l) of this section.

(2) *Signs.* (i) The employer shall post the following warning signs in each work area where the PEL is exceeded:

DANGER
LEAD
MAY DAMAGE FERTILITY OR THE UNBORN CHILD
CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM
DO NOT EAT, DRINK OR SMOKE IN THIS AREA

(ii) The employer shall ensure that no statement appears on or near any sign required by this paragraph (m)(2) which contradicts or detracts from the meaning of the required sign.

(iii) The employer shall ensure that signs required by this paragraph (m)(2) are illuminated and cleaned as necessary so that the legend is readily visible.

(iv) The employer may use signs required by other statutes, regulations, or ordinances in addition to, or in combination with, signs required by this paragraph (m)(2).

(v) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (m)(2)(ii) of this section:

WARNING
LEAD WORK AREA
POISON
NO SMOKING OR EATING

* * * * *

Appendix B to § 1910.1025—Employee Standard Summary

* * * * *

xi. SIGNS—PARAGRAPH (m)

The standard requires that the following warning sign be posted in the work areas when the exposure to lead exceeds the PEL:

DANGER
LEAD
MAY DAMAGE FERTILITY OR THE UNBORN CHILD
CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM
DO NOT EAT, DRINK OR SMOKE IN THIS AREA

However, prior to June 1, 2016, employers may use the following legend in lieu of that specified above:

WARNING
LEAD WORK AREA
POISON
NO SMOKING OR EATING

* * * * *

■ 20. Revise § 1910.1026, paragraphs (h)(2)(iv) and (l)(1) to read as follows:

§ 1910.1026 Chromium (VI).

* * * * *

(h) * * *

(2) * * *

(iv) The employer shall ensure that bags or containers of contaminated protective clothing or equipment that are removed from change rooms for laundering, cleaning, maintenance, or disposal are labeled in accordance with the requirements of the Hazard Communication Standard, § 1910.1200.

* * * * *

(l) * * *

(1) *Hazard communication—general* (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for chromium (VI).

(ii) In classifying the hazards of chromium (VI) at least the following hazards are to be addressed: Cancer, eye irritation, and skin sensitization.

(iii) Employers shall include chromium (VI) in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of chromium (VI) and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (l)(2) of this section.

* * * * *

■ 21. Revise § 1910.1027 paragraphs (k)(7), (m)(1), (m)(2), and (m)(3) to read as follows:

§ 1910.1027 Cadmium.

* * * * *

(k) * * *

(7) Waste, scrap, debris, bags, containers, personal protective equipment, and clothing contaminated with cadmium and consigned for disposal shall be collected and disposed of in sealed impermeable bags or other closed, impermeable containers. These bags and containers shall be labeled in accordance with paragraph (m) of this section.

* * * * *

(m) * * *

(1) *Hazard communication.—general.* (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for cadmium.

(ii) In classifying the hazards of cadmium at least the following hazards are to be addressed: Cancer; lung effects; kidney effects; and acute toxicity effects.

(iii) Employers shall include cadmium in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of cadmium and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (m)(4) of this section.

(2) *Warning signs.* (i) Warning signs shall be provided and displayed in regulated areas. In addition, warning signs shall be posted at all approaches to regulated areas so that an employee may read the signs and take necessary protective steps before entering the area.

(ii) Warning signs required by paragraph (m)(2)(i) of this section shall bear the following legend:

DANGER
CADMIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS AND KIDNEYS
WEAR RESPIRATORY PROTECTION IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(iii) The employer shall ensure that signs required by this paragraph (m)(2) are illuminated, cleaned, and maintained as necessary so that the legend is readily visible.

(iv) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (m)(2)(ii) of this section:

DANGER
CADMIUM
CANCER HAZARD
CAN CAUSE LUNG AND KIDNEY DISEASE
AUTHORIZED PERSONNEL ONLY
RESPIRATORS REQUIRED IN THIS AREA

(3) *Warning labels.* (i) Shipping and storage containers containing cadmium or cadmium compounds shall bear appropriate warning labels, as specified in paragraph (m)(1) of this section.

(ii) The warning labels for containers of contaminated protective clothing, equipment, waste, scrap, or debris shall include at least the following information:

DANGER
CONTAINS CADMIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS AND KIDNEYS
AVOID CREATING DUST

(iii) Prior to June 1, 2015, employers may include the following information on shipping and storage containers containing cadmium, cadmium compounds, or cadmium contaminated clothing, equipment, waste, scrap, or debris in lieu of the labeling requirements specified in paragraphs (m)(1)(i) and (m)(3)(ii) of this section:

DANGER
CONTAINS CADMIUM
CANCER HAZARD
AVOID CREATING DUST
CAN CAUSE LUNG AND KIDNEY DISEASE

(iv) Where feasible, installed cadmium products shall have a visible label or other indication that cadmium is present.

* * * * *

■ 22. Revise § 1910.1028, paragraph (j) heading, and paragraphs (j)(1) and (j)(2) to read as follows:

§ 1910.1028 Benzene.

* * * * *

(j) *Communication of hazards*—(1) *Hazard communication—general.* (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for benzene.

(ii) In classifying the hazards of benzene at least the following hazards are to be addressed: Cancer; central nervous system effects; blood effects; aspiration; skin, eye, and respiratory tract irritation; and flammability.

(iii) Employers shall include benzene in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of benzene and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (j)(3) of this section.

(2) *Warning signs and labels.* (i)The employer shall post signs at entrances to regulated areas. The signs shall bear the following legend:

DANGER
BENZENE
MAY CAUSE CANCER
HIGHLY FLAMMABLE LIQUID AND VAPOR
DO NOT SMOKE
WEAR RESPIRATORY PROTECTION IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(ii) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (j)(2)(i) of this section:

DANGER
BENZENE
CANCER HAZARD
FLAMMABLE—NO SMOKING
AUTHORIZED PERSONNEL ONLY
RESPIRATOR REQUIRED

(iii) The employer shall ensure that labels or other appropriate forms of warning are provided for containers of benzene within the workplace. There is no requirement to label pipes. The labels shall comply with the requirements of paragraph (j)(1) of this section and § 1910.1200(f).

(iv) Prior to June 1, 2015, employers shall include the following legend or similar language on the labels or other appropriate forms of warning:

DANGER
CONTAINS BENZENE
CANCER HAZARD

* * * * *

■ 23. Revise § 1910.1029 paragraph (l) heading, and paragraphs (l)(1) through (l)(3) to read as follows:

§ 1910.1029 Coke oven emissions.

* * * * *

(l) *Communication of hazards*—(1) *Hazard communication—general.* The employer shall include coke oven emissions in the program established to comply with the Hazard Communication Standard (HCS) (§ 1910.1200). The employer shall ensure that each employee has access to labels on containers of chemicals and substances associated with coke oven processes and to safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (k) of this section. The employer shall ensure that at least the following hazard is addressed: Cancer.

(2) *Signs.* (i) The employer shall post signs in the regulated area bearing the legend:

DANGER
COKE OVEN EMISSIONS
MAY CAUSE CANCER
DO NOT EAT, DRINK OR SMOKE
WEAR RESPIRATORY PROTECTION IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(ii) In addition, the employer shall post signs in the areas where the permissible exposure limit is exceeded bearing the legend:

WEAR RESPIRATORY PROTECTION IN THIS AREA

(iii) The employer shall ensure that no statement appears on or near any sign required by this paragraph (l) which contradicts or detracts from the effects of the required sign.

(iv) The employer shall ensure that signs required by this paragraph (l)(2) are illuminated and cleaned as necessary so that the legend is readily visible.

(v) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (l)(2)(i) of this section:

DANGER
CANCER HAZARD
AUTHORIZED PERSONNEL ONLY
NO SMOKING OR EATING

(vi) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (l)(2)(ii) of this section:

DANGER
RESPIRATOR REQUIRED

(3) *Labels.* (i) The employer shall ensure that labels of containers of contaminated protective clothing and equipment include the following information:

CONTAMINATED WITH COKE EMISSIONS
MAY CAUSE CANCER
DO NOT REMOVE DUST BY BLOWING OR SHAKING

(ii) Prior to June 1, 2015, employers may include the following information on contaminated protective clothing and equipment in lieu of the labeling requirements in paragraph (l)(3)(i) of this section:

CAUTION
CLOTHING CONTAMINATED WITH COKE EMISSIONS
DO NOT REMOVE DUST BY BLOWING OR SHAKING

* * * * *

■ 24. Revise § 1910.1043 paragraph (j) to read as follows:

§ 1910.1043 Cotton dust.

* * * * *

(j) *Signs.* (1) The employer shall post the following warning sign in each work area where the permissible exposure limit for cotton dust is exceeded:

DANGER
COTTON DUST
CAUSES DAMAGE TO LUNGS
(BYSSINOSIS)
WEAR RESPIRATORY PROTECTION IN THIS AREA

(2) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (j)(1) of this section:

WARNING
COTTON DUST WORK AREA
MAY CAUSE ACUTE OR DELAYED
LUNG INJURY
(BYSSINOSIS)
RESPIRATORS
REQUIRED IN THIS AREA

* * * * *

■ 25. Revise § 1910.1044 paragraphs (j)(2)(v), (k)(1)(iii)(*b*), and paragraph (o) to read as follows:

§ 1910.1044 1,2-dibromo-3-chloropropane.

* * * * *

(j) * * *

(2) * * *

(v) Containers of DBCP-contaminated protective devices or work clothing which are to be taken out of change rooms or the workplace for cleaning, maintenance or disposal shall bear labels with the following information: CONTAMINATED WITH 1,2–Dibromo-3-chloropropane (DBCP), MAY CAUSE CANCER.

* * * * *

(k) * * *

(1) * * *

(iii) * * *

(*b*) Portable vacuum units used to collect DBCP may not be used for other cleaning purposes and shall be labeled as prescribed by paragraph (j)(2)(v) of this section.

* * * * *

(o) *Communication of hazards*—(1) *Hazard communication—general.* (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for DBCP.

(ii) In classifying the hazards of DBCP at least the following hazards are to be addressed: Cancer; reproductive effects; liver effects; kidney effects; central nervous system effects; skin, eye and respiratory tract irritation; and acute toxicity effects.

(iii) Employers shall include DBCP in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of DBCP and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (n) of this section.

(iv) The employer shall ensure that no statement appears on or near any sign or label required by this paragraph (o) which contradicts or detracts from the meaning of the required sign or label.

(2) *Signs.* (i) The employer shall post signs to clearly indicate all regulated areas. These signs shall bear the legend:

DANGER
1,2-Dibromo-3-chloropropane
MAY CAUSE CANCER
WEAR RESPIRATORY PROTECTION IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(ii) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (o)(2) of this section:

DANGER
1,2-Dibromo-3-chloropropane
(Insert appropriate trade or common names)
CANCER HAZARD
AUTHORIZED PERSONNEL ONLY
RESPIRATOR REQUIRED

(3) *Labels.* (i) Where DBCP or products containing DBCP are sold, distributed or otherwise leave the employer's workplace bearing appropriate labels required by EPA under the regulations in 40 CFR Part 162, the labels required by this paragraph (o)(3) need not be affixed.

(ii) The employer shall ensure that the precautionary labels required by this paragraph (o)(3) are readily visible and legible.

(iii) Prior to June 1, 2015, employers may include the following information on containers of DBCP or products containing DBCP, DBCP-contaminated protective devices or work clothing or DBCP-contaminated portable vacuums in lieu of the labeling requirements in paragraphs (j)(2)(v), (k)(l)(iii)(b) and (o)(1)(i) of this section:

DANGER
1,2-Dibromo-3-chloropropane
CANCER HAZARD

* * * * *

■ 26. Revise § 1910.1045 paragraph (p) to read as follows:

§ 1910.1045 Acrylonitrile.

* * * * *

(p) *Communication of hazards*—(1) *Hazard communication—general.* (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for AN and AN-based materials not exempted under paragraph (a)(2) of this section.

(ii) In classifying the hazards of AN and AN-based materials at least the following hazards are to be addressed: Cancer; central nervous system effects; liver effects; skin sensitization; skin, respiratory, and eye irritation; acute toxicity effects; and flammability.

(iii) Employers shall include AN and AN-based materials in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of AN and AN-based materials and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (o) of this section.

(iv) The employer shall ensure that no statement appears on or near any sign or label required by this paragraph (p) that contradicts or detracts from the required sign or label.

(2) *Signs.* (i) The employer shall post signs to clearly indicate all workplaces where AN concentrations exceed the permissible exposure limits. The signs shall bear the following legend:

DANGER
ACRYLONITRILE (AN)
MAY CAUSE CANCER
RESPIRATORY PROTECTION MAY BE REQURED IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(ii) The employer shall ensure that signs required by this paragraph (p)(2) are illuminated and cleaned as necessary so that the legend is readily visible.

(iii) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (p)(2)(i) of this section:

DANGER
ACRYLONITRILE (AN)
CANCER HAZARD
AUTHORIZED PERSONNEL ONLY
RESPIRATORS MAY BE REQUIRED

(3) *Labels.* (i) The employer shall ensure that precautionary labels are in compliance with paragraph (p)(1)(i) of this section and are affixed to all containers of liquid AN and AN-based materials not exempted under paragraph (a)(2) of this section. The employer shall ensure that the labels remain affixed when the materials are sold, distributed, or otherwise leave the employer's workplace.

(ii) Prior to June 1, 2015, employers may include the following information on precautionary labels required by this paragraph (p)(3) in lieu of the labeling requirements in paragraph (p)(1) of this section:

DANGER
CONTAINS ACRYLONITRILE (AN)
CANCER HAZARD

(iii) The employer shall ensure that the precautionary labels required by this paragraph (p)(3) are readily visible and legible.

* * * * *

■ 27. Revise § 1910.1047 paragraph (j) heading, and paragraphs (j)(1) and (j)(2) to read as follows:

§ 1910.1047 Ethylene oxide.

* * * * *

(j) *Communication of hazards*—(1) *Hazard communication—general.* (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for EtO.

(ii) In classifying the hazards of EtO at least the following hazards are to be addressed: Cancer; reproductive effects; mutagenicity; central nervous system; skin sensitization; skin, eye and respiratory tract irritation; acute toxicity effects; and flammability.

(iii) Employers shall include EtO in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of EtO and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (j)(3) of this section.

(2) *Signs and labels*—(i) *Signs.* (A) The employer shall post and maintain legible signs demarcating regulated areas and entrances or access ways to regulated areas that bear the following legend:

DANGER
ETHYLENE OXIDE
MAY CAUSE CANCER
MAY DAMAGE FERTILITY OR THE UNBORN CHILD
RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING MAY BE REQUIRED IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(B) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (j)(2)(i)(A) of this section:

DANGER
ETHYLENE OXIDE
CANCER HAZARD AND REPRODUCTIVE HAZARD
AUTHORIZED PERSONNEL ONLY
RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN THIS AREA

(ii) *Labels.* (A) The employer shall ensure that labels are affixed to all containers of EtO whose contents are capable of causing employee exposure at or above the action level or whose contents may reasonably be foreseen to cause employee exposure above the excursion limit, and that the labels remain affixed when the containers of EtO leave the workplace. For the purposes of this paragraph (j)(2)(ii), reaction vessels, storage tanks, and pipes or piping systems are not considered to be containers.

(B) Prior to June 1, 2015, employers may include the following information on containers of EtO in lieu of the labeling requirements in paragraph (j)(1)(i) of this section:

(*1*) DANGER
CONTAINS ETHYLENE OXIDE
CANCER HAZARD AND REPRODUCTIVE HAZARD;
(*2*) A warning statement against breathing airborne concentrations of EtO.

(C) The labeling requirements under this section do not apply where EtO is used as a pesticide, as such term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), when it is labeled pursuant to that Act and regulations issued under that Act by the Environmental Protection Agency.

* * * * *

■ 28. Revise § 1910.1048 paragraphs (e)(1), (h)(2)(ii), (j)(4) and (m) to read as follows:

§ 1910.1048 Formaldehyde.

* * * * *

(e) * * *

(1) *Signs.* (i) The employer shall establish regulated areas where the concentration of airborne formaldehyde exceeds either the TWA or the STEL and post all entrances and access ways with signs bearing the following legend:

DANGER
FORMALDEHYDE
MAY CAUSE CANCER
CAUSES SKIN, EYE, AND RESPIRATORY IRRITATION
AUTHORIZED PERSONNEL ONLY

(ii) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (e)(1)(i) of this section:

DANGER
FORMALDEHYDE
IRRITANT AND POTENTIAL CANCER HAZARD
AUTHORIZED PERSONNEL ONLY

* * * * *

(h) * * *

(2) * * *

(ii) When formaldehyde-contaminated clothing and equipment is ventilated, the employer shall establish storage areas so that employee exposure is minimized.

(A) *Signs.* Storage areas for contaminated clothing and equipment shall have signs bearing the following legend:

DANGER
FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT
MAY CAUSE CANCER
CAUSES SKIN, EYE AND RESPIRATORY IRRITATION
DO NOT BREATHE VAPOR
DO NOT GET ON SKIN

(B) *Labels.* The employer shall ensure containers for contaminated clothing and equipment are labeled consistent with the Hazard Communication Standard, § 1910.1200, and shall, as a minimum, include the following:

DANGER
FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT
MAY CAUSE CANCER
CAUSES SKIN, EYE, AND RESPIRATORY IRRITATION
DO NOT BREATHE VAPOR
DO NOT GET ON SKIN

(C) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (h)(2)(ii)(A) of this section:

DANGER
FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT
AVOID INHALATION AND SKIN CONTACT

(D) Prior to June 1, 2015, employers may include the following information on containers of protective clothing and equipment in lieu of the labeling requirements in paragraphs (h)(2)(ii)(B) of this section:

DANGER
FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT
AVOID INHALATION AND SKIN CONTACT

* * * * *

(j) * * *

(4) Formaldehyde-contaminated waste and debris resulting from leaks or spills shall be placed for disposal in sealed containers bearing a label warning of formaldehyde's presence and of the hazards associated with formaldehyde. The employer shall ensure that the labels are in accordance with paragraph (m) of this section.

* * * * *

(m) *Communication of hazards.* (1) *Hazard communication—General.* (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for formaldehyde.

(ii) In classifying the hazards of formaldehyde at least the following hazards are to be addressed: Cancer; skin and respiratory sensitization; eye, skin and respiratory tract irritation; acute toxicity effects; and flammability.

(iii) Employers shall include formaldehyde in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of formaldehyde and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (n) of this section.

(iv) Paragraphs (m)(1)(i), (m)(1)(ii), and (m)(1)(iii) of this section apply to chemicals associated with formaldehyde gas, all mixtures or solutions composed of greater than 0.1 percent formaldehyde, and materials capable of releasing formaldehyde into the air at concentrations reaching or exceeding 0.1 ppm.

(v) In making the determinations of anticipated levels of formaldehyde release, the employer may rely on objective data indicating the extent of potential formaldehyde release under reasonably foreseeable conditions of use.

(2)(i) In addition to the requirements in paragraphs (m)(1) through (m)(1)(iv) of this section, for materials listed in paragraph (m)(1)(iv) capable of releasing formaldehyde at levels above 0.5 ppm, labels shall appropriately address all hazards as defined in paragraph (d) of § 1910.1200 and Appendices A and B to § 1910.1200, including cancer and respiratory sensitization, and shall contain the hazard statement ''May Cause Cancer.''

(ii) As a minimum, for all materials listed in paragraph (m)(1)(i) and (iv) of this section capable of releasing formaldehyde at levels of 0.1 ppm to 0.5 ppm, labels shall identify that the product contains formaldehyde; list the name and address of the responsible party; and state that physical and health hazard information is readily available from the employer and from safety data sheets.

(iii) Prior to June 1, 2015, employers may include the phrase ''Potential Cancer Hazard'' in lieu of ''May Cause Cancer'' as specified in paragraph (m)(2)(i) of this section.

* * * * *

■ 29. Amend § 1910.1050 as follows:
■ A. Revise the heading of paragraph (k);
■ B. Revise paragraphs (k)(1) and (k)(2);
■ C. Redesignate paragraphs (k)(3) and (k)(4) as (k)(4) and (k)(5);
■ D. Add new paragraph (k)(3).

The revisions and additions read as follows:

§ 1910.1050 Methylenedianiline.

* * * * *

(k) *Communication of hazards*—(1) *Hazard communication—general.*

(i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for MDA.

(ii) In classifying the hazards of MDA at least the following hazards are to be addressed: Cancer; liver effects; and skin sensitization.

(iii) Employers shall include MDA in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of MDA and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (k)(4) of this section.

(2) *Signs and labels*—(i) *Signs.* (A) The employer shall post and maintain legible signs demarcating regulated areas and entrances or access ways to regulated areas that bear the following legend:

DANGER
MDA
MAY CAUSE CANCER
CAUSES DAMAGE TO THE LIVER
RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING MAY BE REQUIRED IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(B) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (k)(2)(i)(A) of this section:

DANGER
MDA
MAY CAUSE CANCER
LIVER TOXIN
AUTHORIZED PERSONNEL ONLY
RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN THIS AREA

(ii) *Labels.* Prior to June 1, 2015, employers may include the following information workplace labels in lieu of the labeling requirements in paragraph (k)(1) of this section:

(A) For pure MDA:

DANGER
CONTAINS MDA
MAY CAUSE CANCER
LIVER TOXIN

(B) For mixtures containing MDA:

DANGER
CONTAINS MDA
CONTAINS MATERIALS WHICH MAY CAUSE CANCER
LIVER TOXIN

(3) *Safety data sheets (SDS).* In meeting the obligation to provide safety data sheets, employers shall make appropriate use of the information found in Appendices A and B to § 1910.1050.

* * * * *

■ 30. Revise § 1910.1051 paragraph (l)(1) to read as follows:

§ 1910.1051 1,3-Butadiene.

* * * * *

(l) * * *

(1) *Hazard communication—general.* (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for BD.

(ii) In classifying the hazards of BD at least the following hazards are to be addressed: Cancer; eye and respiratory tract irritation; center nervous system effects; and flammability.

(iii) Employers shall include BD in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of BD and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (l)(2) of this section.

* * * * *

■ 31. Amend § 1910.1052 as follows:
■ A. Revise paragraph (k);
■ B. Remove the phrase ''material safety data sheets (MSDS)'' and add in its place the phrase ''safety data sheets (SDS)'' where it appears in Appendix A, Paragraph X.E.

The revisions read as follows:

§ 1910.1052 Methylene chloride.

* * * * *

(k) *Hazard communication.*—(1) *Hazard communication—general.* (i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for MC.

(ii) In classifying the hazards of MC at least the following hazards are to be addressed: Cancer, cardiac effects (including elevation of carboxyhemoglobin), central nervous system effects, liver effects, and skin and eye irritation.

(iii) Employers shall include MC in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of MC and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (l) of this section.

(2) [Reserved]

* * * * *

■ 32. Amend § 1910.1200 as follows:
■ A. Remove the word ''material'' before the word ''safety'' in the phrase ''material safety data sheet'' or ''material safety data sheets'' wherever they appear in paragraphs (b)(3)(ii), (b)(4)(ii), (e)(1) introductory text, (e)(2)(i), (g)(4), (g)(6)(i) through (iv), (g)(7)(i) through (vii), (g)(9), (g)(11), (h)(1), (h)(2)(iii), and (i)(1)(ii);
■ B. Remove the word ''Material'' before the word ''safety'' in the phrase ''Material safety data sheets'' wherever they appear in paragraphs (g)(10) and (g)(11). In paragraphs (g)(10) and (g)(11) in the first sentence, capitalize the first letter of the word ''safety''.
■ C. Remove the following definitions in paragraph (c) *Combustible liquid, Compressed gas, Explosive, Flammable, Flashpoint, Hazard warning, Identity, Material safety data sheet (MSDS), Organic peroxide, Oxidizer, Pyrophoric, Unstable (reactive),* and *Water-reactive;*
■ D. Revise the following definitions in paragraph (c) *Chemical, Chemical name, Health hazard, Label, Mixture, Physical hazard,* and *Trade secret;*
■ E. Redesignate the definition of the term *Hazardous chemical* in alphabetical order in paragraph (c) and revise the definition;
■ F. Add the following definitions in alphabetical order in paragraph (c) *Classification, Hazard category, Hazard class, Hazard not otherwise classified, Hazard statement, Label elements, Pictogram, Precautionary statement, Product identifier, Pyrophoric gas, Safety Data Sheet (SDS), Signal word, Simple asphyxiant,* and *Substance;*
■ G. Remove the following phrases: ''in'' before the phrase ''in their work area(s)''

in paragraph (g)(10); ''specific chemical identity'' in paragraph (i)(10)(ii); and ''or percentage of mixture'' in paragraph (i)(13);

■ H. Revise paragraphs (a), (b)(1), (b)(3)(iv), (b)(5)(iv), (b)(6)(ii), paragraph (d) (heading), paragraphs (d)(1) through (d)(3), (e)(1)(i), (f), paragraph (g) (heading), paragraphs (g)(1), (g)(2), (g)(3), (g)(5), (g)(8), (g)(11), (h)(1), (h)(3)(ii), (h)(3)(iv), (i)(1) introductory text, (i)(1)(iii) and (iv), (i)(2), (i)(3) introductory text, (i)(3)(iii), (i)(7) introductory text, (i)(7)(iii), (i)(7)(v), (i)(9)(i), (i)(10), (i)(11), and (j).

■ I. Remove Appendices A, B, and E to § 1910.1200.

■ J. Redesignate Appendix D to § 1910.1200 as Appendix E to § 1910.1200.

■ K. Add new Appendices A, B, C, D and F to § 1910.1200.

The revisions and additions read as follows:

§ 1910.1200 Hazard communication.

(a) *Purpose.* (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 Labelling of Chemicals (GHS), Revision 3. 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.

(2) This occupational safety and health standard is intended to address comprehensively the issue of classifying the potential hazards of chemicals, and communicating information concerning hazards and appropriate protective measures to employees, and to preempt any legislative or regulatory enactments of a state, or political subdivision of a state, pertaining to this subject. Classifying the potential hazards of chemicals and communicating information concerning hazards and appropriate protective measures to employees, may include, for example, but is not limited to, provisions for: developing and maintaining a written hazard communication program for the workplace, including lists of hazardous chemicals present; labeling of containers of chemicals in the workplace, as well as of containers of chemicals being shipped to other workplaces; preparation and distribution of safety data sheets to employees and downstream employers; and development and implementation of employee training programs regarding hazards of chemicals and protective measures. Under section 18 of the Act, no state or political subdivision of a state may adopt or enforce any requirement relating to the issue addressed by this Federal standard, except pursuant to a Federally-approved state plan.

(b) * * *

(1) This section requires chemical manufacturers or importers to classify the hazards of chemicals which they produce or import, and 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, and information and training. In addition, this section requires distributors to transmit the required information to employers. (Employers who do not produce or import chemicals need only focus on those parts of this rule that deal with establishing a workplace program and communicating information to their workers.)

* * * * *

(3) * * *

(iv) Laboratory employers that ship hazardous chemicals are considered to be either a chemical manufacturer or a distributor under this rule, and thus must ensure that any containers of hazardous chemicals leaving the laboratory are labeled in accordance with paragraph (f) of this section, and that a safety data sheet is provided to distributors and other employers in accordance with paragraphs (g)(6) and (g)(7) of this section.

* * * * *

(5) * * *

(iv) Any distilled spirits (beverage alcohols), wine, or malt beverage intended for nonindustrial use, as such terms are defined in the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) and regulations issued under that Act, when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Bureau of Alcohol, Tobacco, Firearms and Explosives;

* * * * *

(6) * * *

(ii) Any hazardous substance as such term is defined by the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) (42 U.S.C. 9601 et seq.) when the hazardous substance is the focus of remedial or removal action being conducted under CERCLA in accordance with Environmental Protection Agency regulations.

* * * * *

(c) * * *

Chemical means any substance, or mixture of substances.

* * * * *

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.

* * * * *

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.

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.

Hazardous chemical means any chemical which is classified as a physical hazard or a health hazard, a simple asphyxiant, combustible dust, pyrophoric gas, or hazard not otherwise classified.

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.

* * * * *

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.

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, aerosols, liquids, or solids); oxidizer (liquid, solid or gas); self-reactive; pyrophoric (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; or in contact with water emits flammable gas. *See* Appendix B to § 1910.1200—Physical Hazard Criteria.

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.

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.

* * * * *

Pyrophoric gas means 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.

* * * * *

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.

* * * * *

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.

* * * * *

(d) *Hazard classification.* (1) Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported by them to classify the chemicals in accordance with this section. For each chemical, the chemical manufacturer or importer shall determine the hazard classes, and, where appropriate, the category of each class that apply to the chemical being classified. Employers are not required to classify chemicals unless they choose not to rely on the classification performed by the chemical manufacturer or importer for the chemical to satisfy this requirement.

(2) Chemical manufacturers, importers or employers classifying chemicals shall identify and consider the full range of available scientific literature and other evidence concerning the potential hazards. There is no requirement to test the chemical to determine how to classify its hazards. Appendix A to § 1910.1200 shall be consulted for classification of health hazards, and Appendix B to § 1910.1200 shall be consulted for the classification of physical hazards.

(3) *Mixtures.* (i) Chemical manufacturers, importers, or employers evaluating chemicals shall follow the procedures described in Appendices A and B to § 1910.1200 to classify the hazards of the chemicals, including determinations regarding when mixtures of the classified chemicals are covered by this section.

(ii) When classifying mixtures they produce or import, chemical manufacturers and importers of mixtures may rely on the information provided on the current safety data sheets of the individual ingredients, except where the chemical manufacturer or importer knows, or in the exercise of reasonable diligence should know, that the safety data sheet misstates or omits information required by this section.

* * * * *

(e) * * *

(1) * * *

(i) A list of the hazardous chemicals known to be present using a product identifier that is referenced on the appropriate safety data sheet (the list may be compiled for the workplace as a whole or for individual work areas); and,

* * * * *

(f) *Labels and other forms of warning*—(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 do not have to be addressed on the container. Where the chemical manufacturer or importer is required to label, tag or mark the following information shall be provided:

(i) Product identifier;

(ii) Signal word;

(iii) Hazard statement(s);

(iv) Pictogram(s);

(v) Precautionary statement(s); and,

(vi) Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party.

(2) The chemical manufacturer, importer, or distributor shall ensure that the information provided under paragraphs (f)(1)(i) through (v) of this section is in accordance with Appendix

C to § 1910.1200, for each hazard class and associated hazard category for the hazardous chemical, prominently displayed, and in English (other languages may also be included if appropriate).

(3) The chemical manufacturer, importer, or distributor shall ensure that the information provided under paragraphs (f)(1)(ii) through (iv) of this section is located together on the label, tag, or mark.

(4*) Solid materials.* (i) For solid metal (such as a steel beam or a metal casting), solid wood, or plastic items that are not exempted as articles due to their downstream use, or shipments of whole grain, the required label may be transmitted to the customer at the time of the initial shipment, and need not be included with subsequent shipments to the same employer unless the information on the label changes;

(ii) The label may be transmitted with the initial shipment itself, or with the safety data sheet that is to be provided prior to or at the time of the first shipment; and,

(iii) This exception to requiring labels on every container of hazardous chemicals is only for the solid material itself, and does not apply to hazardous chemicals used in conjunction with, or known to be present with, the material and to which employees handling the items in transit may be exposed (for example, cutting fluids or pesticides in grains).

(5) Chemical manufacturers, importers, or distributors shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked in accordance with this section in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act (49 U.S.C. 1801 *et seq.*) and regulations issued under that Act by the Department of Transportation.

(6) Workplace labeling. Except as provided in paragraphs (f)(7) and (f)(8) of this section, the employer shall ensure that each container of hazardous chemicals in the workplace is labeled, tagged or marked with either:

(i) The information specified under paragraphs (f)(1)(i) through (v) of this section for labels on shipped containers; or,

(ii) Product identifier and words, pictures, symbols, or combination thereof, which provide at least general information regarding the hazards of the chemicals, and which, in conjunction with the other information immediately available to employees under the hazard communication program, will provide employees with the specific information regarding the physical and health hazards of the hazardous chemical.

(7) The employer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys the information required by paragraph (f)(6) of this section to be on a label. The employer shall ensure the written materials are readily accessible to the employees in their work area throughout each work shift.

(8) The employer is not required to label portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer. For purposes of this section, drugs which are dispensed by a pharmacy to a health care provider for direct administration to a patient are exempted from labeling.

(9) The employer shall not remove or deface existing labels on incoming containers of hazardous chemicals, unless the container is immediately marked with the required information.

(10) The employer shall ensure that workplace labels or other forms of warning are legible, in English, and prominently displayed on the container, or readily available in the work area throughout each work shift. Employers having employees who speak other languages may add the information in their language to the material presented, as long as the information is presented in English as well.

(11) Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within six months of becoming aware of the new information, and shall ensure that labels on containers of hazardous chemicals shipped after that time contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.

(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 preparing the safety data sheet shall ensure that it 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 § 1910.1200—Safety Data Sheets, 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) 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.

(3) If no relevant information is found for any sub-heading within a section on the safety data sheet, the chemical manufacturer, importer or employer preparing the safety data sheet shall mark it to indicate that no applicable information was found.

* * * * *

(5) The chemical manufacturer, importer or employer preparing the safety data sheet shall ensure that the information provided accurately reflects the scientific evidence used in making the hazard classification. If the chemical manufacturer, importer or employer preparing the safety data sheet becomes newly aware of any significant information regarding the hazards of a chemical, or ways to protect against the hazards, this new information shall be added to the safety data sheet within three months. If the chemical is not

currently being produced or imported, the chemical manufacturer or importer shall add the information to the safety data sheet before the chemical is introduced into the workplace again.

* * * * *

(8) The employer shall maintain in the workplace copies of the required safety data sheets for each hazardous chemical, and shall ensure that they are readily accessible during each work shift to employees when they are in their work area(s). (Electronic access and other alternatives to maintaining paper copies of the safety data sheets are permitted as long as no barriers to immediate employee access in each workplace are created by such options.)

* * * * *

(11) Safety data sheets shall also be made readily available, upon request, to designated representatives, the Assistant Secretary, and the Director, in accordance with the requirements of § 1910.1020(e).

(h) * * *

(1) Employers shall provide employees with effective information and training on hazardous chemicals in their work area at the time of their initial assignment, and whenever a new chemical hazard the employees have not previously been trained about is introduced into their work area. Information and training may be designed to cover categories of hazards (e.g., flammability, carcinogenicity) or specific chemicals. Chemical-specific information must always be available through labels and safety data sheets.

* * * * *

(3) * * *

(ii) The physical, health, simple asphyxiation, combustible dust, and pyrophoric gas hazards, as well as hazards not otherwise classified, of the chemicals in the work area;

* * * * *

(iv) The details of the hazard communication program developed by the employer, including an explanation of the labels received on shipped containers and the workplace labeling system used by their employer; the safety data sheet, including the order of information and how employees can obtain and use the appropriate hazard information.

(i) * * *

(1) The chemical manufacturer, importer, or employer may withhold the specific chemical identity, including the chemical name, other specific identification of a hazardous chemical, or the exact percentage (concentration) of the substance in a mixture, from the safety data sheet, provided that:

* * * * *

(iii) The safety data sheet indicates that the specific chemical identity and/or percentage of composition is being withheld as a trade secret; and,

(iv) The specific chemical identity and percentage is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of this paragraph (i).

(2) Where a treating physician or nurse determines that a medical emergency exists and the specific chemical identity and/or specific percentage of composition 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 physician or nurse, 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 percentage composition, otherwise permitted to be withheld under paragraph (i)(1) of this section, 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:

* * * * *

(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:

* * * * *

(7) If the chemical manufacturer, importer, or employer denies a written request for disclosure of a specific chemical identity or percentage composition, the denial must:

* * * * *

(iii) Include evidence to support the claim that the specific chemical identity or percent of composition is a trade secret;

* * * * *

(v) Explain in detail how alternative information may satisfy the specific medical or occupational health need without revealing the trade secret.

* * * * *

(9) * * *

(i) The chemical manufacturer, importer, or employer has supported the claim that the specific chemical identity or percentage composition is a trade secret;

* * * * *

(10) * * *

(i) If OSHA determines that the specific chemical identity or percentage composition requested under paragraph (i)(3) of this section is not a ''bona fide'' trade secret, or that it is a trade secret, but the requesting health professional, employee, or designated representative has a legitimate medical or occupational health need for the information, has executed a written confidentiality agreement, and has shown adequate means to protect the confidentiality of the information, the chemical manufacturer, importer, or employer will be subject to citation by OSHA.

(ii) If a chemical manufacturer, importer, or employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon the disclosure of the requested chemical information as may be appropriate to assure that the occupational health services are provided without an undue risk of harm to the chemical manufacturer, importer, or employer.

(11) If a citation for a failure to release trade secret information is contested by the chemical manufacturer, importer, or employer, the matter will be adjudicated before the Occupational Safety and Health Review Commission in accordance with the Act's enforcement scheme and the applicable Commission rules of procedure. In accordance with the Commission rules, when a chemical manufacturer, importer, or employer continues to withhold the information during the contest, the Administrative Law Judge may review the citation and supporting documentation ''in camera'' or issue appropriate orders to protect the confidentiality of such matters.

* * * * *

(j) *Effective dates.* (1) Employers shall train employees regarding the new label elements and safety data sheets format by December 1, 2013.

(2) Chemical manufacturers, importers, distributors, and employers

shall be in compliance with all modified provisions of this section no later than June 1, 2015, except:

(i) After December 1, 2015, the distributor shall not ship containers labeled by the chemical manufacturer or importer unless the label has been modified to comply with paragraph (f)(1) of this section.

(ii) 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), and provide any additional employee training in accordance with paragraph (h)(3) for newly identified physical or health hazards no later than June 1, 2016.

(3) Chemical manufacturers, importers, distributors, and employers may comply with either § 1910.1200 revised as of October 1, 2011, or the current version of this standard, 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.0.2 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 For most hazard classes, the recommended process of classification of mixtures is based on the following sequence:

(a) Where test data are available for the complete mixture, the classification of the mixture will always be based on those data;

(b) Where test data are not available for the mixture itself, the bridging principles designated in each health hazard chapter of this appendix shall be considered for classification of the mixture;

(c) If test data are not available for the mixture itself, and the available information is not sufficient to allow application of the above-mentioned bridging principles, then the method(s) described in each chapter for estimating the hazards based on the information known will be applied to classify the mixture (e.g., application of cut-off values/concentration limits).

A.0.4.2 An exception to the above order or precedence is made for Carcinogenicity, Germ Cell Mutagenicity, and Reproductive Toxicity. For these three hazard classes, mixtures shall be classified based upon information on the ingredient substances, unless on a case-by-case basis, justification can be provided for classifying based upon the mixture as a whole. See chapters A.5, A.6, and A.7 for further information on case-by-case bases.

A.0.4.3 Use of cut-off values/ concentration limits.

A.0.4.3.1 When classifying an untested mixture based on the hazards of its ingredients, cut-off values/concentration limits for the classified ingredients of the mixture are used for several hazard classes. While the adopted cut-off values/ concentration limits adequately identify the hazard for most mixtures, there may be some that contain hazardous ingredients at lower concentrations than the specified cut-off values/concentration limits that still pose an identifiable hazard. There may also be cases where the cut-off value/concentration limit is considerably lower than the established non-hazardous level for an ingredient.

A.0.4.3.2 If the classifier has information that the hazard of an ingredient will be evident (i.e., it presents a health risk) below the specified cut-off value/concentration limit, the mixture containing that ingredient shall be classified accordingly.

A.0.4.3.3 In exceptional cases, conclusive data may demonstrate that the hazard of an ingredient will not be evident (i.e., it does not present a health risk) when present at a level above the specified cut-off value/ concentration limit(s). In these cases the mixture may be classified according to those data. The data must exclude the possibility that the ingredient will behave in the mixture in a manner that would increase the hazard over that of the pure substance. Furthermore, the mixture must not contain ingredients that would affect that determination.

A.0.4.4 Synergistic or antagonistic effects. When performing an assessment in accordance with these requirements, the evaluator must take into account all available information about the potential occurrence of synergistic effects among the ingredients of the mixture. Lowering classification of a mixture to a less hazardous category on the basis of antagonistic effects may be done only if the determination is supported by sufficient data.

A.0.5 Bridging Principles for the Classification of Mixtures Where Test Data Are Not Available for the Complete Mixture

A.0.5.1 Where the mixture itself has not been tested to determine its toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles, subject to any specific provisions for mixtures for each hazard class. These principles ensure that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture.

A.0.5.1.1 Dilution.

For mixtures classified in accordance with A.1 through A.10 of this Appendix, if a tested mixture is diluted with a diluent that has an equivalent or lower toxicity classification than the least toxic original ingredient, and which is not expected to affect the toxicity of other ingredients, then:

(a) The new diluted mixture shall be classified as equivalent to the original tested mixture; or

(b) For classification of acute toxicity in accordance with A.1 of this Appendix, paragraph A.1.3.6 (the additivity formula) shall be applied.

A.0.5.1.2 Batching.

For mixtures classified in accordance with A.1 through A.10 of this Appendix, the toxicity of a tested production batch of a mixture can be assumed to be substantially equivalent to that of another untested production batch of the same mixture, when produced by or under the control of the same *chemical manufacturer,* unless there is reason to believe there is significant variation such that the toxicity of the untested batch has changed. If the latter occurs, a new classification is necessary.

A.0.5.1.3 Concentration of mixtures.

For mixtures classified in accordance with A.1, A.2, A.3, A.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 toxicity category.

For mixtures classified in accordance with A.1, A.2, A.3, 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 toxicity 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 toxicity 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 those adverse effects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours.

A.1.2 Classification Criteria for Substances

A.1.2.1 Substances can be allocated to one of four toxicity 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). See the footnotes following Table A.1.1 for further explanation on the application of these values.

TABLE A.1.1—ACUTE TOXICITY HAZARD CATEGORIES AND ACUTE TOXICITY ESTIMATE (ATE) VALUES DEFINING THE RESPECTIVE CATEGORIES

Exposure route	Category 1	Category 2	Category 3	Category 4
Oral (mg/kg bodyweight) *see: Note (a), Note (b)*	≤5	>5 and ≤50	>50 and ≤300	>300 and ≤2000.
Dermal (mg/kg bodyweight) *see: Note (a), Note (b)*	≤5	>50 and ≤200	>200 and ≤1000	>1000 and ≤2000.
Inhalation—Gases (ppmV) *see: Note (a), Note (b), Note (c)*	≤100	>100 and ≤500	>500 and ≤2500	>2500 and ≤20000.
Inhalation—Vapors (mg/l) *see: Note (a), Note (b), Note (c), Note (d).*	≤0.5	>0.5 and ≤2.0	>2.0 and ≤10.0	>10.0 and ≤20.0.
Inhalation—Dusts and Mists (mg/l) *see: Note (a), Note (b), Note (c)*	≤0.05	>0.05 and ≤0.5	>0.5 and ≤1.0	>1.0 and ≤5.0.

Note: *Gas concentrations are expressed in parts per million per volume (ppmV).*

Notes to Table A.1.1:

(a) *The acute toxicity estimate (ATE) for the classification of a substance is derived using the LD_{50}/LC_{50} Stewardwhere available;*

(b) The acute toxicity estimate (ATE) for the classification of a substance or ingredient in a mixture is derived using:

(i) the LD_{50}/LC_{50} where available. Otherwise,

(ii) the appropriate conversion value from Table 1.2 that relates to the results of a range test, or

(iii) the appropriate conversion value from Table 1.2 that relates to a classification category;

(c) Inhalation cut-off values in the table are based on 4 hour testing exposures. Conversion of existing inhalation toxicity data which has been generated according to 1 hour exposure is achieved by dividing by a factor of 2 for gases and vapors and 4 for dusts and mists;

(d) For some substances the test atmosphere will be a vapor which consists of a combination of liquid and gaseous phases. For other substances the test atmosphere may consist of a vapor which is nearly all the gaseous phase. In these latter cases, classification is based on ppmV as follows: Category 1 (100 ppmV), Category 2 (500 ppmV), Category 3 (2500 ppmV), Category 4 (20000 ppmV).

The terms "dust", "mist" and "vapor" are defined as follows:

(i) Dust: solid particles of a substance or mixture suspended in a gas (usually air);

(ii) Mist: liquid droplets of a substance or mixture suspended in a gas (usually air);

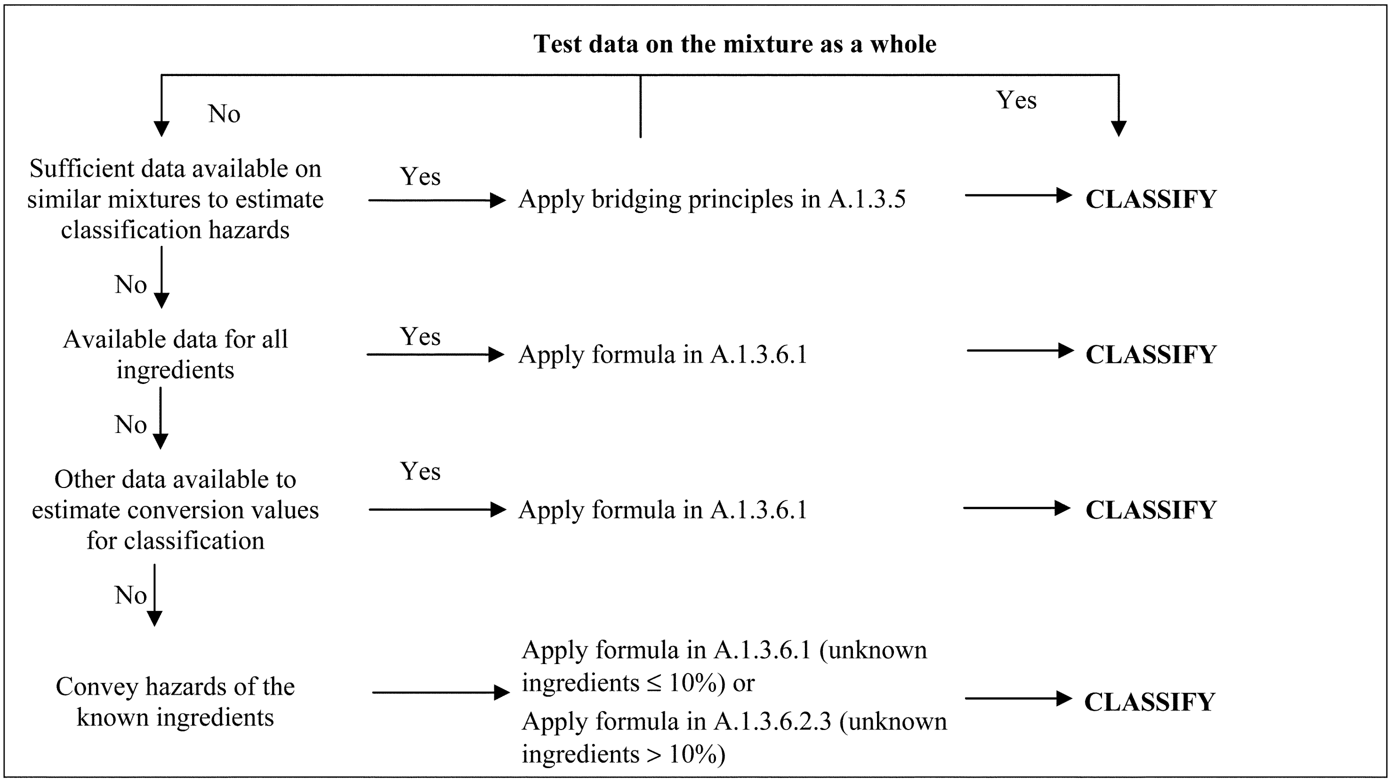
(iii) Vapor: the gaseous form of a substance or mixture released from its liquid or solid state.

A.1.2.3 The preferred test species for evaluation of acute toxicity by the oral and inhalation routes is the rat, while the rat or rabbit are preferred for evaluation of acute dermal toxicity. Test data already generated for the classification of chemicals under existing systems should be accepted when reclassifying these chemicals under the harmonized system. When experimental data for acute toxicity are available in several animal species, scientific judgment should be used in selecting the most appropriate LD_{50} value from among scientifically validated tests.

A.1.3 Classification Criteria for Mixtures

A.1.3.1 The approach to classification of mixtures for acute toxicity is tiered, and is dependent upon the amount of information available for the mixture itself and for its ingredients. The flow chart of Figure A.1.1 indicates the process that must be followed:

Figure A.1.1: Tiered approach to classification of mixtures for acute toxicity



A.1.3.2 Classification of mixtures for acute toxicity may be carried out for each route of exposure, but is only required for one route of exposure as long as this route is followed (estimated or tested) for all ingredients and there is no relevant evidence to suggest acute toxicity by multiple routes. When there is relevant evidence of acute toxicity by multiple routes of exposure, classification is to be conducted for all appropriate routes of exposure. All available information shall be considered. The pictogram and signal word used shall reflect the most severe hazard category; and all relevant hazard statements shall be used.

A.1.3.3 For purposes of classifying the hazards of mixtures in the tiered approach:

(a) The ''relevant ingredients'' of a mixture are those which are present in concentrations ≥1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases). If there is reason to suspect that an ingredient present at a concentration <1% will affect classification of the mixture for acute toxicity, that ingredient shall also be considered relevant. Consideration of ingredients present at a concentration <1% is particularly important when classifying untested mixtures which contain ingredients that are classified in Category 1 and Category 2;

(b) Where a classified mixture is used as an ingredient of another mixture, the actual or derived acute toxicity estimate (ATE) for that mixture is used when calculating the classification of the new mixture using the formulas in A.1.3.6.1 and A.1.3.6.2.4.

(c) If the converted acute toxicity point estimates for all ingredients of a mixture are within the same category, then the mixture should be classified in that category.

(d) When only range data (or acute toxicity hazard category information) are available for ingredients in a mixture, they may be converted to point estimates in accordance with Table A.1.2 when calculating the classification of the new mixture using the formulas in A.1.3.6.1 and A.1.3.6.2.4.

A.1.3.4 Classification of Mixtures Where Acute Toxicity Test Data Are Available for the Complete Mixture

Where the mixture itself has been tested to determine its acute toxicity, it is classified according to the same criteria as those used for substances, presented in Table A.1.1. If test data for the mixture are not available, the procedures presented below must be followed.

A.1.3.5 Classification of Mixtures Where Acute Toxicity Test Data Are Not Available for the Complete Mixture: Bridging Principles

A.1.3.5.1 Where the mixture itself has not been tested to determine its acute toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, and Aerosols.

A.1.3.6 Classification of Mixtures Based on Ingredients of the Mixture (Additivity Formula)

A.1.3.6.1 Data available for all ingredients.

The acute toxicity estimate (ATE) of ingredients is considered as follows:

(a) Include ingredients with a known acute toxicity, which fall into any of the acute toxicity categories, or have an oral or dermal LD_{50} 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:

$$\frac{100}{\text{ATEmix}} = \sum_{n} \frac{\text{Ci}}{\text{ATE}_{\text{i}}}$$

Where:

Ci = concentration of ingredient i

n ingredients and i is running from 1 to n

ATEi = acute toxicity estimate of ingredient i.

A.1.3.6.2 Data are not available for one or more ingredients of the mixture.

A.1.3.6.2.1 Where an ATE is not available for an individual ingredient of the mixture, but available information provides a derived conversion value, the formula in A.1.3.6.1 may be applied. This information may include evaluation of:

(a) Extrapolation between oral, dermal and inhalation acute toxicity estimates. Such an evaluation requires appropriate pharmacodynamic and pharmacokinetic data;

(b) Evidence from human exposure that indicates toxic effects but does not provide lethal dose data;

(c) Evidence from any other toxicity tests/assays available on the substance that indicates toxic acute effects but does not necessarily provide lethal dose data; or

(d) Data from closely analogous substances using structure/activity relationships.

A.1.3.6.2.2 This approach requires substantial supplemental technical information, and a highly trained and experienced expert, to reliably estimate acute toxicity. If sufficient information is not available to reliably estimate acute toxicity, proceed to the provisions of A.1.3.6.2.3.

A.1.3.6.2.3 In the event that an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥1%, and the mixture has not been classified based on testing of the mixture as a whole, the mixture cannot be attributed a definitive acute toxicity estimate. In this situation the mixture is classified based on the known ingredients only. (Note: A statement that × percent of the mixture consists of ingredient(s) of unknown 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.)

Where an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥1%, and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required on the label and safety data sheet in such cases; see Appendix C to this section, Allocation of Label Elements and Appendix D to this section, Safety Data Sheets.)

A.1.3.6.2.4 If the total concentration of the relevant ingredient(s) with unknown acute toxicity is ≤10% then the formula presented in A.1.3.6.1 must be used. If the total concentration of the relevant ingredient(s) with unknown acute toxicity is >10%, the formula presented in A.1.3.6.1 is corrected to adjust for the percentage of the unknown ingredient(s) as follows:

$$\frac{100-\left(\sum C_{unknown} \text{ if } > 10\%\right)}{ATE_{mix}} = \sum_{n} \frac{Ci}{ATE_{i}}$$

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 ≤5	0.5
	5 <Category 2 ≤50	5
	50 <Category 3 ≤300	100
	300 <Category 4 ≤2000	500
Dermal (mg/kg bodyweight)	0 <Category 1 ≤50	5
	50 <Category 2 ≤200	50
	200 <Category 3 ≤1000	300
	1000 <Category 4 ≤2000	1100
Gases (ppmV)	0 <Category 1 ≤100	10
	100 <Category 2 ≤500	100
	500 <Category 3 ≤2500	700
	2500 <Category 4 ≤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* is the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to 4 hours. Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia, and scars. Histopathology should be considered to evaluate questionable lesions.

Skin irritation is the production of reversible damage to the skin following the application of a test substance for up to 4 hours.

A.2.1.2 Skin corrosion/irritation shall be classified using a tiered approach as detailed in figure A.2.1. Emphasis shall be placed upon existing human data (See A.0.2.6), followed by other sources of information. Classification results directly when the data satisfy the criteria in this section. In case the criteria cannot be directly applied, classification of a substance or a mixture is made on the basis of the total weight of evidence (See A.0.3.1). This means that all available information bearing on the determination of skin corrosion/irritation is considered together, including the results of appropriate scientifically validated in-vitro tests, relevant animal data, and human data such as epidemiological and clinical studies and well-documented case reports and observations.

A.2.2 Classification Criteria for Substances Using Animal Test Data

A.2.2.1 Corrosion

A.2.2.1.1 A corrosive substance is a chemical that produces destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least 1 of 3 tested animals after exposure up to a 4-hour duration. Corrosive reactions are typified by ulcers, bleeding, bloody scabs and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia and scars. Histopathology should be considered to discern questionable lesions.

A.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

Category 1: corrosive	Corrosive sub-categories	Corrosive in ≥1 of 3 animals	
		Exposure	Observation
	1A	≤3 min	≤1 h.
	1B	>3 min ≤1 h	≤14 days.
	1C	>1 h ≤4 h	≤14 days.

A.2.2.2 Irritation

A.2.2.2.1 A single irritant category (Category 2) is presented in the Table A.2.2. The major criterion for the irritant category is that at least 2 tested animals have a mean score of ≥2.3 ≤4.0.

TABLE A.2.2—SKIN IRRITATION CATEGORY

	Criteria
Irritant (Category 2)	(1) Mean value of ≥2.3 ≤4.0 for erythema/eschar or for edema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions; or (2) Inflammation that persists to the end of the observation period normally 14 days in at least 2 animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia, and scaling; or (3) In some cases where there is pronounced variability of response among animals, with very definite positive effects related to chemical exposure in a single animal but less than the criteria above.

A.2.2.2.2 Animal irritant responses within a test can be quite variable, as they are with corrosion. A separate irritant criterion accommodates cases when there is a significant irritant response but less than the mean score criterion for a positive test. For example, a substance might be designated as an irritant if at least 1 of 3 tested animals shows a very elevated mean score throughout the study, including lesions persisting at the end of an observation period of normally 14 days. Other responses could also 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.

A.2.2.2.3 Reversibility of skin lesions is another consideration in evaluating irritant responses. When inflammation persists to the end of the observation period in 2 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.2.3 Classification Criteria for Substances Using Other Data Elements

A.2.3.1 Existing human and animal data including information from single or repeated exposure should be the first line of analysis, as they give information directly relevant to effects on the skin. If a substance is highly toxic by the dermal route, a skin corrosion/irritation study may not be practicable since the amount of test substance to be applied would considerably exceed the toxic dose and, consequently, would result in the death of the animals. When observations are made of skin corrosion/irritation in acute toxicity studies and are observed up through the limit dose, these data may be used for classification provided that the dilutions used and species tested are equivalent. *In vitro* alternatives that have been scientifically validated shall be used to make classification decisions. Solid substances (powders) may become corrosive or irritant when moistened or in contact with moist skin or mucous membranes. Likewise, pH extremes like ≤2 and ≥11.5 may indicate skin effects, especially when associated with significant 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 alkali/acid reserve suggests the substance or mixture may not be corrosive despite the low or high pH value, then further evaluation may be necessary. In some cases enough information may be available from structurally related compounds to make classification decisions.

A.2.3.2 A *tiered approach* to the evaluation of initial information shall be used (Figure A.2.1) recognizing that all elements may not be relevant in certain cases.

A.2.3.3 The tiered approach explains how to organize information on a substance and to make a weight-of-evidence decision about hazard assessment and hazard classification.

A.2.3.4 All the above information that is available on a substance shall be evaluated. Although information might be gained from the evaluation of single parameters within a tier, there is merit in considering the totality of existing information and making an overall weight of evidence determination. This is especially true when there is information available on some but not all parameters. Emphasis shall be placed upon existing human experience and data, followed by animal experience and testing data, followed by other sources of information, but case-by-case determinations are necessary.

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Figure A.2.1: Tiered evaluation of skin corrosion and irritation potential

Step	Parameter	Finding	Conclusion
1a	Existing human or animal data[1]	Skin corrosive	Category 1[2]
	Not corrosive or no data		
1b	Existing human or animal data[1]	Skin irritant	Category 2[2]
	Not an irritant or no data		
1c	Existing human or animal data[1]	Not a skin corrosive or skin irritant	Not classified
	No/Insufficient data		
2:	Other, existing skin data in animals[3]	Skin corrosive Skin irritant	Category 1[2] Category 2[2]
	No/Insufficient data		
3:	Existing skin corrosive *ex vivo / in vitro* data[4]	Positive: Skin corrosive	Category 1[2]
	Not corrosive or no data		
	Existing skin irritation *ex vivo / in vitro* data[4]	Positive: Skin irritant	Category 2[2]
		Negative: Not a skin irritant[5]	Not classified
	No/Insufficient data		
4:	pH-Based assessment (with consideration of buffering capacity of the chemical, or no buffering capacity data)[5]	pH ≤ 2 or ≥ 11.5	Category 1[2]
	Not a pH extreme, No pH data or extreme pH with low/no buffering capacity		
5:	Validated Structure/Activity Relationship (SAR) models	Skin corrosive	Category 1[2]
		Skin irritant	Category 2[2]
	No/Insufficient data		
6:	Consideration of the total Weight of Evidence[6]	Skin corrosive	Category 1[2]
	No concern based on consideration of the sum of available data	Skin irritant	Category 2[2]
7:	**Not Classified**		Not classified

Notes to Figure A.2.1:

1 Evidence of existing human or animal data may be derived from single or repeated exposure(s) in occupational, consumer, transportation, or emergency response scenarios; from ethically-conducted human clinical studies; or from purposely-generated data from animal studies conducted according to scientifically validated test methods (at present, there is no internationally accepted test method for human skin irritation testing).

2 Classify in the appropriate harmonized category, as shown in Tables A.2.1 and A.2.2.

[3] Pre-existing animal data (e.g. from an acute dermal toxicity test or a sensitisation test) should be carefully reviewed to determine if sufficient skin corrosion/irritation evidence is available through other, similar information. For example, classification/categorization may be done on the basis of whether a chemical has or has not produced any skin irritation in an acute dermal toxicity test in animals at the limit dose, or produces very toxic effects in an acute dermal toxicity test in animals. In the latter case, the chemical would be classified as being very hazardous by the dermal route for acute toxicity, and it would be moot whether the chemical is also irritating or corrosive on the skin. It should be kept in mind in evaluating acute dermal toxicity information that the reporting of dermal lesions may be incomplete, testing and observations may be made on a species other than the rabbit, and species may differ in sensitivity in their responses.

[4] Evidence from studies using scientifically validated protocols with isolated human/animal tissues or other, non-tissue-based, though scientifically validated, protocols should be assessed. Examples of scientifically validated test methods for skin corrosion include OECD TG 430 (Transcutaneous Electrical Resistance Test (TER)), 431 (Human Skin Model Test), and 435 (Membrane Barrier Test Method). OECD TG 439 (Reconstructed Human Epidermis Test Method) is a scientifically validated in vitro test method for skin irritation.

[5] Measurement of pH alone may be adequate, but assessment of acid or alkali reserve (buffering capacity) would be preferable. Presently, there is no scientifically validated and internationally accepted method for assessing this parameter.

[6] All information that is available on a chemical should 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. Professional judgment should be exercised in making such a determination.

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A.2.4 Classification Criteria for Mixtures

A.2.4.1 Classification of Mixtures When Data Are Available for the Complete Mixture

A.2.4.1.1 The mixture shall be classified using the criteria for substances (See A.2.3).

A.2.4.2 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

A.2.4.2.1 Where the mixture itself has not been tested to determine its skin corrosion/irritation, 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 toxicity category, Substantially similar mixtures, and Aerosols.

A.2.4.3 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

A.2.4.3.1 For purposes of classifying the skin corrosion/irritation hazards of mixtures in the tiered approach:

The ''relevant ingredients'' of a mixture are those which are present in concentrations >1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases.) If the classifier has reason to suspect that an ingredient present at a concentration <1% will affect classification of the mixture for skin corrosion/irritation, that ingredient shall also be considered relevant.

A.2.4.3.2 In general, the approach to classification of mixtures as irritant or corrosive to 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 irritant or corrosive properties of the mixture in proportion to its potency and concentration. A weighting factor of 10 is used for corrosive ingredients when they are present at a concentration below the concentration limit for classification with Category 1, but are at a concentration that will contribute to the classification of the mixture as an irritant. The mixture is classified as corrosive or irritant when the sum of the concentrations of such ingredients exceeds a cut-off value/concentration limit.

A.2.4.3.3 Table A.2.3 below provides the cut-off value/concentration limits to be used to determine if the mixture is considered to be an irritant or a corrosive to the skin.

A.2.4.3.4 Particular care shall be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in A.2.4.3.1 and A.2.4.3.2 might not work given that many of such substances are corrosive or irritant at concentrations <1%. For mixtures containing strong acids or bases the pH should be used as classification criteria since pH will be a better indicator of corrosion than the concentration limits of 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 Category 1 if it contains ≥1% of a corrosive ingredient and as Skin Category 2 when it contains ≥3% of an irritant ingredient. Classification of mixtures with ingredients for which the approach in Table A.2.3 does not apply is summarized in Table A.2.4 below.

A.2.4.3.5 On occasion, reliable data may show that the skin corrosion/irritation of an ingredient will not be evident when present at a level above the generic concentration cut-off values mentioned in Tables A.2.3 and A.2.4. In these cases the mixture could be classified according to those data (See *Use of cut-off values/concentration limits,* paragraph A.0.4.3 of this Appendix).

A.2.4.3.6 If there are data showing that (an) ingredient(s) may be corrosive or irritant 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

[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%.

TABLE A.2.4—CONCENTRATION OF INGREDIENTS OF A MIXTURE FOR WHICH THE ADDITIVITY APPROACH DOES NOT APPLY, THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE AS HAZARDOUS TO SKIN

Ingredient:	Concentration:	Mixture classified as: Skin
Acid with pH ≤2	≥1%	Category 1.
Base with pH ≥11.5	≥1%	Category 1.
Other corrosive (Category 1) ingredients for which additivity does not apply	≥1%	Category 1.
Other irritant (Category 2) ingredients for which additivity does not apply, including acids and bases	≥3%	Category 2.

A.3 SERIOUS EYE DAMAGE/EYE IRRITATION

A.3.1 Definitions and General Considerations

A.3.1.1 *Serious eye damage* is the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application.

Eye irritation is the production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application.

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 animal data, followed by 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 Using Animal Test Data

A.3.2.1 Irreversible effects on the eye/serious damage to eyes (Category 1).

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 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—IRREVERSIBLE EYE EFFECTS

A substance is classified as Serious Eye Damage Category 1 (irreversible effects on the eye) when it produces:
(a) at least in one tested 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) at least in 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 substance.

A.3.2.2 Reversible effects on the eye (Category 2).

A single category is provided in Table A.3.2 for substances that have the potential to induce reversible eye irritation.

TABLE A.3.2—REVERSIBLE EYE EFFECTS

A substance is classified as Eye irritant Category 2A (irritating to eyes) when it produces in at least in 2 of 3 tested animals a positive response of:
(i) corneal opacity ≥1; and/or
(ii) iritis ≥1; and/or
(iii) conjunctival redness ≥2; and/or
(iv) conjunctival edema (chemosis) ≥2

TABLE A.3.2—REVERSIBLE EYE EFFECTS—Continued

calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the substance, and which fully reverses within an observation period of normally 21 days.
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.3.2.3 For those chemicals where there is pronounced variability among animal responses, this information may be taken into account in determining the classification.

A.3.3 Classification Criteria for Substances Using Other Data Elements

A.3.3.1 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 serious eye damage/eye irritation in order to avoid testing for local effects on eyes with skin corrosive substances. *In vitro* alternatives that have been scientifically validated and accepted shall be used to make classification decisions. Likewise, pH extremes like ≤2 and ≥11.5, may indicate serious eye damage, especially when associated with significant buffering capacity. Generally, such substances are expected to produce significant effects on the eyes. In the absence of any other information, a mixture/substance is considered to cause serious eye damage (Eye Category 1) if it has a pH ≤2 or ≥11.5. However, if consideration of acid/alkaline reserve suggests the substance may not have the potential to cause serious eye damage despite the low or high pH value, then further evaluation may be necessary. In some cases enough information may be available from structurally related compounds to make classification decisions.

A.3.3.2 A tiered approach to the evaluation of initial information shall be used where applicable, recognizing that all elements may not be relevant in certain cases (Figure A.3.1).

A.3.3.3 The tiered approach explains how to organize existing information on a substance and to make a weight-of-evidence decision, where appropriate, about hazard assessment and hazard classification.

A.3.3.4 All the above information that is available on a substance shall be evaluated. Although information might be gained from the evaluation of single parameters within a tier, consideration should be given to the totality of existing information and making an overall weight-of-evidence determination. This is especially true when there is conflict in information available on some parameters.

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Figure A.3.1 Evaluation strategy for serious eye damage and eye irritation (See also Figure A.2.1)

Step	Parameter	Finding	Conclusion
1a:	Existing human or animal data, eye[1]	Serious Eye Damage	Category 1[2]
		Eye Irritant	Category 2[2]
	No/insufficient data or unknown		
1b:	Existing human or animal data, skin corrosion	Skin corrosive	Category 1[2]
	No/insufficient data or unknown		
1c:	Existing human or animal data, eye[1]	Existing data that show that substance does not cause serious eye damage or eye irritation	Not Classified
	No/insufficient data		
2:	Other, existing skin/eye data in animals[3]	Yes; existing data that show that substance may cause serious eye damage or eye irritation	Category1 or Category 2[2]
	No/insufficient data		
3:	Existing *ex vivo* / *in vitro* data[4]	Positive: serious eye damage	Category 1[2]
		Positive: eye irritant	Category 2[2]
	No/insufficient data / negative response		
4:	pH-Based assessment (with consideration of buffering capacity of the chemical, or no buffering capacity data)[5]	pH ≤ 2 or ≥11.5	Category 1[2]
	Not a pH extreme, no pH data, or extreme pH with low/no buffering capacity		
5:	Validated structure/activity relationship (SAR) models	Severe damage to eyes	Category 1[2]
		Eye irritant	Category 2[2]
		Skin Corrosive	Category 1[2]
	No/insufficient data		
6:	Consideration of the total weight of evidence[6]	Serious eye damage	Category 1[2]
		Eye irritant	Category 2[2]
	No concern based on consideration of the sum of available data		
7:	**Not Classified**		

Notes to Figure A.3.1:

[1] *Evidence of existing human or animal data may be derived from single or repeated exposure(s) in occupational, consumer, transportation, or emergency response scenarios; from ethically-conducted human clinical studies; or from purposely-generated data from animal studies conducted according to scientifically validated test methods. At present, there are no internationally accepted test methods for human skin or eye irritation testing.*

[2] *Classify in the appropriate harmonized category, as shown in Tables A.3.1 and A.3.2.*

[3] Pre-existing animal data should be carefully reviewed to determine if sufficient skin or eye corrosion/irritation evidence is available through other, similar information.

[4] Evidence from studies using scientifically validated protocols with isolated human/animal tissues or other, non-tissue-based, though scientifically validated, protocols should be assessed. Examples of, scientifically validated test methods for identifying eye corrosives and severe irritants (i.e., Serious Eye Damage) include OECD TG 437 (Bovine Corneal Opacity and Permeability (BCOP)) and TG 438 (Isolated Chicken Eye). Positive test results from a scientifically validated in vitro test for skin corrosion would likely also lead to a conclusion to classify as causing Serious Eye Damage.

[5] Measurement of pH alone may be adequate, but assessment of acid or alkali reserve (buffering capacity) would be preferable.

[6] All information that is available on a chemical should 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 could lead to classification of eye irritation. It is recognized that not all skin irritants are eye irritants as well. Professional judgment should be exercised in making such a determination.

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A.3.4 Classification Criteria for Mixtures

A.3.4.1 Classification of Mixtures When Data Are Available for the Complete Mixture

A.3.4.1.1 The mixture will be classified using the criteria for substances.

A.3.4.1.2 Unlike other hazard classes, there are alternative tests available for skin corrosivity of certain types of chemicals that can give an accurate result for classification purposes, as well as being simple and relatively inexpensive to perform. When considering testing of the mixture, chemical manufacturers are encouraged to use a tiered weight of evidence strategy 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 avoid unnecessary animal testing. In the absence of any other information, a mixture is considered to cause serious eye damage (Eye Category 1) if it has a pH ≤2 or ≥11.5. However, if consideration of acid/alkaline reserve suggests the substance or mixture may not have the potential to cause serious eye damage despite the low or high pH value, then further evaluation may be necessary.

A.3.4.2 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

A.3.4.2.1 Where the mixture itself has not been tested to determine its skin corrosivity or potential to cause serious eye damage or eye irritation, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles, as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, and Aerosols.

A.3.4.3 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

A.3.4.3.1 For purposes of classifying the eye corrosion/irritation hazards of mixtures in the tiered approach:

The ''relevant ingredients'' of a mixture are those which are present in concentrations >1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases). If the classifier has reason to suspect that an ingredient present at a concentration <1% will affect classification of the mixture for eye corrosion/irritation, that ingredient shall also be considered relevant.

A.3.4.3.2 In general, the approach to classification of mixtures as seriously damaging to the eye or eye irritant when data are available on the ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each corrosive or irritant ingredient contributes to the overall irritant or corrosive 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 seriously damaging to the eye or eye irritant when the sum of the concentrations of such ingredients exceeds a threshold cut-off value/concentration limit.

A.3.4.3.3 Table A.3.3 provides the cut-off value/concentration limits to be used to determine if the mixture should be classified as seriously damaging to the eye or an eye irritant.

A.3.4.3.4 Particular care must be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in A.3.4.3.1 and A.3.4.3.2 might not work given that many of such substances are corrosive or irritant at concentrations <1%. For mixtures containing strong acids or bases, the pH should be used as classification criteria (See A.3.4.1) since pH will be a better indicator of serious eye damage than the concentration limits of Table A.3.3. A mixture containing corrosive or irritant 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 Eye Category 1 if it contains ≥1% of a corrosive ingredient and as Eye Category 2 when it contains ≥3% of an irritant ingredient. Classification of mixtures with ingredients for which the approach in Table A.3.3 does not apply is summarized in Table A.3.4.

A.3.4.3.5 On occasion, reliable data may show that the reversible/irreversible 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 strategy should be applied as referred to in section A.3.3, Figure A.3.1 and explained in detail in this chapter.

A.3.4.3.6 If there are data showing that (an) ingredient(s) may be corrosive or irritant at a concentration of <1% (corrosive) or <3% (irritant), the mixture should 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:	
	Irreversible eye effects	Reversible eye effects
	Category 1	Category 2
Eye or Skin Category 1	≥3%	≥1% but <3%.

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—Continued

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Irreversible eye effects	Reversible eye effects
	Category 1	Category 2
Eye Category 2		≥10%.
(10 × Eye Category 1) + Eye Category 2		≥10%.
Skin Category 1 + Eye Category 1	≥3%	≥1% but <3%.
10 × (Skin Category 1 + Eye Category 1) + Eye Category 2		≥10%.

Note: *A mixture may be classified as Eye Category 2B in cases when all relevant ingredients are classified as Eye Category 2B.*

TABLE A.3.4—CONCENTRATION OF INGREDIENTS OF A MIXTURE FOR WHICH THE ADDITIVITY APPROACH DOES NOT APPLY, THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE AS HAZARDOUS TO THE EYE

Ingredient	Concentration	Mixture classified as: Eye
Acid with pH ≤2	≥1%	Category 1.
Base with pH ≥11.5	≥1%	Category 1.
Other corrosive (Category 1) ingredients for which additivity does not apply	≥1%	Category 1.
Other irritant (Category 2) ingredients for which additivity does not apply, including acids and bases	≥3%	Category 2.

A.4 RESPIRATORY OR SKIN SENSITIZATION

A.4.1 Definitions and General Considerations

A.4.1.1 *Respiratory sensitizer* means a chemical that will lead to hypersensitivity of the airways following inhalation of the chemical.

Skin sensitizer means a chemical that will lead to an allergic response following skin contact.

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

[1] *At this writing, recognized and validated animal models for the testing of respiratory hypersensitivity are not available. Under certain circumstances, data from animal studies may provide valuable information in a weight of evidence assessment.*

the evidence from the cases, the following be taken into account:

(a) The size of the population exposed;

(b) The extent of exposure.

A.4.2.1.2.3 The evidence referred to above could be:

(a) Clinical history and data from appropriate lung function tests related to exposure to the substance, confirmed by other supportive evidence which may include:

(i) *In vivo* immunological test (e.g., skin prick test);

(ii) *In vitro* immunological test (e.g., serological analysis);

(iii) Studies that may indicate other specific hypersensitivity reactions where immunological mechanisms of action have not been proven, e.g., repeated low-level irritation, pharmacologically mediated effects;

(iv) A chemical structure related to substances known to cause respiratory hypersensitivity;

(b) Data from positive bronchial challenge tests with the substance conducted according to accepted guidelines for the determination of a specific hypersensitivity reaction.

A.4.2.1.2.4 Clinical history should include both medical and occupational history to determine a relationship between exposure to a specific substance and development of respiratory hypersensitivity. Relevant information includes aggravating factors both in the home and workplace, the onset and progress of the disease, family history and medical history of the patient in question. The medical history should also include a note of other allergic or airway disorders from childhood and smoking history.

A.4.2.1.2.5 The results of positive bronchial challenge tests are considered to provide sufficient evidence for classification on their own. It is, however, recognized that in practice many of the examinations listed above will already have been carried out.

A.4.2.1.3 Animal studies.

A.4.2.1.3.1 Data from appropriate animal studies [2] which may be indicative of the potential of a substance to cause sensitization by inhalation in humans [3] may include:

(a) Measurements of Immunoglobulin E (IgE) and other specific immunological parameters, for example in mice

(b) Specific pulmonary responses in guinea pigs.

A.4.2.2 Skin Sensitizers

A.4.2.2.1 Hazard categories.

A.4.2.2.1.1 Effects seen in either humans or animals will normally justify classification in a weight of evidence approach for skin sensitizers. Substances may be allocated to one of the two sub-categories 1A or 1B using a weight of evidence approach in accordance with the criteria given in Table A.4.2 and on the basis of reliable and good quality evidence from human cases or epidemiological studies and/or observations from appropriate studies in experimental animals according to the guidance values provided in A.4.2.2.2.1 and A.4.2.2.3.2 for sub-category 1A and in A.4.2.2.2.2 and A.4.2.2.3.3 for sub-category 1B.

A.4.2.2.1.2 Where data are not sufficient for sub-categorization, skin sensitizers shall be classified in Category 1.

TABLE A.4.2—HAZARD CATEGORY AND SUB-CATEGORIES FOR SKIN SENSITIZERS

Category 1	Skin sensitizer
	A substance is classified as a skin sensitizer. (a) if there is evidence in humans that the substance can lead to sensitization by skin contact in a substantial number of persons, or (b) if there are positive results from an appropriate animal test.
Sub-category 1A	Substances showing a high frequency of occurrence in humans and/or a high potency in animals can be presumed to have the potential to produce significant sensitization in humans. Severity of reaction may also be considered.
Sub-category 1B	Substances showing a low to moderate frequency of occurrence in humans and/or a low to moderate potency in animals can be presumed to have the potential to produce sensitization in humans. Severity of reaction may also be considered.

A.4.2.2.2 Human evidence.

A.4.2.2.2.1 Human evidence for sub-category 1A may include:

(a) Positive responses at ≤500 μg/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 μg/cm^2 (HRIPT, HMT—induction threshold);

(b) Diagnostic patch test data where there is a relatively low but substantial incidence of reactions in a defined population in relation to relatively high exposure;

(c) Other epidemiological evidence where there is a relatively low but substantial incidence of allergic contact dermatitis in relation to relatively high exposure.

A.4.2.2.3 Animal studies

A.4.2.2.3.1 For Category 1, when an adjuvant type test method for skin sensitization is used, a response of at least 30% of the animals is considered as positive. For a non-adjuvant Guinea pig test method a response of at least 15% of the animals is considered positive. For Category 1, a stimulation index of three or more is considered a positive response in the local lymph node assay.[4]

A.4.2.2.3.2 Animal test results for sub-category 1A can include data with values indicated in Table A.4.3 below:

TABLE A.4.3—ANIMAL TEST RESULTS FOR SUB-CATEGORY 1A

Assay	Criteria
Local lymph node assay	EC3 value ≤2%.
Guinea pig maximization test	≥30% responding at ≤0.1% intradermal induction dose *or* ≥60% responding at >0.1% to ≤1% intradermal induction dose.
Buehler assay	≥15% responding at ≤0.2% topical induction dose *or*

[2] *At this writing, recognized and validated animal models for the testing of respiratory hypersensitivity are not available. Under certain circumstances, data from animal studies may provide valuable information in a weight of evidence assessment.*

[3] *The mechanisms by which substances induce symptoms of asthma are not yet fully known. For preventive measures, these substances are considered respiratory sensitizers. However, if on the basis of the evidence, it can be demonstrated that these substances induce symptoms of asthma by irritation only in people with bronchial hyperactivity, they should not be considered as respiratory sensitizers.*

[4] *Test methods for skin sensitization are described in OECD Guideline 406 (the Guinea Pig Maximization test and the Buehler guinea pig test) and Guideline 429 (Local Lymph Node Assay). Other methods may be used provided that they are scientifically validated. The Mouse Ear Swelling Test (MEST), appears to be a reliable screening test to detect moderate to strong sensitizers, and can be used, in accordance with professional judgment, as a first stage in the assessment of skin sensitization potential.*

TABLE A.4.3—ANIMAL TEST RESULTS FOR SUB-CATEGORY 1A—Continued

Assay	Criteria
	≥60% responding at >0.2% to ≤20% topical induction dose.

Note: *EC3 refers to the estimated concentration of test chemical required to induce a stimulation index of 3 in the local lymph node assay.*

A.4.2.2.3.3 Animal test results for sub-category 1B can include data with values indicated in 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 man (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, Substantially similar mixtures, and Aerosols.

A.4.3.3 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

The mixture shall be classified as a respiratory or skin sensitizer when at least one ingredient has been classified as a respiratory or skin sensitizer and is present at or above the appropriate cut-off value/concentration limit for the specific endpoint as shown in Table A.4.5.

TABLE A.4.5—CUT-OFF VALUES/CONCENTRATION LIMITS OF INGREDIENTS OF A MIXTURE CLASSIFIED AS EITHER RESPIRATORY SENSITIZERS OR SKIN SENSITIZERS THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE

Ingredient classified as:	Cut-off values/concentration limits triggering classification of a mixture as:		
	Respiratory Sensitizer Category 1		Skin Sensitizer Category 1
	Solid/liquid	Gas	All physical states
Respiratory Sensitizer, Category 1	≥0.1%	≥0.1%	
Respiratory Sensitizer, Sub-category 1A	≥0.1%	≥0.1%	
Respiratory Sensitizer, Sub-category 1B	≥1.0%	≥0.2%	
Skin Sensitizer, Category 1			≥0.1%
Skin Sensitizer, Sub-category 1A			≥0.1%
Skin Sensitizer, Sub-category 1B			≥1.0%

A.5 GERM CELL MUTAGENICITY

A.5.1 Definitions and General Considerations

A.5.1.1 A *mutation* is defined as a permanent change in the amount or structure of the genetic material in a cell. The term *mutation* applies both to heritable genetic changes that may be manifested at the phenotypic level and to the underlying DNA modifications when known (including, for example, specific base pair changes and chromosomal translocations). The term *mutagenic* and *mutagen* will be used for agents giving rise to an increased occurrence of mutations in populations of cells and/or organisms.

A.5.1.2 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.5.1.3 This hazard class is primarily concerned with chemicals that may cause mutations in the germ cells of humans that can be transmitted to the progeny. However, mutagenicity/genotoxicity tests *in vitro* and in mammalian somatic cells *in vivo* are also considered in classifying substances and mixtures within this hazard class.

A.5.2 Classification Criteria for Substances

A.5.2.1 The classification system provides for two different categories of germ cell mutagens to accommodate the weight of evidence available. The two-category system is described in the Figure A.5.1.

FIGURE A.5.1—HAZARD CATEGORIES FOR GERM CELL MUTAGENS

CATEGORY 1: Substances known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans.

Category 1A: Substances known to induce heritable mutations in germ cells of humans.
Positive evidence from human epidemiological studies.

Category 1B: Substances which should be regarded as if they induce heritable mutations in the germ cells of humans.
(a) Positive result(s) from *in vivo* heritable germ cell mutagenicity tests in mammals; or
(b) Positive result(s) from *in vivo* somatic cell mutagenicity tests in mammals, in combination with some evidence that the substance has potential to cause mutations to germ cells. This supporting evidence may, for example, be derived from mutagenicity/genotoxicity tests in germ cells *in vivo,* or by demonstrating the ability of the substance or its metabolite(s) to interact with the genetic material of germ cells; or
(c) Positive results from tests showing mutagenic effects in the germ cells of humans, without demonstration of transmission to progeny; for example, an increase in the frequency of aneuploidy in sperm cells of exposed people.

CATEGORY 2: Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans.
Positive evidence obtained from experiments in mammals and/or in some cases from *in vitro* experiments, obtained from:
(a) Somatic cell mutagenicity tests *in vivo,* in mammals; or
(b) Other *in vivo* somatic cell genotoxicity tests which are supported by positive results from *in vitro* mutagenicity assays.
Note: *Substances which are positive in in vitro mammalian mutagenicity assays, and which also show chemical structure activity relationship to known germ cell mutagens, should be considered for classification as Category 2 mutagens.*

A.5.2.2 Specific considerations for classification of substances as germ cell mutagens:

A.5.2.2.1 To arrive at a classification, test results are considered from experiments determining mutagenic and/or genotoxic effects in germ and/or somatic cells of exposed animals. Mutagenic and/or genotoxic effects determined in *in vitro* tests shall also be considered.

A.5.2.2.2 The system is hazard based, classifying chemicals on the basis of their intrinsic ability to induce mutations in germ cells. The scheme is, therefore, not meant for the (quantitative) risk assessment of chemical substances.

A.5.2.2.3 Classification for heritable effects in human germ cells is made on the basis of scientifically validated tests. Evaluation of the test results shall be done using expert judgment and all the available evidence shall be weighed for classification.

A.5.2.2.4 The classification of substances shall be based on the total weight of evidence available, using expert judgment. In those instances where a single well-conducted test is used for classification, it shall provide clear and unambiguous positive results. The relevance of the route of exposure used in the study of the substance compared to the route of human exposure should also be taken into account.

A.5.3 Classification Criteria for Mixtures [5]

A.5.3.1 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

A.5.3.1.1 Classification of mixtures shall be based on the available test data for the

[5] *It should be noted that the classification criteria for health hazards usually include a tiered scheme in which test data available on the complete mixture are considered as the first tier in the 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*

Continued

individual ingredients of the mixture using cut-off values/concentration limits for the ingredients classified as germ cell mutagens.

A.5.3.1.2 The mixture will be classified as a mutagen when at least one ingredient has been classified as a Category 1A, Category 1B or Category 2 mutagen and is present at or above the appropriate cut-off value/concentration limit as shown in Table A.5.1 below for Category 1 and 2 respectively.

TABLE A.5.1—CUT-OFF VALUES/CONCENTRATION LIMITS OF INGREDIENTS OF A MIXTURE CLASSIFIED AS GERM CELL MUTAGENS THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE

Ingredient classified as:	Cut-off/concentration limits triggering classification of a mixture as:	
	Category 1 mutagen	Category 2 mutagen
Category 1A/B mutagen	≥0.1%	
Category 2 mutagen		≥1.0%

Note: *The cut-off values/concentration limits in the table above apply to solids and liquids (w/w units) as well as gases (v/v units).*

A.5.3.2 Classification of Mixtures When Data Are Available for the Mixture Itself

The classification may be modified on a case-by-case basis based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g. statistical analysis, test sensitivity) of germ cell mutagenicity test systems.

A.5.3.3 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

A.5.3.3.1 Where the mixture itself has not been tested to determine its germ cell mutagenicity hazard, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, and Substantially similar mixtures.

A.5.4 Examples of Scientifically Validated Test Methods

A.5.4.1 Examples of *in vivo* heritable germ cell mutagenicity tests are:
(a) Rodent dominant lethal mutation test (OECD 478)
(b) Mouse heritable translocation assay (OECD 485)
(c) Mouse specific locus test

A.5.4.2 Examples of *in vivo* somatic cell mutagenicity tests are:
(a) Mammalian bone marrow chromosome aberration test (OECD 475)
(b) Mouse spot test (OECD 484)
(c) 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

Carcinogen means a substance or a mixture of substances which induce cancer or increase its incidence. Substances and mixtures which have induced benign and malignant tumors in well-performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumor formation is not relevant for humans.

Classification of a substance or mixture as posing a carcinogenic hazard is based on its inherent properties and does not provide information on the level of the human cancer risk which the use of the substance or mixture may represent.

A.6.2 Classification Criteria for Substances[6]

A.6.2.1 For the purpose of classification for carcinogenicity, substances are allocated to one of two categories based on strength of evidence and additional weight of evidence considerations. In certain instances, route-specific classification may be warranted.

FIGURE A.6.1—HAZARD CATEGORIES FOR CARCINOGENS

CATEGORY 1: Known or presumed human carcinogens.

The classification of a substance as a Category 1 carcinogen is done on the basis of epidemiological and/or animal data. This classification is further distinguished on the basis of whether the evidence for classification is largely from human data (Category 1A) or from animal data (Category 1B):

Category 1A: Known to have carcinogenic potential for humans. Classification in this category is largely based on human evidence.

Category 1B: Presumed to have carcinogenic potential for humans. Classification in this category is largely based on animal evidence.

The classification of a substance in Category 1A and 1B is based on strength of evidence together with weight of evidence considerations (See paragraph A.6.2.5). Such evidence may be derived from:

—human studies that establish a causal relationship between human exposure to a substance and the development of cancer (known human carcinogen); or

—animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity (presumed human carcinogen).

In addition, on a case by case basis, scientific judgment may warrant a decision of presumed human carcinogenicity derived from studies showing limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in experimental animals.

CATEGORY 2: Suspected human carcinogens.

the classification to be modified only on a case-by-case evaluation based on available test data for the mixture as a whole.

[6] *See Non-mandatory Appendix F Part A for further guidance regarding hazard classification for carcinogenicity. This appendix is consistent with the GHS adn is provided as guidance excerpted from the International Agency for Research on Cancer (IARC) ''Monographs on the Evaluation of Carcinogenic Risks to Humans'' (2006).*

FIGURE A.6.1—HAZARD CATEGORIES FOR CARCINOGENS—Continued

The classification of a substance in Category 2 is done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1A or B. This classification is based on strength of evidence together with weight of evidence considerations (See paragraph A.6.2.5). Such evidence may be from either limited evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies.
Other considerations: Where the weight of evidence for the carcinogenicity of a substance does not meet the above criteria, any positive study conducted in accordance with established scientific principles, and which reports statistically significant findings regarding the carcinogenic potential of the substance, must be noted on the safety data sheet.

A.6.2.2 Classification as a carcinogen is made on the basis of evidence from reliable and acceptable methods, and is intended to be used for substances which have an intrinsic property to produce such toxic effects. The evaluations are to be based on all existing data, peer-reviewed published studies and additional data accepted by regulatory agencies.

A.6.2.3 *Carcinogen classification* is a one-step, criterion-based process that involves two interrelated determinations: evaluations of strength of evidence and consideration of all other relevant information to place substances with human cancer potential into hazard categories.

A.6.2.4 *Strength of evidence* involves the enumeration of tumors in human and animal studies and determination of their level of statistical significance. Sufficient human evidence demonstrates causality between human exposure and the development of cancer, whereas sufficient evidence in animals shows a causal relationship between the agent and an increased incidence of tumors. Limited evidence in humans is demonstrated by a positive association between exposure and cancer, but a causal relationship cannot be stated. Limited evidence in animals is provided when data suggest a carcinogenic effect, but are less than sufficient. (Guidance on consideration of important factors in the classification of carcinogenicity and a more detailed description of the terms ''limited'' and ''sufficient'' have been developed by the International Agency for Research on Cancer (IARC) and are provided in non-mandatory Appendix F).

A.6.2.5 *Weight of evidence:* Beyond the determination of the strength of evidence for carcinogenicity, a number of other factors should be considered that influence the overall likelihood that an agent may pose a carcinogenic hazard in humans. The full list of factors that influence this determination is very lengthy, but some of the important ones are considered here.

A.6.2.5.1 These factors can be viewed as either increasing or decreasing the level of concern for human carcinogenicity. The relative emphasis accorded to each factor depends upon the amount and coherence of evidence bearing on each. Generally there is a requirement for more complete information to decrease than to increase the level of concern. Additional considerations should be used in evaluating the tumor findings and the other factors in a case-by-case manner.

A.6.2.5.2 Some important factors which may be taken into consideration, when assessing the overall level of concern are:

(a) Tumor type and background incidence;

(b) Multisite responses;

(c) Progression of lesions to malignancy;

(d) Reduced tumor latency;

Additional factors which may increase or decrease the level of concern include:

(e) Whether responses are in single or both sexes;

(f) Whether responses are in a single species or several species;

(g) Structural similarity or not to a substance(s) for which there is good evidence of carcinogenicity;

(h) Routes of exposure;

(i) Comparison of absorption, distribution, metabolism and excretion between test animals and humans;

(j) The possibility of a confounding effect of excessive toxicity at test doses; and,

(k) Mode of action and its relevance for humans, such as mutagenicity, cytotoxicity with growth stimulation, mitogenesis, immunosuppression.

Mutagenicity: It is recognized that genetic events are central in the overall process of cancer development. Therefore evidence of mutagenic activity *in vivo* may indicate that a substance has a potential for carcinogenic effects.

A.6.2.5.3 A substance that has not been tested for carcinogenicity may in certain instances be classified in Category 1A, Category 1B, or Category 2 based on tumor data from a structural analogue together with substantial support from consideration of other important factors such as formation of common significant metabolites, e.g., for benzidine congener dyes.

A.6.2.5.4 The classification should also take into consideration whether or not the substance is absorbed by a given route(s); or whether there are only local tumors at the site of administration for the tested route(s), and adequate testing by other major route(s) show lack of carcinogenicity.

A.6.2.5.5 It is important that whatever is known of the physico-chemical, toxicokinetic and toxicodynamic properties of the substances, as well as any available relevant information on chemical analogues, i.e., structure activity relationship, is taken into consideration when undertaking classification.

A.6.3 Classification Criteria for Mixtures [7]

A.6.3.1 The mixture shall be classified as a carcinogen when at least one ingredient has been classified as a Category 1 or Category 2 carcinogen and is present at or above the appropriate cut-off value/concentration limit as shown in Table A.6.1.

TABLE A.6.1—CUT-OFF VALUES/CONCENTRATION LIMITS OF INGREDIENTS OF A MIXTURE CLASSIFIED AS CARCINOGEN THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE

Ingredient classified as:	Category 1 carcinogen	Category 2 carcinogen
Category 1 carcinogen	≥0.1%	
Category 2 carcinogen		≥0.1% (note 1).

Note: *If a Category 2 carcinogen ingredient is present in the mixture at a concentration between 0.1% and 1%, information is required on the SDS for a product. However, a label warning is optional. If a Category 2 carcinogen ingredient is present in the mixture at a concentration of ≥1%, both an SDS and a label is required and the information must be included on each.*

[7] *It should be noted that the classification criteria for health hazards usually include a tiered scheme in which test data available on the complete mixture are considered as the first tier in the evaluation, followed by the applicable bridging principles, and lastly, cut-off values/concentration limit or additivity. However, this approach is not used for Carcinogenicity. These criteria for Carcinogenicity consider the cut-off values/concentration limits as the primary tier and allow the classification to be modified only on a case-by-case evaluation based on available test data for the mixture as a whole.*

A.6.3.2 Classification of Mixtures When Data Are Available for the Complete Mixture

A mixture may be classified based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g., statistical analysis, test sensitivity) of carcinogenicity test systems.

A.6.3.3 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

Where the mixture itself has not been tested to determine its carcinogenic hazard, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution; Batching; and Substantially similar mixtures.

A.6.4 Classification of Carcinogenicity [8]

A.6.4.1 Chemical manufacturers, importers and employers evaluating chemicals may treat the following sources as establishing that a substance is a carcinogen or potential carcinogen for hazard communication purposes in lieu of applying the criteria described herein:

A.6.4.1.1 National Toxicology Program (NTP), ''Report on Carcinogens'' (latest edition);

A.6.4.1.2 International Agency for Research on Cancer (IARC) ''Monographs on the Evaluation of Carcinogenic Risks to Humans'' (latest editions)

A.6.4.2 Where OSHA has included cancer as a health hazard to be considered by classifiers for a chemical covered by 29 CFR part 1910, Subpart Z, Toxic and Hazardous Substances, chemical manufacturers, importers, and employers shall classify the chemical as a carcinogen.

A.7 REPRODUCTIVE TOXICITY

A.7.1 Definitions and General Considerations

A.7.1.1 *Reproductive toxicity* includes *adverse effects on sexual function and fertility* in adult males and females, as well as *adverse effects on development of the offspring.* Some reproductive toxic effects cannot be clearly assigned to either impairment of sexual function and fertility or to developmental toxicity. Nonetheless, chemicals with these effects shall be classified as reproductive toxicants.

For classification purposes, the known induction of genetically based inheritable effects in the offspring is addressed in *Germ cell mutagenicity* (See A.5).

A.7.1.2 *Adverse effects on sexual function and fertility* means any effect of chemicals that interferes with reproductive ability or sexual capacity. This includes, but is not limited to, alterations to the female and male reproductive system, adverse effects on onset of puberty, gamete production and transport, reproductive cycle normality, sexual behaviour, fertility, parturition, pregnancy outcomes, premature reproductive senescence, or modifications in other functions that are dependent on the integrity of the reproductive systems.

A.7.1.3 *Adverse effects on development of the offspring* means any effect of chemicals which interferes with normal development of the conceptus either before or after birth, which is induced during pregnancy or results from parental exposure. These effects can be manifested at any point in the life span of the organism. The major manifestations of developmental toxicity include death of the developing organism, structural abnormality, altered growth and functional deficiency.

A.7.1.4 Adverse effects on or via lactation are also included in reproductive toxicity, but for classification purposes, such effects are treated separately (See A.7.2.1).

A.7.2 Classification Criteria for Substances

A.7.2.1 For the purpose of classification for reproductive toxicity, substances shall be classified in one of two categories in accordance with Figure A.7.1(a). Effects on sexual function and fertility, and on development, shall be considered. In addition, effects on or via lactation shall be classified in a separate hazard category in accordance with Figure A.7.1(b).

FIGURE A.7.1(a)—HAZARD CATEGORIES FOR REPRODUCTIVE TOXICANTS

CATEGORY 1: Known or presumed human reproductive toxicant.

Substance shall be classified in Category 1 for reproductive toxicity when they are known to have produced an adverse effect on sexual function and fertility or on development in humans or when there is evidence from animal studies, possibly supplemented with other information, to provide a strong presumption that the substance has the capacity to interfere with reproduction in humans. The classification of a substance is further distinguished on the basis of whether the evidence for classification is primarily from human data (Category 1A) or from animal data (Category 1B).

Category 1A: Known human reproductive toxicant.

The classification of a substance in this category is largely based on evidence from humans.

Category 1B: Presumed human reproductive toxicant.

The classification of a substance in this category is largely based on evidence from experimental animals. Data from animal studies shall provide sufficient evidence of an adverse effect on sexual function and fertility or on development in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of other toxic effects. However, when there is mechanistic information that raises doubt about the relevance of the effect for humans, classification in Category 2 may be more appropriate.

CATEGORY 2: Suspected human reproductive toxicant.

Substances shall be classified in Category 2 for reproductive toxicity when there is some evidence from humans or experimental animals, possibly supplemented with other information, of an adverse effect on sexual function and fertility, or on development, in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of the other toxic effects, and where the evidence is not sufficiently convincing to place the substance in Category 1. For instance, deficiencies in the study may make the quality of evidence less convincing, and in view of this, Category 2 would be the more appropriate classification.

FIGURE A.7.1(b)—HAZARD CATEGORY FOR EFFECTS ON OR VIA LACTATION

EFFECTS ON OR VIA LACTATION

Effects on or via lactation shall be classified in a separate single category. Chemicals that are absorbed by women and have been shown to interfere with lactation or that may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed child, shall be classified to indicate this property hazardous to breastfed babies. This classification shall be assigned on the basis of:

(a) absorption, metabolism, distribution and excretion studies that indicate the likelihood the substance would be present in potentially toxic levels in breast milk; and/or

[8] *See Non-mandatory Appendix F for further guidance regarding hazard classification for carcinogenicity and how to relate carcinogenicity classification information from IARC and NTP to GHS.*

FIGURE A.7.1(b)—HAZARD CATEGORY FOR EFFECTS ON OR VIA LACTATION—Continued

(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 × 100)

(c) Fertility index (Number of animals with implants/Number of matings × 100)

(d) Gestation length (If allowed to deliver)

(e) Body weight and body weight change: Consideration of the maternal body weight change and/or adjusted (corrected) maternal body weight shall be included in the evaluation of maternal toxicity whenever such data are available. The calculation of an adjusted (corrected) mean maternal body weight change, which is the difference between the initial and terminal body weight minus the gravid uterine weight (or alternatively, the sum of the weights of the fetuses), may indicate whether the effect is maternal or intrauterine. In rabbits, the body weight gain may not be a useful indicator of maternal toxicity because of normal fluctuations in body weight during pregnancy.

(f) Food and water consumption (if relevant): The observation of a significant decrease in the average food or water consumption in treated dams (mothers) compared to the control group may be useful in evaluating maternal toxicity, particularly when the test material is administered in the diet or drinking water. Changes in food or water consumption must be evaluated in conjunction with maternal body weights when determining if the effects noted are reflective of maternal toxicity or more simply, unpalatability of the test material in feed or water.

(g) Clinical evaluations (including clinical signs, markers, and hematology and clinical chemistry studies): The observation of increased incidence of significant clinical signs of toxicity in treated dams (mothers) relative to the control group is useful in evaluating maternal toxicity. If this is to be used as the basis for the assessment of maternal toxicity, the types, incidence, degree and duration of clinical signs shall be reported in the study. Clinical signs of maternal intoxication include, but are not limited to: coma, prostration, hyperactivity, loss of righting reflex, ataxia, or labored breathing.

(h) Post-mortem data: Increased incidence and/or severity of post-mortem findings may be indicative of maternal toxicity. This can include gross or microscopic pathological findings or organ weight data, including absolute organ weight, organ-to-body weight ratio, or organ-to-brain weight ratio. When supported by findings of adverse histopathological effects in the affected organ(s), the observation of a significant change in the average weight of suspected target organ(s) of treated dams (mothers), compared to those in the control group, may be considered evidence of maternal toxicity.

A.7.2.5 Animal and Experimental Data

A.7.2.5.1 A number of scientifically validated test methods are available, including methods for developmental toxicity testing (e.g., OECD Test Guideline 414, ICH Guideline S5A, 1993), methods for peri- and post-natal toxicity testing (e.g., ICH S5B, 1995), and methods for one or two-generation toxicity testing (e.g., OECD Test Guidelines 415, 416)

A.7.2.5.2 Results obtained from screening tests (e.g., OECD Guidelines 421—Reproduction/Developmental Toxicity Screening Test, and 422—Combined Repeated Dose Toxicity Study with Reproduction/Development Toxicity Screening Test) can also be used to justify classification, although the quality of this evidence is less reliable than that obtained through full studies.

A.7.2.5.3 Adverse effects or changes, seen in short- or long-term repeated dose toxicity studies, which are judged likely to impair reproductive function and which occur in the absence of significant generalized toxicity, may be used as a basis for classification, e.g., histopathological changes in the gonads.

A.7.2.5.4 Evidence from *in vitro* assays, or non-mammalian tests, and from analogous substances using structure-activity relationship (SAR), can contribute to the procedure for classification. In all cases of this nature, expert judgment must be used to assess the adequacy of the data. Inadequate data shall not be used as a primary support for classification.

A.7.2.5.5 It is preferable that animal studies are conducted using appropriate routes of administration which relate to the potential route of human exposure. However, in practice, reproductive toxicity studies are commonly conducted using the oral route, and such studies will normally be suitable for evaluating the hazardous properties of the substance with respect to reproductive toxicity. However, if it can be conclusively demonstrated that the clearly identified mechanism or mode of action has no relevance for humans or when the toxicokinetic differences are so marked that it is certain that the hazardous property will not be expressed in humans then a substance which produces an adverse effect on reproduction in experimental animals should not be classified.

A.7.2.5.6 Studies involving routes of administration such as intravenous or intraperitoneal injection, which may result in exposure of the reproductive organs to unrealistically high levels of the test substance, or elicit local damage to the reproductive organs, e.g., by irritation, must be interpreted with extreme caution and on their own are not normally the basis for classification.

A.7.2.5.7 There is general agreement about the concept of a limit dose, above which the production of an adverse effect may be considered to be outside the criteria which lead to classification. Some test guidelines specify a limit dose, other test guidelines qualify the limit dose with a statement that higher doses may be necessary if anticipated human exposure is sufficiently high that an adequate margin of exposure would not be achieved. Also, due to species differences in toxicokinetics, establishing a specific limit dose may not be adequate for situations where humans are more sensitive than the animal model.

A.7.2.5.8 In principle, adverse effects on reproduction seen only at very high dose levels in animal studies (for example doses that induce prostration, severe inappetence, excessive mortality) do not normally lead to classification, unless other information is available, for example, toxicokinetics information indicating that humans may be more susceptible than animals, to suggest that classification is appropriate.

A.7.2.5.9 However, specification of the actual ''limit dose'' will depend upon the test method that has been employed to provide the test results.

A.7.3 Classification Criteria for Mixtures [9]

A.7.3.1 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

A.7.3.1.1 The mixture shall be classified as a reproductive toxicant when at least one ingredient has been classified as a Category 1 or Category 2 reproductive toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.7.1 for Category 1 and 2, respectively.

A.7.3.1.2 The mixture shall be classified for effects on or via lactation when at least one ingredient has been classified for effects on or via lactation and is present at or above the appropriate cut-off value/concentration limit specified in Table A.7.1 for the additional category for effects on or via lactation.

[9] *It should be noted that the classification criteria for health hazards usually include a tiered scheme in which test data available on the complete mixture are considered as the first tier in the evaluation, followed by the applicable bridging principles, and lastly, cut-off values/concentration limits or additivity. However, this approach is not used for Reproductive Toxicity. These criteria for Reproductive Toxicity consider the cut-off values/concentration limits as the primary tier and allow the classification to be modified only on a case-by-case evaluation based on available test data for the mixture as a whole.*

TABLE A.7.1—CUT-OFF VALUES/CONCENTRATION LIMITS OF INGREDIENTS OF A MIXTURE CLASSIFIED AS REPRODUCTIVE TOXICANTS OR FOR EFFECTS ON OR VIA LACTATION THAT TRIGGER CLASSIFICATION OF THE MIXTURE

Ingredients classified as:	Cut-off values/concentration limits triggering classification of a mixture as:		
	Category 1 reproductive toxicant	Category 2 reproductive toxicant	Additional category for effects on or via lactation
Category 1 reproductive toxicant	≥0.1%		
Category 2 reproductive toxicant		≥0.1%	
Additional category for effects on or via lactation			≥0.1%

A.7.3.2 Classification of Mixtures When Data Are Available for the Complete Mixture

Available test data for the mixture as a whole may be used for classification on a case-by-case basis. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g., statistical analysis, test sensitivity) of reproduction test systems.

A.7.3.3 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

A.7.3.3.1 Where the mixture itself has not been tested to determine its reproductive toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, and Substantially similar mixtures.

A.8 SPECIFIC TARGET ORGAN TOXICITY SINGLE EXPOSURE

A.8.1 Definitions and General Considerations

A.8.1.1 *Specific target organ toxicity—single exposure, (STOT–SE)* means specific, non-lethal target organ toxicity arising from a single exposure to a chemical. 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 organ systemic toxicity single exposure are organized as criteria for substances Categories 1 and 2 (See A.8.2.1), criteria for substances Category 3 (See A.8.2.2) and criteria for mixtures (See A.8.3). See also Figure A.8.1.

A.8.2 Classification Criteria for Substances

A.8.2.1 Substances of Category 1 and Category 2

A.8.2.1.1 Substances shall be classified for immediate or delayed effects separately, by the use of expert judgment on the basis of the weight of all evidence available, including the use of recommended guidance values (See A.8.2.1.9). Substances shall then be classified in Category 1 or 2, depending upon the nature and severity of the effect(s) observed, in accordance with Figure A.8.1.

FIGURE A.8.1—HAZARD CATEGORIES FOR SPECIFIC TARGET ORGAN TOXICITY FOLLOWING SINGLE EXPOSURE

CATEGORY 1: Substances that have produced significant toxicity in humans, or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following single exposure

Substances are classified in Category 1 for STOT–SE on the basis of:

(a) reliable and good quality evidence from human cases or epidemiological studies; or

(b) observations from appropriate studies in experimental animals in which significant and/or severe toxic effects of relevance to human health were produced at generally low exposure concentrations. Guidance dose/concentration values are provided below (See A.8.2.1.9) to be used as part of weight-of-evidence evaluation.

CATEGORY 2: Substances that, on the basis of evidence from studies in experimental animals, can be presumed to have the potential to be harmful to human health following single exposure

Substances are classified in Category 2 for STOT–SE on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations. Guidance dose/concentration values are provided below (See A.8.2.1.9) in order to help in classification.

In exceptional cases, human evidence can also be used to place a substance in Category 2 (See A.8.2.1.6).

CATEGORY 3: Transient target organ effects

There are target organ effects for which a substance does not meet the criteria to be classified in Categories 1 or 2 indicated above. These are effects which adversely alter human function for a short duration after exposure and from which humans may recover in a reasonable period without leaving significant alteration of structure or function. This category only includes narcotic effects and respiratory tract irritation. Substances are classified specifically for these effects as discussed in A.8.2.2.

Note: The primary target organ/system shall be identified where possible, and where this is not possible, the substance shall be identified as a general toxicant. The data shall be evaluated and, where possible, shall not include secondary effects (e.g., a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems).

A.8.2.1.2 The relevant route(s) of exposure by which the classified substance produces damage shall be identified.

A.8.2.1.3 Classification is determined by expert judgment, on the basis of the weight of all evidence available including the guidance presented below.

A.8.2.1.4 Weight of evidence of all available data, including human incidents, epidemiology, and studies conducted in experimental animals is used to substantiate specific target organ toxic effects that merit classification.

A.8.2.1.5 The information required to evaluate specific target organ toxicity comes either from single exposure in humans (e.g., exposure at home, in the workplace or environmentally), or from studies conducted in experimental animals. The standard animal studies in rats or mice that provide this information are acute toxicity studies which can include clinical observations and detailed macroscopic and microscopic examination to enable the toxic effects on target tissues/organs to be identified. Results of acute toxicity studies conducted in other species may also provide relevant information.

A.8.2.1.6 In exceptional cases, based on expert judgment, it may be appropriate to place certain substances with human evidence of target organ toxicity in Category 2: (a) when the weight of human evidence is not sufficiently convincing to warrant Category 1 classification, and/or (b) based on the nature and severity of effects. Dose/concentration levels in humans shall not be considered in the classification and any available evidence from animal studies shall be consistent with the Category 2 classification. In other words, if there are also animal data available on the substance that warrant Category 1 classification, the chemical shall be classified as Category 1.

A.8.2.1.7 Effects considered to support classification for Category 1 and 2

A.8.2.1.7.1 Classification is supported by evidence associating single exposure to the substance with a consistent and identifiable toxic effect.

A.8.2.1.7.2 Evidence from human experience/incidents is usually restricted to reports of adverse health consequences, often with uncertainty about exposure conditions, and may not provide the scientific detail that can be obtained from well-conducted studies in experimental animals.

A.8.2.1.7.3 Evidence from appropriate studies in experimental animals can furnish much more detail, in the form of clinical observations, and macroscopic and microscopic pathological examination and this can often reveal hazards that may not be life-threatening but could indicate functional impairment. Consequently all available evidence, and evidence 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 ≤300	2000 ≥C >300	Guidance values do not apply.
Dermal (rat or rabbit)	mg/kg body weight	C ≤1,000	2000 ≥C >1,000.	
Inhalation (rat) gas	ppmV/4h	C ≤2,500	20,000 ≥C >2,500.	
Inhalation (rat) vapor	mg/1/4h	C ≤10	20 ≥C >10.	
Inhalation (rat) dust/mist/fume.	mg/l/4h	C ≤1.0	5.0 ≥C >1.0.	

A.8.2.1.9.4 The guidance values and ranges mentioned in Table A.8.1 are intended only for guidance purposes, i.e., to be used as part of the weight of evidence approach, and to assist with decisions about classification. They are not intended as strict demarcation values. Guidance values are not provided for Category 3 since this classification is primarily based on human data; animal data may be included in the weight of evidence evaluation.

A.8.2.1.9.5 Thus, it is feasible that a specific profile of toxicity occurs at a dose/concentration below the guidance value, e.g., <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 produced in the exposed population rather than being an isolated idiosyncratic reaction or response triggered only in individuals with hypersensitive airways. Ambiguous reports simply of ''irritation'' should be excluded as this term is commonly used to describe a wide range of sensations including those such as smell, unpleasant taste, a tickling sensation, and dryness, which are outside the scope of classification for respiratory tract irritation;

(d) There are currently no scientifically validated animal tests that deal specifically with RTI; however, useful information may be obtained from the single and repeated inhalation toxicity tests. For example, animal studies may provide useful information in terms of clinical signs of toxicity (dyspnoea, rhinitis etc) and histopathology (e.g., hyperemia, edema, minimal inflammation, thickened mucous layer) which are reversible and may be reflective of the characteristic clinical symptoms described above. Such animal studies can be used as part of weight of evidence evaluation; and,

(e) This special classification will occur only when more severe organ effects including the respiratory system are not observed as those effects would require a higher classification.

A.8.2.2.2 Criteria for narcotic effects

The criteria for classifying substances in Category 3 for narcotic effects are:

(a) Central nervous system depression including narcotic effects in humans such as drowsiness, narcosis, reduced alertness, loss of reflexes, lack of coordination, and vertigo are included. These effects can also be manifested as severe headache or nausea, and can lead to reduced judgment, dizziness, irritability, fatigue, impaired memory function, deficits in perception and coordination, reaction time, or sleepiness; and,

(b) Narcotic effects observed in animal studies may include lethargy, lack of coordination righting reflex, narcosis, and ataxia. If these effects are not transient in nature, then they shall be considered for classification as Category 1 or 2.

A.8.3 Classification Criteria for Mixtures

A.8.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures may be classified for specific target organ toxicity following single exposure, repeated exposure, or both.

A.8.3.2 Classification of Mixtures When Data Are Available for the Complete Mixture

When reliable and good quality evidence from human experience or appropriate studies in experimental animals, as described in the criteria for substances, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of this data. Care shall be exercised in evaluating data on mixtures, that the dose, duration, observation or analysis, do not render the results inconclusive.

A.8.3.3 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

A.8.3.3.1 Where the mixture itself has not been tested to determine its specific target organ toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, or Aerosols.

A.8.3.4 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

A.8.3.4.1 Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, repeated exposure, or both when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.8.2 for Categories 1 and 2, respectively.

TABLE A.8.2—CUT-OFF VALUES/CONCENTRATION LIMITS OF INGREDIENTS OF A MIXTURE CLASSIFIED AS A SPECIFIC TARGET ORGAN TOXICANT THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE AS CATEGORY 1 OR 2

Ingredient classified as:	Cut-off values/concentration limits triggering classification of a mixture as:	
	Category 1	Category 2
Category 1 Target organ toxicant	≥1.0%	
Category 2 Target organ toxicant		≥1.0%

A.8.3.4.2 These cut-off values and consequent classifications shall be applied equally and appropriately to both single- and repeated-dose target organ toxicants.

A.8.3.4.3 Mixtures shall be classified for either or both single and repeated dose toxicity independently.

A.8.3.4.4 Care shall be exercised when toxicants affecting more than one organ system are combined that the potentiation or synergistic interactions are considered, because certain substances can cause target organ toxicity at <1% concentration when other ingredients in the mixture are known to potentiate its toxic effect.

A.8.3.4.5 Care shall be exercised when extrapolating the toxicity of a mixture that contains Category 3 ingredient(s). A cut-off value/concentration limit of 20%, considered as an additive of all Category 3 ingredients for each hazard endpoint, is appropriate; however, this cut-off value/concentration limit may be higher or lower depending on the Category 3 ingredient(s) involved and the fact that some effects such as respiratory tract irritation may not occur below a certain concentration while other effects such as narcotic effects may occur below this 20% value. Expert judgment shall be exercised. Respiratory tract irritation and narcotic effects are to be evaluated separately in accordance with the criteria given in A.8.2.2. When conducting classifications for these hazards, the contribution of each ingredient should be considered additive, unless there is evidence that the effects are not additive.

A.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)* means specific target organ toxicity arising from repeated exposure to a substance or mixture. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in A.1 to A.7 and A.10 of this Appendix are included. Specific target organ toxicity following a single-event exposure is classified in accordance with *SPECIFIC TARGET ORGAN TOXICITY—SINGLE EXPOSURE* (A.8 of this Appendix) and is therefore not included here.

A.9.1.2 Classification identifies the substance or mixture as being a specific target organ toxicant and, as such, it may present a potential for adverse health effects in people who are exposed to it.

A.9.1.3 These adverse health effects produced by repeated exposure include consistent and identifiable toxic effects in humans, or, in experimental animals, toxicologically significant changes which have affected the function or morphology of a tissue/organ, or have produced serious changes to the biochemistry or hematology of the organism and these changes are relevant for human health. Human data will be the primary source of evidence for this hazard class.

A.9.1.4 Assessment shall take into consideration not only significant changes in a single organ or biological system but also generalized changes of a less severe nature involving several organs.

A.9.1.5 Specific target organ toxicity can occur by any route that is relevant for humans, e.g., principally oral, dermal or inhalation.

A.9.2 Classification Criteria for Substances

A.9.2.1 Substances shall be classified as STOT–RE by expert judgment on the basis of the weight of all evidence available, including the use of recommended guidance values which take into account the duration of exposure and the dose/concentration which produced the effect(s), (See A.9.2.9). Substances shall be placed in one of two categories, depending upon the nature and severity of the effect(s) observed, in accordance with Figure A.9.1.

FIGURE A.9.1—HAZARD CATEGORIES FOR SPECIFIC TARGET ORGAN TOXICITY FOLLOWING REPEATED EXPOSURE

CATEGORY 1: Substances that have produced significant toxicity in humans, or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following repeated or prolonged exposure
Substances are classified in Category 1 for specific target organ toxicity (repeated exposure) on the basis of:
(a) reliable and good quality evidence from human cases or epidemiological studies; or,
(b) observations from appropriate studies in experimental animals in which significant and/or severe toxic effects, of relevance to human health, were produced at generally low exposure concentrations. Guidance dose/concentration values are provided below (See A.9.2.9) to be used as part of weight-of-evidence evaluation.
CATEGORY 2: Substances that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to be harmful to human health following repeated or prolonged exposure
Substances are classified in Category 2 for specific target organ toxicity (repeated exposure) on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations. Guidance dose/concentration values are provided below (See A.9.2.9) in order to help in classification.
In exceptional cases human evidence can also be used to place a substance in Category 2 (See A.9.2.6).
Note: The primary target organ/system shall be identified where possible, or the substance shall be identified as a general toxicant. The data shall be carefully evaluated and, where possible, shall not include secondary effects (e.g., a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems).

A.9.2.2 The relevant route of exposure by which the classified substance produces damage shall be identified.

A.9.2.3 Classification is determined by expert judgment, on the basis of the weight of all evidence available including the guidance presented below.

A.9.2.4 Weight of evidence of all data, including human incidents, epidemiology, and studies conducted in experimental animals, is used to substantiate specific target organ toxic effects that merit classification.

A.9.2.5 The information required to evaluate specific target organ toxicity comes either from repeated exposure in humans, e.g., exposure at home, in the workplace or environmentally, or from studies conducted in experimental animals. The standard animal studies in rats or mice that provide this information are 28 day, 90 day or lifetime studies (up to 2 years) that include hematological, clinico-chemical and detailed macroscopic and microscopic examination to enable the toxic effects on target tissues/organs to be identified. Data from repeat dose studies performed in other species may also be used. Other long-term exposure studies, e.g., for carcinogenicity, neurotoxicity or reproductive toxicity, may also provide evidence of specific target organ toxicity that could be used in the assessment of classification.

A.9.2.6 In exceptional cases, based on expert judgment, it may be appropriate to place certain substances with human evidence of specific target organ toxicity in Category 2: (a) when the weight of human evidence is not sufficiently convincing to warrant Category 1 classification, and/or (b) based on the nature and severity of effects. Dose/concentration levels in humans shall not be considered in the classification and any available evidence from animal studies shall be consistent with the Category 2 classification. In other words, if there are also animal data available on the substance that warrant Category 1 classification, the substance shall be classified as Category 1.

A.9.2.7 Effects Considered To Support Classification

A.9.2.7.1 Classification is supported by reliable evidence associating repeated exposure to the substance with a consistent and identifiable toxic effect.

A.9.2.7.2 Evidence from human experience/incidents is usually restricted to reports of adverse health consequences, often with uncertainty about exposure conditions, and may not provide the scientific detail that can be obtained from well-conducted studies in experimental animals.

A.9.2.7.3 Evidence from appropriate studies in experimental animals can furnish much more detail, in the form of clinical observations, hematology, clinical chemistry, macroscopic and microscopic pathological examination and this can often reveal hazards that may not be life-threatening but could indicate functional impairment. Consequently all available evidence, and relevance to human health, must be taken into consideration in the classification process. Relevant toxic effects in humans and/or animals include, but are not limited to:

(a) Morbidity or death resulting from repeated or long-term exposure. Morbidity or death may result from repeated exposure, even to relatively low doses/concentrations, due to bioaccumulation of the substance or its metabolites, or due to the overwhelming of the de-toxification process by repeated exposure;

(b) Significant functional changes in the central or peripheral nervous systems or other organ systems, including signs of central nervous system depression and effects on special senses (e.g., sight, hearing and sense of smell);

(c) Any consistent and significant adverse change in clinical biochemistry, hematology, or urinalysis parameters;

(d) Significant organ damage that may be noted at necropsy and/or subsequently seen or confirmed at microscopic examination;

(e) Multi-focal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;

(f) Morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction (e.g., severe fatty change in the liver); and,

(g) Evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.

A.9.2.8 Effects Considered Not To Support Classification

Effects may be seen in humans and/or animals that do not justify classification. Such effects include, but are not limited to:

(a) Clinical observations or small changes in bodyweight gain, food consumption or water intake that may have some toxicological importance but that do not, by themselves, indicate ''significant'' toxicity;

(b) Small changes in clinical biochemistry, hematology or urinalysis parameters and/or transient effects, when such changes or effects are of doubtful or of minimal toxicological importance;

(c) Changes in organ weights with no evidence of organ dysfunction;

(d) Adaptive responses that are not considered toxicologically relevant;

(e) Substance-induced species-specific mechanisms of toxicity, i.e., demonstrated with reasonable certainty to be not relevant for human health, shall not justify classification.

A.9.2.9 Guidance Values To Assist With Classification Based on the Results Obtained From Studies Conducted in Experimental Animals

A.9.2.9.1 In studies conducted in experimental animals, reliance on observation of effects alone, without reference to the duration of experimental exposure and dose/concentration, omits a fundamental concept of toxicology, i.e., all substances are potentially toxic, and what determines the toxicity is a function of the dose/concentration and the duration of exposure. In most studies conducted in experimental animals the test guidelines use an upper limit dose value.

A.9.2.9.2 In order to help reach a decision about whether a substance shall be classified or not, and to what degree it shall be classified (Category 1 vs. Category 2), dose/concentration ''guidance values'' are provided in Table A.9.1 for consideration of the dose/concentration which has been shown to produce significant health effects. The principal argument for proposing such guidance values is that all chemicals are potentially toxic and there has to be a reasonable dose/concentration above which a degree of toxic effect is acknowledged. Also, repeated-dose studies conducted in experimental animals are designed to produce toxicity at the highest dose used in order to optimize the test objective and so most studies will reveal some toxic effect at least at this highest dose. What is therefore to be decided is not only what effects have been produced, but also at what dose/concentration they were produced and how relevant is that for humans.

A.9.2.9.3 Thus, in animal studies, when significant toxic effects are observed that indicate classification, consideration of the duration of experimental exposure and the dose/concentration at which these effects were seen, in relation to the suggested guidance values, provides useful information to help assess the need to classify (since the toxic effects are a consequence of the hazardous property(ies) and also the duration of exposure and the dose/concentration).

A.9.2.9.4 The decision to classify at all can be influenced by reference to the dose/concentration guidance values at or below which a significant toxic effect has been observed.

A.9.2.9.5 The guidance values refer to effects seen in a standard 90-day toxicity study conducted in rats. They can be used as a basis to extrapolate equivalent guidance values for toxicity studies of greater or lesser duration, using dose/exposure time extrapolation similar to Haber's rule for inhalation, which states essentially that the effective dose is directly proportional to the exposure concentration and the duration of exposure. The assessment should be done on a case-by-case basis; for example, for a 28-day study the guidance values below would be increased by a factor of three.

A.9.2.9.6 Thus for Category 1 classification, significant toxic effects observed in a 90-day repeated-dose study conducted in experimental animals and seen to occur at or below the (suggested) guidance values (C) as indicated in Table A.9.1 would justify classification:

TABLE A.9.1—GUIDANCE VALUES TO ASSIST IN CATEGORY 1 CLASSIFICATION

[Applicable to a 90-day study]

Route of exposure	Units	Guidance values (dose/concentration)
Oral (rat)	mg/kg body weight/day	C ≤10.
Dermal (rat or rabbit)	mg/kg body weight/day	C ≤20.
Inhalation (rat) gas	ppmV/6h/day	C ≤50.
Inhalation (rat) vapor	mg/liter/6h/day	C ≤0.2.
Inhalation (rat) dust/mist/fume	mg/liter/6h/day	C ≤0.02.

A.9.2.9.7 For Category 2 classification, significant toxic effects observed in a 90-day repeated-dose study conducted in experimental animals and seen to occur within the (suggested) guidance value ranges as indicated in Table A.9.2 would justify classification:

TABLE A.9.2—GUIDANCE VALUES TO ASSIST IN CATEGORY 2 CLASSIFICATION

[Applicable to a 90-day study]

Route of exposure	Units	Guidance values (dose/concentration)
Oral (rat)	mg/kg body weight/day	10 <C ≤100.
Dermal (rat or rabbit)	mg/kg body weight/day	20 <C ≤200.
Inhalation (rat) gas	ppmV/6h/day	50 <C ≤250.
Inhalation (rat) vapor	mg/liter/6h/day	0.2 <C ≤1.0.
Inhalation (rat) dust/mist/fume	mg/liter/6h/day	0.02 <C ≤0.2.

A.9.2.9.8 The guidance values and ranges mentioned in A.2.9.9.6 and A.2.9.9.7 are intended only for guidance purposes, i.e., to be used as part of the weight of evidence approach, and to assist with decisions about classification. They are not intended as strict demarcation values.

A.9.2.9.9 Thus, it is possible that a specific profile of toxicity occurs in repeat-dose animal studies at a dose/concentration below the guidance value, e.g., <100 mg/kg body weight/day by the oral route, however the nature of the effect, e.g., nephrotoxicity seen only in male rats of a particular strain known to be susceptible to this effect, may result in the decision not to classify. Conversely, a specific profile of toxicity may be seen in animal studies occurring at above a guidance value, e.g., ≥100 mg/kg body weight/day by the oral route, and in addition there is supplementary information from other sources, e.g., other long-term administration studies, or human case experience, which supports a conclusion that, in view of the weight of evidence, classification is prudent.

A.9.2.10 Other Considerations

A.9.2.10.1 When a substance is characterized only by use of animal data the classification process includes reference to dose/concentration guidance values as one of the elements that contribute to the weight of evidence approach.

A.9.2.10.2 When well-substantiated human data are available showing a specific target organ toxic effect that can be reliably attributed to repeated or prolonged exposure to a substance, the substance shall be classified. Positive human data, regardless of probable dose, predominates over animal data. Thus, if a substance is unclassified because no specific target organ toxicity was seen at or below the dose/concentration guidance value for animal testing, if subsequent human incident data become available showing a specific target organ toxic effect, the substance shall be classified.

A.9.2.10.3 A substance that has not been tested for specific target organ toxicity may in certain instances, where appropriate, be classified on the basis of data from a scientifically validated structure activity relationship and expert judgment-based extrapolation from a structural analogue that has previously been classified together with substantial support from consideration of other important factors such as formation of common significant metabolites.

A.9.3 Classification Criteria for Mixtures

A.9.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures may be classified for specific target organ toxicity following single exposure, repeated exposure, or both.

A.9.3.2 Classification of Mixtures When Data Are Available for the Complete Mixture

When reliable and good quality evidence from human experience or appropriate studies in experimental animals, as described in the criteria for substances, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of these data. Care shall be exercised in evaluating data on mixtures, that the dose, duration, observation or analysis, do not render the results inconclusive.

A.9.3.3 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

A.9.3.3.1 Where the mixture itself has not been tested to determine its specific target organ toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution; Batching; Concentration of mixtures; Interpolation within one toxicity category; Substantially similar mixtures; and Aerosols.

A.9.3.4 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

A.9.3.4.1 Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, repeated exposure, or both when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.9.3 for Category 1 and 2 respectively.

TABLE A.9.3—CUT-OFF VALUE/CONCENTRATION LIMITS OF INGREDIENTS OF A MIXTURE CLASSIFIED AS A SPECIFIC TARGET ORGAN TOXICANT THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE AS CATEGORY 1 OR 2

Ingredient classified as:	Cut-off values/concentration limits triggering classification of a mixture as:	
	Category 1	Category 2
Category 1 Target organ toxicant	≥1.0%	
Category 2 Target organ toxicant		≥1.0%

A.9.3.4.2 These cut-off values and consequent classifications shall be applied equally and appropriately to both single- and repeated-dose target organ toxicants.

A.9.3.4.3 Mixtures shall be classified for either or both single- and repeated-dose toxicity independently.

A.9.3.4.4 Care shall be exercised when toxicants affecting more than one organ system are combined that the potentiation or synergistic interactions are considered, because certain substances can cause specific target organ toxicity at <1% concentration when other ingredients in the mixture are known to potentiate its toxic effect.

A.10 ASPIRATION HAZARD

A.10.1 Definitions and General and Specific Considerations

A.10.1.1 *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.10.1.2 Aspiration toxicity includes severe acute effects such as chemical pneumonia, varying degrees of pulmonary injury or death following aspiration.

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 (See note); or (b) If it is a hydrocarbon and has a kinematic viscosity ≤20.5 mm^2/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 toxicity 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 A mixture which contains ≥10% of an ingredient or ingredients classified in Category 1, and has a kinematic viscosity ≤20.5 mm^2/s, measured at 40 °C, shall be classified in Category 1.

A.10.3.3.2 In the case of a mixture which separates into two or more distinct layers, one of which contains ≥10% of an ingredient or ingredients classified in Category 1 and has a kinematic viscosity ≤20.5 mm^2/s, measured at 40 °C, then the entire mixture shall be classified in Category 1.

APPENDIX B TO § 1910.1200—PHYSICAL 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) above 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 contain only extremely insensitive detonating chemicals and which demonstrate a negligible probability of accidental initiation or propagation.

B.1.3 Additional Classification Considerations

B.1.3.1 Explosives shall be classified as unstable explosives or shall be assigned to one of the six divisions identified in B.1.2 in accordance with the three step procedure in Part I of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6). The first step is to ascertain whether the substance or mixture has explosive effects (Test Series 1). The second step is the acceptance procedure (Test Series 2 to 4) and the third step is the assignment to a hazard division (Test Series 5 to 7). The assessment whether a candidate for ''ammonium nitrate emulsion or suspension or gel, intermediate for blasting explosives (ANE)'' is insensitive enough for inclusion as an oxidizing liquid (See B.13) or an oxidizing solid (See B.14) is determined by Test Series 8 tests.

Note: 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.1.3.2 Explosive properties are associated with the presence of certain chemical groups in a molecule which can react to produce very rapid increases in temperature or pressure. The screening procedure in B.1.3.1 is aimed at identifying the presence of such reactive groups and the potential for rapid energy release. If the screening procedure identifies the chemical as a potential explosive, the acceptance procedure (See section 10.3 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6)) is necessary for classification.

Note: Neither a Series 1 type (a) propagation of detonation test nor a Series 2 type (a) test of sensitivity to detonative shock is necessary if the exothermic decomposition energy of organic materials is less than 800 J/g.

B.1.3.3 If a mixture contains any known explosives, the acceptance procedure is necessary for classification.

B.1.3.4 A chemical is not classified as explosive if:

(a) There are no chemical groups associated with explosive properties present in the molecule. Examples of groups which may indicate explosive properties are given in Table A6.1 in Appendix 6 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6); or

(b) The substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than −200.

The oxygen balance is calculated for the chemical reaction:

$C_xH_yO_z + [x + (y/4) - (z/2)]\ O_2 \rightarrow x.\ CO_2 + (y/2)\ H_2O$

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).

B.2.2 Classification Criteria

A flammable gas shall be classified in one of the two categories for this class in accordance with Table B.2.1:

TABLE B.2.1—CRITERIA FOR FLAMMABLE GASES

Category	Criteria
1	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 flammable limit.
2	Gases, other than those of Category 1, 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: Aerosols should not be classified as flammable gases. See B.3.

B.2.3 Additional Classification Considerations

Flammability shall be determined by tests or by calculation in accordance with ISO 10156 (incorporated by reference; See § 1910.6). Where insufficient data are available to use this method, equivalent validated methods may be used.

B.3 FLAMMABLE AEROSOLS

B.3.1 Definition

Aerosol means any non-refillable receptacle containing a gas compressed, liquefied or dissolved under pressure, and fitted with a release device allowing the contents to be ejected as particles in suspension in a gas, or as a foam, paste, powder, liquid or gas.

B.3.2 Classification Criteria

B.3.2.1 Aerosols shall be considered for classification as flammable if they contain any component which is classified as flammable in accordance with this Appendix, i.e.:

Flammable liquids (See B.6);
Flammable gases (See B.2);
Flammable solids (See B.7).

Note 1: Flammable components do not include pyrophoric, self-heating or water-reactive chemicals.

Note 2: Flammable aerosols do not fall additionally within the scope of flammable gases, flammable liquids, or flammable solids.

B.3.2.2 A flammable aerosol shall be classified in one of the two categories for this class in accordance with Table B.3.1.

TABLE B.3.1—CRITERIA FOR FLAMMABLE AEROSOLS

Category	Criteria
1	Contains ≥85% flammable components and the chemical heat of combustion is ≥30 kJ/g; or (a) For spray aerosols, in the ignition distance test, ignition occurs at a distance ≥75 cm (29.5 in), or (b) For foam aerosols, in the aerosol foam flammability test. (i) The flame height is ≥20 cm (7.87 in) and the flame duration ≥2 s; or (ii) The flame height is ≥4 cm (1.57 in) and the flame duration ≥7 s.
2	Contains >1% flammable components, or the heat of combustion is ≥20 kJ/g; and (a) for spray aerosols, in the ignition distance test, ignition occurs at a distance ≥15 cm (5.9 in), or in the enclosed space ignition test, the (i) Time equivalent is ≤300 s/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.

Note: Aerosols not submitted to the flammability classification procedures in this Appendix shall be classified as extremely flammable (Category 1).

B.3.3 Additional Classification Considerations

B.3.3.1 To classify a flammable aerosol, data on its flammable components, on its chemical heat of combustion and, if applicable, the results of the aerosol foam flammability test (for foam aerosols) and of the ignition distance test and enclosed space test (for spray aerosols) are necessary.

B.3.3.2 The chemical heat of combustion (ΔHc), in kilojoules per gram (kJ/g), is the product of the theoretical heat of combustion (ΔHcomb), and a combustion efficiency, usually less than 1.0 (a typical combustion efficiency is 0.95 or 95%).

For a composite aerosol formulation, the chemical heat of combustion is the summation of the weighted heats of combustion for the individual components, as follows:

$$\Delta Hc\ (\text{product}) = \sum_{i}^{n} [\ wi\% \times \Delta Hc(i)]$$

Where:

ΔHc = chemical heat of combustion (kJ/g);
wi% = mass fraction of component i in the product;
ΔHc(i) = specific heat of combustion (kJ/g) of component i in the product;

The chemical heats of combustion shall be found in literature, calculated or determined by tests (See ASTM D240–02, ISO 13943, Sections 86.1 to 86.3, and NFPA 30B (incorporated by reference; See § 1910.6)).

B.3.3.3 The Ignition Distance Test, Enclosed Space Ignition Test and Aerosol Foam Flammability Test shall be performed in accordance with sub-sections 31.4, 31.5 and 31.6 of the of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6).

B.4 OXIDIZING GASES

B.4.1 Definition

Oxidizing gas means any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.

Note: ''Gases which cause or contribute to the combustion of other material more than air does'' means pure gases or gas mixtures with an oxidizing power greater than 23.5% (as determined by a method specified in ISO 10156 or 10156–2 (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 (incorporated by reference; See § 1910.6) and ISO 10156–2 (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, 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 (−8 °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.*

B.6 FLAMMABLE LIQUIDS

B.6.1 Definition

Flammable liquid means a liquid having a flash point of not more than 93 °C (199.4 °F).

Flash point means the minimum temperature at which a liquid gives off vapor in sufficient concentration to form an ignitable mixture with air near the surface of the liquid, as determined by a method identified in Section B.6.3.

B.6.2 Classification Criteria

A flammable liquid shall be classified in one of four categories in accordance with Table B.6.1:

TABLE B.6.1—CRITERIA FOR FLAMMABLE LIQUIDS

Category	Criteria
1	Flash point <23 °C (73.4 °F) and initial boiling point ≤35 °C (95 °F).

TABLE B.6.1—CRITERIA FOR FLAMMABLE LIQUIDS—Continued

Category	Criteria
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).

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 other method specified in GHS Revision 3, 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).

B.7 FLAMMABLE SOLIDS

B.7.1 Definitions

Flammable solid means a solid which is a readily combustible solid, or which may cause or contribute to fire through friction.

Readily combustible solids are powdered, granular, or pasty chemicals which are dangerous if they can be easily ignited by brief contact with an ignition source, such as a burning match, and if the flame spreads rapidly.

B.7.2 Classification Criteria

B.7.2.1 Powdered, granular or pasty chemicals shall be classified as flammable solids when the time of burning of one or more of the test runs, performed in accordance with the test method described in the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), Part III, sub-section 33.2.1, is less than 45 s or the rate of burning is more than 2.2 mm/s (0.0866 in/s).

B.7.2.2 Powders of metals or metal alloys shall be classified as flammable solids when they can be ignited and the reaction spreads over the whole length of the sample in 10 min or less.

B.7.2.3 Solids which may cause fire through friction shall be classified in this class by analogy with existing entries (e.g., matches) until definitive criteria are established.

B.7.2.4 A flammable solid shall be classified in one of the two categories for this class using Method N.1 as described in Part III, sub-section 33.2.1 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), in accordance with Table B.7.1:

TABLE B.7.1—CRITERIA FOR FLAMMABLE SOLIDS

Category	Criteria
1	Burning rate test: Chemicals other than metal powders: (a) Wetted zone does not stop fire; and (b) Burning time <45 s or burning rate >2.2 mm/s. Metal powders: Burning time ≤5 min.
2	Burning rate test: 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: 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.8 SELF-REACTIVE CHEMICALS

B.8.1 Definitions

Self-reactive chemicals are thermally unstable liquid or solid chemicals liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). This definition excludes chemicals classified under this section as explosives, organic peroxides, oxidizing liquids or oxidizing solids.

A self-reactive chemical is regarded as possessing explosive properties when in laboratory testing the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement.

B.8.2 Classification Criteria

B.8.2.1 A self-reactive chemical shall be considered for classification in this class unless:

(a) It is classified as an explosive according to B.1 of this appendix;

(b) It is classified as an oxidizing liquid or an oxidizing solid according to B.13 or B.14 of this appendix, except that a mixture of oxidizing substances which contains 5% or more of combustible organic substances shall be classified as a self-reactive chemical according to the procedure defined in B.8.2.2;

(c) It is classified as an organic peroxide according to B.15 of this appendix;

(d) Its heat of decomposition is less than 300 J/g; or

(e) Its self-accelerating decomposition temperature (SADT) is greater than 75 °C (167 °F) for a 50 kg (110 lb) package.

B.8.2.2 Mixtures of oxidizing substances, meeting the criteria for classification as oxidizing liquids or oxidizing solids, which contain 5% or more of combustible organic substances and which do not meet the criteria mentioned in B.8.2.1 (a), (c), (d) or (e), shall be subjected to the self-reactive chemicals classification procedure in B.8.2.3. Such a mixture showing the properties of a self-reactive chemical type B to F shall be classified as a self-reactive chemical.

B.8.2.3 Self-reactive chemicals shall be classified in one of the seven categories of ''types A to G'' for this class, according to the following principles:

(a) Any self-reactive chemical which can detonate or deflagrate rapidly, as packaged, will be defined as self-reactive chemical TYPE A;

(b) Any self-reactive chemical possessing explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package will be defined as self-reactive chemical TYPE B;

(c) Any self-reactive chemical possessing explosive properties when the chemical as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion will be defined as self-reactive chemical TYPE C;

(d) Any self-reactive chemical which in laboratory testing meets the criteria in (d)(i), (ii), or (iii) will be defined as self-reactive chemical TYPE D:

(i) Detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or

(ii) Does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement; or

(iii) Does not detonate or deflagrate at all and shows a medium effect when heated under confinement;

(e) Any self-reactive chemical which, in laboratory testing, neither detonates nor deflagrates at all and shows low or no effect when heated under confinement will be defined as self-reactive chemical TYPE E;

(f) Any self-reactive chemical which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power will be defined as self-reactive chemical TYPE F;

(g) Any self-reactive chemical which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (self-accelerating decomposition temperature is 60 °C (140 °F) to 75 °C (167 °F) for a 50 kg (110 lb) package), and, for liquid mixtures, a diluent having a boiling point greater than or equal to 150 °C (302 °F) is used for desensitization will be defined as self-reactive chemical TYPE G. If the mixture is not thermally stable or a diluent having a boiling point less than 150 °C (302 °F) is used for desensitization, the mixture shall be defined as self-reactive chemical TYPE F.

B.8.3 Additional Classification Considerations

B.8.3.1 For purposes of classification, the properties of self-reactive chemicals shall be determined in accordance with test series A to H as described in Part II of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6).

B.8.3.2 Self-accelerating decomposition temperature (SADT) shall be determined in accordance with the UN ST/SG/AC.10, Part II, section 28 (incorporated by reference; See § 1910.6).

B.8.3.3 The classification procedures for self-reactive substances and mixtures need not be applied if:

(a) There are no chemical groups present in the molecule associated with explosive or self-reactive properties; examples of such groups are given in Tables A6.1 and A6.2 in the Appendix 6 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6); or

(b) For a single organic substance or a homogeneous mixture of organic substances, the estimated SADT is greater than 75 °C (167 °F) or the exothermic decomposition energy is less than 300 J/g. The onset temperature and decomposition energy may be estimated using a suitable calorimetric technique (See 20.3.3.3 in Part II of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6)).

B.9 PYROPHORIC LIQUIDS

B.9.1 Definition

Pyrophoric liquid means a liquid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air.

B.9.2 Classification Criteria

A pyrophoric liquid shall be classified in a single category for this class using test N.3 in Part III, sub-section 33.3.1.5 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), in accordance with Table B.9.1:

TABLE B.9.1—CRITERIA FOR PYROPHORIC LIQUIDS

Category	Criteria
1	The liquid ignites within 5 min when added to an inert carrier and exposed to air, or it ignites or chars a filter paper on contact with air within 5 min.

B.9.3 Additional Classification Considerations

The classification procedure for pyrophoric liquids need not be applied when experience in production or handling shows that the chemical does not ignite spontaneously on coming into contact with air at normal temperatures (i.e., the substance is known to be stable at room temperature for prolonged periods of time (days)).

B.10 PYROPHORIC SOLIDS

B.10.1 Definition

Pyrophoric solid means a solid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air.

B.10.2 Classification Criteria

A pyrophoric solid shall be classified in a single category for this class using test N.2 in Part III, sub-section 33.3.1.4 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), in accordance with Table B.10.1:

TABLE B.10.1—CRITERIA FOR PYROPHORIC SOLIDS

Category	Criteria
1	The solid ignites within 5 min of coming into contact with air.

Note: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.10.3 Additional Classification Considerations

The classification procedure for pyrophoric solids need not be applied when experience in production or handling shows that the chemical does not ignite spontaneously on coming into contact with air at normal temperatures (i.e., the chemical is known to be stable at room temperature for prolonged periods of time (days)).

B.11 SELF-HEATING CHEMICALS

B.11.1 Definition

A *self-heating chemical* is a solid or liquid chemical, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat; this chemical differs from a pyrophoric liquid or solid in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days).

Note: Self-heating of a substance or mixture is a process where the gradual reaction of that substance or mixture with oxygen (in air) generates heat. If the rate of heat production exceeds the rate of heat loss, then the temperature of the substance or mixture will rise which, after an induction time, may lead to self-ignition and combustion.

B.11.2 Classification Criteria

B.11.2.1 A self-heating chemical shall be classified in one of the two categories for this class if, in tests performed in accordance with test method N.4 in Part III, sub-section 33.3.1.6 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), the result meets the criteria shown in Table B.11.1.

TABLE B.11.1—CRITERIA FOR SELF-HEATING CHEMICALS

Category	Criteria
1	A positive result is obtained in a test using a 25 mm sample cube at 140 °C (284 °F).
2	A negative result is obtained in a test using a 25 mm cube sample at 140 °C (284 °F), a positive result is obtained in a test using a 100 mm sample cube at 140 °C (284 °F), and: (a) The unit volume of the chemical is more than 3 m^3; or (b) A positive result is obtained in a test using a 100 mm cube sample at 120 °C (248 °F) and the unit volume of the chemical is more than 450 liters; or (c) A positive result is obtained in a test using a 100 mm cube sample at 100 °C (212 °F).

B.11.2.2 Chemicals with a temperature of spontaneous combustion higher than 50 °C (122 °F) for a volume of 27 m^3 shall not be classified as self-heating chemicals.

B.11.2.3 Chemicals with a spontaneous ignition temperature higher than 50 °C (122 °F) for a volume of 450 liters shall not be classified in Category 1 of this class.

B.11.3 Additional Classification Considerations

B.11.3.1 The classification procedure for self-heating chemicals need not be applied if the results of a screening test can be adequately correlated with the classification test and an appropriate safety margin is applied.

B.11.3.2 Examples of screening tests are:

(a) The Grewer Oven test (VDI guideline 2263, part 1, 1990, Test methods for the Determination of the Safety Characteristics of Dusts) with an onset temperature 80°K above the reference temperature for a volume of 1 *l;*

(b) The Bulk Powder Screening Test (Gibson, N. Harper, D. J. Rogers, R. Evaluation of the fire and explosion risks in drying powders, Plant Operations Progress, 4 (3), 181–189, 1985) with an onset temperature 60°K above the reference temperature for a volume of 1 *l.*

B.12 CHEMICALS WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES

B.12.1 Definition

Chemicals which, in contact with water, emit flammable gases are solid or liquid chemicals which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities.

B.12.2 Classification Criteria

B.12.2.1 A chemical which, in contact with water, emits flammable gases shall be classified in one of the three categories for this class, using test N.5 in Part III, sub-section 33.4.1.4 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), in accordance with Table B.12.1:

TABLE B.12.1—CRITERIA FOR CHEMICALS WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES

Category	Criteria
1	Any chemical which reacts vigorously with water at ambient temperatures and demonstrates generally a tendency for the gas produced to ignite spontaneously, or which reacts readily with water at ambient temperatures such that the rate of evolution of flammable gas is equal to or greater than 10 liters per kilogram of chemical over any one minute.
2	Any chemical which reacts readily with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 20 liters per kilogram of chemical per hour, and which does not meet the criteria for Category 1.
3	Any chemical which reacts slowly with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 1 liter per kilogram of chemical per hour, and which does not meet the criteria for Categories 1 and 2.

Note: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.12.2.2 A chemical is classified as a chemical which, in contact with water emits flammable gases if spontaneous ignition takes place in any step of the test procedure.

B.12.3 Additional Classification Considerations

The classification procedure for this class need not be applied if:

(a) The chemical structure of the chemical does not contain metals or metalloids;

(b) Experience in production or handling shows that the chemical does not react with water, (e.g., the chemical is manufactured with water or washed with water); or

(c) The chemical is known to be soluble in water to form a stable mixture.

B.13 OXIDIZING LIQUIDS

B.13.1 Definition

Oxidizing liquid means a liquid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

B.13.2 Classification Criteria

An oxidizing liquid shall be classified in one of the three categories for this class using test O.2 in Part III, sub-section 34.4.2 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), in accordance with Table B.13.1:

TABLE B.13.1—CRITERIA FOR OXIDIZING LIQUIDS

Category	Criteria
1	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, spontaneously ignites; or the mean pressure rise time of a 1:1 mixture, by mass, of chemical and cellulose is less than that of a 1:1 mixture, by mass, of 50% perchloric acid and cellulose;

TABLE B.13.1—CRITERIA FOR OXIDIZING LIQUIDS—Continued

Category	Criteria
2	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 40% aqueous sodium chlorate solution and cellulose; and the criteria for Category 1 are not met;
3	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 65% aqueous nitric acid and cellulose; and the criteria for Categories 1 and 2 are not met.

B.13.3 Additional Classification Considerations

B.13.3.1 For organic chemicals, the classification procedure for this class shall not be applied if:

(a) The chemical does not contain oxygen, fluorine or chlorine; or

(b) The chemical contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.

B.13.3.2 For inorganic chemicals, the classification procedure for this class shall not be applied if the chemical does not contain oxygen or halogen atoms.

B.13.3.3 In the event of divergence between test results and known experience in the handling and use of chemicals which shows them to be oxidizing, judgments based on known experience shall take precedence over test results.

B.13.3.4 In cases where chemicals generate a pressure rise (too high or too low), caused by chemical reactions not characterizing the oxidizing properties of the chemical, the test described in Part III, sub-section 34.4.2 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6) shall be repeated with an inert substance (e.g., diatomite (kieselguhr)) in place of the cellulose in order to clarify the nature of the reaction.

B.14 OXIDIZING SOLIDS

B.14.1 Definition

Oxidizing solid means a solid which, while in itself is not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

B.14.2 Classification Criteria

An oxidizing solid shall be classified in one of the three categories for this class using test O.1 in Part III, sub-section 34.4.1 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), in accordance with Table B.14.1:

TABLE B.14.1—CRITERIA FOR OXIDIZING SOLIDS

Category	Criteria
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.
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.
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.

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'' (IMO: Code of Safe Practice for Solid Bulk Cargoes, 2005, Annex 3, Test 5) may be used to assess this hazard. When information indicates that an oxidizing solid may present an explosion hazard, it shall be indicated on the Safety Data Sheet.

Note 2: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.14.3 Additional Classification Considerations

B.14.3.1 For organic chemicals, the classification procedure for this class shall not be applied if:

(a) The chemical does not contain oxygen, fluorine or chlorine; or

(b) The chemical contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.

B.14.3.2 For inorganic chemicals, the classification procedure for this class shall not be applied if the chemical does not contain oxygen or halogen atoms.

B.14.3.3 In the event of divergence between test results and known experience in the handling and use of chemicals which shows them to be oxidizing, judgements based on known experience shall take precedence over test results.

B.15 ORGANIC PEROXIDES

B.15.1 Definition

B.15.1.1 *Organic peroxide* means a liquid or solid organic chemical which contains the bivalent –0–0– structure and as such is considered a derivative of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term organic peroxide includes organic peroxide mixtures containing at least one organic peroxide. Organic peroxides are thermally unstable chemicals, which may undergo exothermic self-accelerating decomposition. In addition, they may have one or more of the following properties:

(a) Be liable to explosive decomposition;

(b) Burn rapidly;

(c) Be sensitive to impact or friction;

(d) React dangerously with other substances.

B.15.1.2 An organic peroxide is regarded as possessing explosive properties when in laboratory testing the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement.

B.15.2 Classification Criteria

B.15.2.1 Any organic peroxide shall be considered for classification in this class, unless it contains:

(a) Not more than 1.0% available oxygen from the organic peroxides when containing not more than 1.0% hydrogen peroxide; or

(b) Not more than 0.5% available oxygen from the organic peroxides when containing more than 1.0% but not more than 7.0% hydrogen peroxide.

Note: The available oxygen content (%) of an organic peroxide mixture is given by the formula:

$$16 \times \sum_{i}^{n} \left(\frac{n_i \times c_i}{m_i} \right)$$

Where:

n_i = number of peroxygen groups per molecule of organic peroxide i;

c_i = concentration (mass %) of organic peroxide i;

m_i = molecular mass of organic peroxide i.

B.15.2.2 Organic peroxides shall be classified in one of the seven categories of ''Types A to G'' for this class, according to the following principles:

(a) Any organic peroxide which, as packaged, can detonate or deflagrate rapidly shall be defined as organic peroxide TYPE A;

(b) Any organic peroxide possessing explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package shall be defined as organic peroxide TYPE B;

(c) Any organic peroxide possessing explosive properties when the chemical as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion shall be defined as organic peroxide TYPE C;

(d) Any organic peroxide which in laboratory testing meets the criteria in (d)(i), (ii), or (iii) shall be defined as organic peroxide TYPE D:

(i) Detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or

(ii) Does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement; or

(iii) Does not detonate or deflagrate at all and shows a medium effect when heated under confinement;

(e) Any organic peroxide which, in laboratory testing, neither detonates nor deflagrates at all and shows low or no effect when heated under confinement shall be defined as organic peroxide TYPE E;

(f) Any organic peroxide which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power shall be defined as organic peroxide TYPE F;

(g) Any organic peroxide which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (self-accelerating decomposition temperature is 60 °C (140 °F) or higher for a 50 kg (110 lb) package), and, for liquid mixtures, a diluent having a boiling point of not less than 150 °C (302 °F) is used for desensitization, shall be defined as organic peroxide TYPE G. If the organic peroxide is not thermally stable or a diluent having a boiling point less than 150 °C (302 °F) is used for desensitization, it shall be defined as organic peroxide TYPE F.

B.15.3 Additional Classification Considerations

B.15.3.1 For purposes of classification, the properties of organic peroxides shall be determined in accordance with test series A to H as described in Part II of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6).

B.15.3.2 Self-accelerating decomposition temperature (SADT) shall be determined in accordance with the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), Part II, section 28.

B.15.3.3 Mixtures of organic peroxides may be classified as the same type of organic peroxide as that of the most dangerous ingredient. However, as two stable ingredients can form a thermally less stable mixture, the SADT of the mixture shall be determined.

B.16 CORROSIVE TO METALS

B.16.1 Definition

A *chemical which is corrosive to metals* means a chemical which by chemical action will materially damage, or even destroy, metals.

B.16.2 Classification Criteria

A chemical which is corrosive to metals shall be classified in a single category for this class, using the test in Part III, sub-section 37.4 of the UN ST/SG/AC.10 (incorporated by reference; See § 1910.6), in accordance with Table B.16.1:

TABLE B.16.1—CRITERIA FOR CHEMICALS CORROSIVE TO METAL

Category	Criteria
1	Corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm per year at a test temperature of 55 °C (131 °F) when tested on both materials.

Note: Where an initial test on either steel or aluminium indicates the chemical being tested is corrosive, the follow-up test on the other metal is not necessary.

B.16.3 Additional Classification Considerations

The specimen to be used for the test shall be made of the following materials:

(a) For the purposes of testing steel, steel types S235JR+CR (1.0037 resp.St 37–2), S275J2G3+CR (1.0144 resp.St 44–3), ISO 3574, Unified Numbering System (UNS) G 10200, or SAE 1020;

(b) For the purposes of testing aluminium: Non-clad types 7075–T6 or AZ5GU–T6.

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.

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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

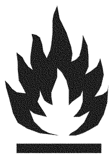
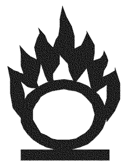
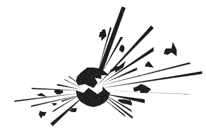
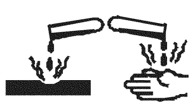
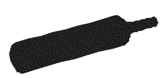
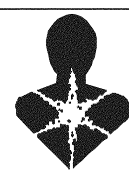
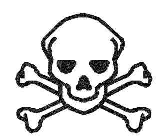
Flame	Flame Over Circle	Exclamation Mark	Exploding Bomb
 Flammables Self Reactives Pyrophorics Self-heating Emits Flammable Gas Organic Peroxides	 Oxidizers	 Irritant Dermal Sensitizer Acute Toxicity (harmful) Narcotic Effects Respiratory Tract Irritation	 Explosives Self Reactives Organic Peroxides
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 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 C.4 for the same hazard shall not appear.

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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 In most cases, the precautionary statements are independent (e.g., the phrases for explosive hazards do not modify those related to certain health hazards, and products that are classified for both hazard classes shall bear appropriate precautionary statements for both). Where a chemical is classified for a number of hazards, and the precautionary statements are similar, the most stringent shall be included on the label (this will be applicable mainly to preventive measures). An order of precedence may be imposed by the chemical manufacturer, importer or responsible party in situations where phrases concern ''Response.'' Rapid action may be crucial. For example, if a chemical is carcinogenic and acutely toxic, rapid action may be crucial, and first aid measures for acute toxicity will take precedence over those for long-term effects. In addition, medical attention to delayed health effects may be required in cases of incidental exposure, even if not associated with immediate symptoms of intoxication.

C.2.4.8 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.3 Supplementary Hazard Information

C.3.1 To ensure that non-standardized information does not lead to unnecessarily wide variation or undermine the required information, supplementary information on the label is limited to when it provides further detail and does not contradict or cast doubt on the validity of the standardized hazard information.

C.3.2 Where the chemical manufacturer, importer, or distributor chooses to add supplementary information on the label, the placement of supplemental information shall not impede identification of information required by this section.

C.3.3 Where an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥1%, and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required on the label.

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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)

Pictogram
Skull and crossbones

Hazard category	Signal word	Hazard statement
1	Danger	Fatal if swallowed
2	Danger	Fatal if swallowed

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash …thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**If swallowed: Immediately call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see … on this label)** … Reference to supplemental first aid instruction. - *if immediate administration of antidote is required*. **Rinse mouth.**	**Store locked up.**	**Dispose of contents/container to…** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.1 ACUTE TOXICITY – ORAL (CONTINUED)
(Classified in Accordance with Appendix A.1)

Hazard category	Signal word	Hazard statement	Pictogram Skull and crossbones
3	Danger	Toxic if swallowed	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**If swallowed: Immediately call a poison center/doctor/...** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - *if immediate administration of antidote is required*. **Rinse mouth.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.1 ACUTE TOXICITY – ORAL (CONTINUED)
(Classified in Accordance with Appendix A.1)

Hazard category	Signal word	Hazard statement	Pictogram Exclamation mark
4	Warning	Harmful if swallowed	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**If swallowed: 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).

C.4.2 ACUTE TOXICITY - DERMAL
(Classified in Accordance with Appendix A.1)

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.	**If on skin: Wash with plenty of water/**... … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Immediately call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - *if immediate measures such as specific cleansing agent is advised*. **Take off immediately all contaminated clothing and wash it before reuse.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.2 ACUTE TOXICITY – DERMAL (CONTINUED)
(Classified in Accordance with Appendix A.1)

Hazard category	Signal word	Hazard statement	Pictogram Skull and crossbones
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.	**If on skin: Wash with plenty of water/…** … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Call a poison center/doctor/…/if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - *if measures such as specific cleansing agent is advised.* **Take off 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).

C.4.2 ACUTE TOXICITY – DERMAL (CONTINUED)
(Classified in Accordance with Appendix A.1)

Hazard category	Signal word	Hazard statement	Pictogram Exclamation mark
4	Warning	Harmful 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.	**If on skin: Wash with plenty of water/...** … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Call a poison center/doctor/…/if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - *if measures such as specific cleansing agent is advised.* **Take off contaminated clothing and wash it before reuse.**		**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.3 ACUTE TOXICITY - INHALATION
(Classified in Accordance with Appendix A.1)

Hazard category	Signal word	Hazard statement
1	Danger	Fatal if inhaled
2	Danger	Fatal if inhaled

Pictogram
Skull and crossbones

Precautionary statements

Prevention	Response	Storage	Disposal
Do not breathe dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.** **[In case of inadequate ventilation] wear respiratory protection.** Chemical manufacturer, importer, or distributor to specify equipment. - *Text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use*.	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Immediately call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment is urgent (see ... on this label)** ... Reference to supplemental first aid instruction. - *if immediate administration of antidote is required*.	**Store in a well-ventilated place. Keep container tightly closed.** - *if product is volatile as to generate hazardous atmosphere.* **Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.3 ACUTE TOXICITY – INHALATION (CONTINUED)
(Classified in Accordance with Appendix A.1)

Hazard category	Signal word	Hazard statement
3	Danger	Toxic if inhaled

Pictogram
Skull and crossbones

Precautionary statements

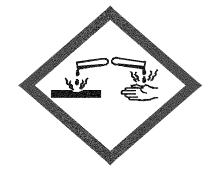
Prevention	Response	Storage	Disposal
Avoid breathing dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.**	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Call 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. - *if immediate specific measures are required*.	**Store in a well-ventilated place. Keep container tightly closed.** - *if product is volatile so as to generate hazardous atmosphere.* **Store locked up.**	**Dispose of content/container to…** … in accordance with local/regional/national/international regulations (to be specified).

C.4.3 ACUTE TOXICITY – INHALATION (CONTINUED)
(Classified in Accordance with Appendix A.1)

Hazard category	Signal word	Hazard statement	Pictogram Exclamation mark
4	Warning	Harmful if inhaled	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.**	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Call a poison center/doctor/…/if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.		

C.4.4 SKIN CORROSION/IRRITATION
(Classified in Accordance with Appendix A.2)

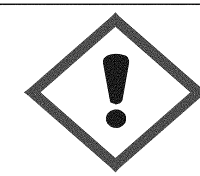
Hazard category	Signal word	Hazard statement	Pictogram
1A to 1C	Danger	Causes severe skin burns and eye damage	Corrosion 

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dusts or mists. - *if inhalable particles of dusts or mists may occur during use.* **Wash …thoroughly after handling.** **…**Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Wear protective gloves/protective clothing/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**If swallowed: Rinse mouth. Do NOT induce vomiting.** **If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.** **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. - *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).

C.4.4 SKIN CORROSION/IRRITATION (CONTINUED)
(Classified in Accordance with Appendix A.2)

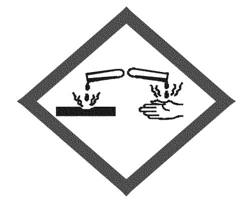
Hazard category	Signal word	Hazard statement
2	Warning	Causes skin irritation

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.	**If on skin: Wash with plenty of water/...** … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - *Manufacturer, importer, or distributor may specify a cleansing agent if appropriate.* **If skin irritation occurs: Get medical advice/attention.** **Take off contaminated clothing and wash it before reuse.**		

C.4.5 EYE DAMAGE/IRRITATION
(Classified in Accordance with Appendix A.3)

Hazard category	Signal word	Hazard statement	Pictogram Corrosion
1	Danger	Causes serious eye damage	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.	**If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.** **Immediately call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.		

C.4.5 EYE DAMAGE/IRRITATION (CONTINUED)
(Classified in Accordance with Appendix A.3)

Pictogram
Exclamation mark

Hazard category	**Signal word**	**Hazard statement**
2A	Warning	Causes serious eye irritation

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. **…** Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Wear eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**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.**		

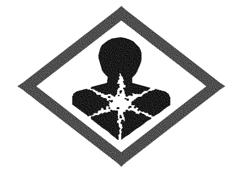
C.4.5 EYE DAMAGE/IRRITATION (CONTINUED)
(Classified in Accordance with Appendix A.3)

Pictogram
No Pictogram

Hazard category	Signal word	Hazard statement
2B	Warning	Causes eye irritation

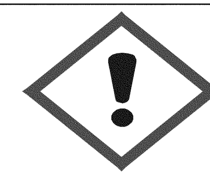
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.	**If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.** **If eye irritation persists: Get medical advice/attention.**		

C.4.6 SENSITIZATION - RESPIRATORY
(Classified in Accordance with Appendix A.4)

Hazard category	Signal word	Hazard statement	Pictogram Health hazard
1 (including both sub-categories 1A and 1B)	Danger	May cause allergy or asthma symptoms or breathing difficulties if inhaled	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **[In case of inadequate ventilation] wear respiratory protection.** Chemical manufacturer, importer, or distributor to specify equipment - <u>*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*</u>.	**If inhaled: If breathing is difficult, 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).

C.4.7 SENSITIZATION - SKIN
(Classified in Accordance with Appendix A.4)

Hazard category	Signal word	Hazard statement	Pictogram Exclamation mark
1 (including both sub-categories 1A and 1B)	Warning	May cause an allergic skin reaction	

Precautionary statements

Prevention	Response	Storage	Disposal
Avoid breathing dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Contaminated work clothing must not be allowed out of the workplace.** **Wear protective gloves.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**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.** **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. - *Manufacturer, importer, or distributor may specify a cleansing agent if appropriate.* **Wash contaminated clothing before reuse.**		**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.8 GERM CELL MUTAGENICITY
(Classified in Accordance with Appendix A.5)

Pictogram
Health hazard

Hazard category	**Signal word**	Hazard statement
1A and 1B	Danger	May cause genetic defects <...>
2	Warning	Suspected of causing genetic defects <...>
		(state route of exposure if no other routes of exposure cause the hazard)

Precautionary statements

Prevention	Response	Storage	Disposal
Obtain special instructions before use. **Do not handle until all safety precautions have been read and understood.** **Wear protective gloves/protective clothing/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment, as required.	**If exposed or concerned: Get medical advice/attention.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.9 CARCINOGENICITY
(Classified in Accordance with Appendix A.6)

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

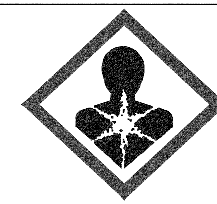
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not handle until all safety precautions have been read and understood.** **Wear protective gloves/protective clothing/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment, as required.	**If exposed or concerned: Get medical advice/attention.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

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 TOXIC TO REPRODUCTION
(Classified in Accordance with Appendix A.7)

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)

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 type of equipment, as required.	**If exposed or concerned: Get medical advice/attention.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.10 TOXIC TO REPRODUCTION (CONTINUED)
(Classified in Accordance with Appendix A.7)
(EFFECTS ON OR VIA LACTATION)

Pictogram
No Pictogram

Hazard category	**Signal word**	**Hazard statement**
No designated number (See Table A.7.1 in Appendix A.7)	*No signal word*	May cause harm to breast-fed children

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not breathe dusts or mists.** - *if inhalable particles of dusts or mists may occur during use.* **Avoid contact during pregnancy/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.**		

C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure) (Classified in Accordance with Appendix A.8)

Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
1	Danger	Causes damage to organs <...> <<...>> <...> *(or state all organs affected if known)* <<...>> *(state route of exposure if no other routes of exposure cause the hazard)*

Precautionary statements

Prevention	Response	Storage	Disposal
Do not breathe dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Wash …thoroughly after handling.** … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**If exposed: 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).

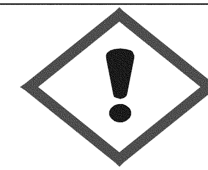
C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure) (CONTINUED) (Classified in Accordance with Appendix A.8)

Hazard category	Signal word	Hazard statement	Pictogram Health hazard
2	Warning	May cause damage to organs <...> <<...>> <...> *(or state all organs affected, if known)* <<...>> *(state route of exposure if no other routes of exposure cause the hazard)*	

Precautionary statements

Prevention	Response	Storage	Disposal
Do not breathe dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Wash … thoroughly after handling.** … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**If exposed or concerned: Call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.11 SPECIFIC TARGET ORGAN TOXICITY (Single Exposure) (CONTINUED)
(Classified in Accordance with Appendix A.8)

Hazard category	Signal word	Hazard statement	Pictogram Exclamation mark
3	Warning	May cause respiratory irritation; or May cause drowsiness or dizziness	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.**	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Call a poison center/doctor/…/if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.	**Store in a well-ventilated place. Keep container tightly closed.** **-** *if product is volatile so as to generate hazardous atmosphere.* **Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.12 SPECIFIC TARGET ORGAN TOXICITY (Repeated Exposure) (Classified in Accordance with Appendix A.9)

Hazard category	Signal word	Hazard statement	Pictogram Health hazard
1	Danger	Causes damage to organs <...> through prolonged or repeated exposure <<...>> <...> <u>*(state all organs affected, if known)*</u> <<...>> <u>*(state route of exposure if no other routes of exposure cause the hazard)*</u>	

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.**		**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.12 SPECIFIC TARGET ORGAN TOXICITY (Repeated Exposure) (CONTINUED) (Classified in Accordance with Appendix A.9)

Hazard category	Signal word	Hazard statement	Pictogram Health hazard
2	Warning	May cause damage to organs <...> through prolonged or repeated exposure <<...>> <...> <u>*(state all organs affected, if known)*</u> <<...>> <u>*(state route of exposure if no other routes of exposure cause the hazard)*</u>	

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.**		**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

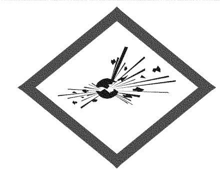
C.4.13 ASPIRATION HAZARD
(Classified in Accordance with Appendix A.10)

Hazard category	Signal word	Hazard statement	Pictogram Health hazard
1	Danger	May be fatal if swallowed and enters airways	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
	If swallowed: Immediately call a poison center/doctor/… … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Do NOT induce vomiting.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.14 EXPLOSIVES
(Classified in Accordance with Appendix B.1)

Pictogram
Exploding bomb



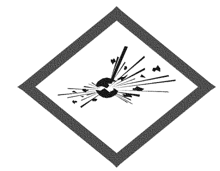
Hazard category	**Signal word**	**Hazard statement**
Unstable explosive	Danger	Unstable explosive

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not handle until all safety precautions have been read and understood.** **Wear personal protective equipment/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment, as required.	**Explosion risk in case of fire.** **Do NOT fight fire when fire reaches explosives.** **Evacuate area.**	**Store ...** …in accordance with local/regional/ national/international regulations (to be specified).	**Dispose of contents/container to ...** …in accordance with local/regional/ national/international regulations (to be specified).

C.4.14 EXPLOSIVES (CONTINUED)
(Classified in Accordance with Appendix B.1)

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 hazard

Pictogram
Exploding bomb

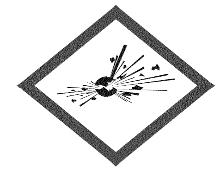


Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep wetted with...** … Chemical manufacturer, importer, or distributor to specify appropriate material. - *if drying out increases explosion hazard, except as needed for manufacturing or operating processes (e.g., nitrocellulose).* **Ground/bond container and receiving equipment.** - *if the explosive is electrostatically sensitive.* **Do not subject to grinding/shock/…/friction.** …Chemical manufacturer, importer, or distributor to specify applicable rough handling. **Wear face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: evacuate area.** **Explosion risk in case of fire.** **Do NOT fight fire when fire reaches explosives.**	**Store ...** …in accordance with local/regional/national/ international regulations (to be specified).	**Dispose of contents/container to ...** … in accordance with local/ regional/national/ international regulations (to be specified).

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, 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)

Hazard category	Signal word	Hazard statement	Pictogram
Division 1.4	Warning	Fire or projection hazard	Exploding bomb[1] 

Precautionary statements[1]			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Ground/bond container and receiving equipment.** - <u>*if the explosive is electrostatically sensitive.*</u> **Do not subject to grinding/shock/…/friction.** Chemical manufacturer, importer, or distributor to specify applicable rough handling. **Wear face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Evacuate area.** **Explosion risk in case of fire.** - <u>*except if explosives are 1.4S ammunition and components thereof.*</u> **Do NOT fight fire when fire reaches explosives.** **Fight fire with normal precautions from a reasonable distance** - <u>*if explosives are 1.4S ammunition and components thereof.*</u>	**Store ...** …in accordance with local/regional/national/international regulations (to be specified).	**Dispose of contents/container to...** … in accordance with local/regional/national/international regulations (to be specified).

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, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.[1]

[1] <u>*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.*</u>

C.4.14 EXPLOSIVES (CONTINUED)
(Classified in Accordance with Appendix B.1)

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/sparks/open flames/hot surfaces. **- No smoking**. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep wetted with**... … Chemical manufacturer, importer, or distributor to specify appropriate material. **-** *if drying out increases explosion hazard, except as needed for manufacturing or operating processes (e.g., nitrocellulose).* **Ground/bond container and receiving equipment** - *if the explosive is electrostatically sensitive*. **Do not subject to grinding/shock/…/friction**. **…**Chemical manufacturer, importer, or distributor to specify applicable rough handling. **Wear face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Evacuate area.** **Explosion risk in case of fire.** **Do NOT fight fire when fire reaches explosives.**	**Store ...** …in accordance with local/regional/ national/international regulations (to be specified).	**Dispose of contents/container to ...** … in accordance with local/regional/ national/international regulations (to be specified).

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, 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)

Pictogram
No pictogram

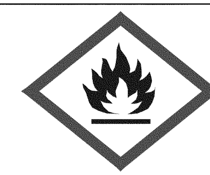
Hazard category	Signal word	Hazard statement
Division 1.6	*No signal word*	*No hazard statement*

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, 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)

Hazard category	Signal word	Hazard statement	Pictogram
1	Danger	Extremely flammable gas	Flame



Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. -No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).	**Leaking gas fire:** **Do not extinguish, unless leak can be stopped safely.** **Eliminate all ignition sources if safe to do so.**	**Store in well-ventilated place.**	

C.4.15 FLAMMABLE GASES (CONTINUED)
(Classified in Accordance with Appendix B.2)

Pictogram
No Pictogram

Hazard category	Signal word	Hazard statement
2	Warning	Flammable gas

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. -No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition sources(s).	**Leaking gas fire: Do not extinguish, unless leak can be stopped safely.** **Eliminate all ignition sources if safe to do so.**	**Store in well-ventilated place.**	

C.4.16 FLAMMABLE AEROSOLS
(Classified in Accordance with Appendix B.3)

Pictogram
Flame

Hazard category	Signal word	Hazard statement
1	Danger	Extremely flammable aerosol
2	Warning	Flammable aerosol

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. -No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition sources(s). **Do not spray on an open flame or other ignition source.** **Pressurized container: Do not pierce or burn, even after use.**		**Protect from sunlight. Do not expose to temperatures exceeding 50 ºC/122 ºF.**	

C.4.17 OXIDIZING GASES
(Classified in Accordance with Appendix B.4)

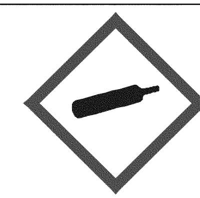
Pictogram
Flame over circle

Hazard category	**Signal word**	**Hazard statement**
1	Danger	May cause or intensify fire; oxidizer

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep/Store away from clothing/…/combustible materials. …Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Keep reduction valves/valves and fittings free from oil and grease.**	**In case of fire: Stop leak if safe to do so.**	**Store in well-ventilated place.**	

C.4.18 GASES UNDER PRESSURE
(Classified in Accordance with Appendix B.5)

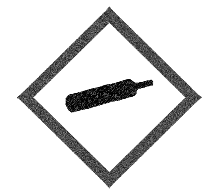
Pictogram
Gas cylinder



Hazard category	Signal word	Hazard statement
Compressed gas	Warning	Contains gas under pressure; may explode if heated
Liquefied gas	Warning	Contains gas under pressure; may explode if heated
Dissolved gas	Warning	Contains gas under pressure; may explode if heated

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
		Protect from sunlight. Store in a well-ventilated place.	

C.4.18 GASES UNDER PRESSURE (CONTINUED)
(Classified in Accordance with Appendix B.5)

Hazard category	Signal word	Hazard statement	Pictogram Gas cylinder
Refrigerated liquefied gas	Warning	Contains refrigerated gas; may cause cryogenic burns or injury	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear cold insulating gloves/face shield/eye protection.	**Thaw frosted parts with lukewarm water. Do not rub affected area.** **Get immediate medical advice/attention**	**Store in well-ventilated place.**	

C.4.19 FLAMMABLE LIQUIDS
(Classified in Accordance with Appendix B.6)

Pictogram
Flame

Hazard category	**Signal word**	**Hazard statement**
1	Danger	Extremely flammable liquid and vapor
2	Danger	Highly flammable liquid and vapor
3	Warning	Flammable liquid and vapor

Precautionary statements

Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces.– No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep container tightly closed.** **Ground/Bond container and receiving equipment** - *if electrostatically sensitive material is for reloading*. - *if product is volatile so as to generate hazardous atmosphere*. **Use explosion-proof electrical/ventilating/ lighting/.../equipment.** ... Chemical manufacturer, importer, or distributor to specify other equipment. **Use only non-sparking tools.** **Take precautionary measures against static discharge.** **Wear protective gloves/eye protection/face protection** Chemical manufacturer, importer, or distributor to specify type of equipment.	**If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.** **In case of fire: Use ... to extinguish.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. - *if water increases risk.*	**Store in a well-ventilated place. Keep cool.**	**Dispose of contents/container to...** … in accordance with local/regional/national/ international regulations (to be specified).

C.4.19 FLAMMABLE LIQUIDS (CONTINUED)
(Classified in Accordance with Appendix B.6)

Pictogram
No Pictogram

Hazard category	Signal word	Hazard statement
4	Warning	Combustible liquid

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from flames and hot surfaces. – No smoking. **Wear protective gloves/eye protection/face protection** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... to extinguish.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. - *if water increases risk.*	**Store in a well-ventilated place. Keep cool.**	**Dispose of contents/container to...** in accordance with local/regional/ national/international regulations (to be specified).

C.4.20 FLAMMABLE SOLIDS
(Classified in Accordance with Appendix B.7)

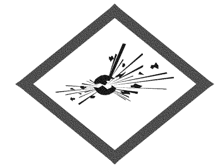
Hazard category	Signal word	Hazard statement
1	Danger	Flammable solid
2	Warning	Flammable solid

Pictogram
Flame

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Ground/Bond container and receiving equipment.** - *if electrostatically sensitive material is for reloading*. **Use explosion-proof electrical/ventilating/ lighting/... /equipment.** ... Chemical manufacturer, importer, or distributor to specify other equipment. - *if dust clouds can occur*. **Wear protective gloves/eye protection/face protection** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... to extinguish** ... Chemical manufacturer, importer, or distributor to specify appropriate media. - *if water increases risk*.		

C.4.21 SELF-REACTIVE SUBSTANCES AND MIXTURES (Classified in Accordance with Appendix B.8)

Pictogram
Exploding bomb



Hazard category	Signal word	Hazard statement
Type A	Danger	Heating may cause an explosion

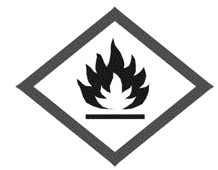
Precautionary statements

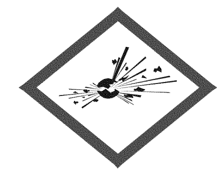
Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep/Store away from clothing/…/combustible materials.** **...** Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... to extinguish** ... Chemical manufacturer, importer, or distributor to specify appropriate media. - *if water increases risk.* **In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.**	**Store in a well-ventilated place. Keep cool.** **Store at temperatures not exceeding …°C/…°F.** ... Chemical manufacturer, importer, or distributor to specify temperature. **Store away from other materials.**	**Dispose of contents/container to...** … in accordance with local/regional/national/international regulations (to be specified).

C.4.21 SELF-REACTIVE SUBSTANCES AND MIXTURES (CONTINUED)
(Classified in Accordance with Appendix B.8)

Hazard category	Signal word	Hazard statement
Type B	Danger	Heating may cause a fire or explosion

Pictograms
Exploding bomb and flame





Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep/Store away from clothing/.../combustible materials.** ... Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... to extinguish.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. - *if water increases risk*. **In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.**	**Store in a well-ventilated place. Keep cool.** **Store at temperatures not exceeding …°C/…°F.** ... Chemical manufacturer, importer, or distributor to specify temperature. **Store away from other materials.**	**Dispose of contents/container to**... …in accordance with local/regional/national/international regulations (to be specified).

C.4.21 SELF-REACTIVE SUBSTANCES AND MIXTURES(CONTINUED)
(Classified in Accordance with Appendix B.8)

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

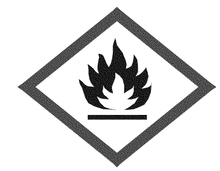
Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep/Store away from clothing/…/combustible materials.** …Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... to extinguish** ... Chemical manufacturer, importer, or distributor to specify appropriate media. - *if water increases risk.*	**Store in a well-ventilated place. Keep cool.** **Store at temperatures not exceeding …°C/…°F.** ...Chemical manufacturer, importer, or distributor to specify temperature. **Store away from other materials.**	**Dispose of contents/container to...** …in accordance with local/regional/national/international regulations (to be specified).

C.4.22 PYROPHORIC LIQUIDS
(Classified in Accordance with Appendix B.9)

Hazard category	Signal word	Hazard statement
1	Danger	Catches fire spontaneously if exposed to air

Pictogram
Flame

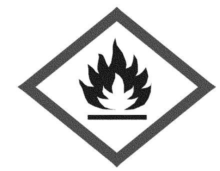


Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition sources(s). **Do not allow contact with air.** **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**If on skin: Immerse in cool water/wrap with wet bandages** **In case of fire: Use ... to extinguish** ... Chemical manufacturer, importer, or distributor to specify appropriate media. - *if water increases risk.*	**Store contents under ...** ... Chemical manufacturer, importer, or distributor to specify appropriate liquid or inert gas.	

C.4.23 PYROPHORIC SOLIDS
(Classified in Accordance with Appendix B.10)

Hazard category	Signal word	Hazard statement
1	Danger	Catches fire spontaneously if exposed to air

Pictogram
Flame

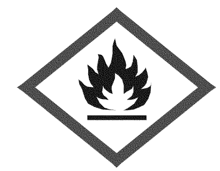


Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Do not allow contact with air.** **Wear protective gloves/eye protection/face protection** Chemical manufacturer, importer, or distributor to specify type of equipment.	**Brush off loose particles from skin. Immerse in cool water/wrap in wet bandages.** **In case of fire: Use ... to extinguish** ... Chemical manufacturer, importer, or distributor to specify appropriate media. - *if water increases risk*.	**Store contents under ...** …Chemical manufacturer, importer, or distributor to specify appropriate liquid or inert gas.	

C.4.24 SELF-HEATING SUBSTANCES AND MIXTURES (Classified in Accordance with Appendix B.11)

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

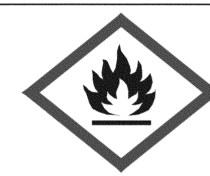
Precautionary statements

Prevention	Response	Storage	Disposal
Keep cool. Protect from sunlight. **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.		**Maintain air gap between stacks/pallets.** **Store bulk masses greater than … kg/…lbs at temperatures not exceeding …°C/…°F.** ... Chemical manufacturer, importer, or distributor to specify mass and temperature. **Store away from other materials.**	

C.4.25 SUBSTANCES AND MIXTURES WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES (Classified in Accordance with Appendix B.12)

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

Pictogram
Flame



Precautionary statements

Prevention	Response	Storage	Disposal
Do not allow contact with water. **Handle under inert gas. Protect from moisture.** **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**Brush off loose particles from skin and immerse in cool water/wrap in wet bandages.** **In case of fire: Use ... to extinguish** ... Chemical manufacturer, importer, or distributor to specify appropriate media. - *if water increases risk*.	**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).

C.4.25 SUBSTANCES AND MIXTURES WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES (CONTINUED)

(Classified in Accordance with Appendix B.12)

Hazard category	Signal word	Hazard statement	Pictogram Flame
3	Warning	In contact with water releases flammable gas	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Handle under inert gas. Protect from moisture. **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... to extinguish.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. - *if water increases risk*.	**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).

C.4.26 OXIDIZING LIQUIDS
(Classified in Accordance with Appendix B.13)

Hazard category	Signal word	Hazard statement	Pictogram Flame over circle
1	Danger	May cause fire or explosion; strong oxidizer	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat. **Keep/Store away from clothing and other combustible materials.** **Take any precaution to avoid mixing with combustibles/...** ... Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Wear protective gloves /eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment. **Wear fire/flame resistant/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.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. - *if water increases risk*.		**Dispose of contents/container to...** …in accordance with local/regional/ national/international regulations (to be specified).

C.4.26 OXIDIZING LIQUIDS (CONTINUED)
(Classified in Accordance with Appendix B.13)

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. **Keep/Store away from clothing/…/combustible materials.** **…**Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Take any precaution to avoid mixing with combustibles/...** ... Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... to extinguish.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. - *if water increases risk*.		**Dispose of contents/container to...** …in accordance with local/regional/ national/international regulations (to be specified).

C.4.27 OXIDIZING SOLIDS
(Classified in Accordance with Appendix B.14)

Hazard category	Signal word	Hazard statement	Pictogram Flame over circle
1	Danger	May cause fire or explosion; strong oxidizer	

Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat. **Keep away from clothing and other combustible materials.** **Take any precaution to avoid mixing with combustibles/...** …Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment. **Wear fire/flame resistant/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.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. - *if water increases risk*.		**Dispose of contents/container to...** …in accordance with local/regional/ national/international regulations (to be specified).

C.4.27 OXIDIZING SOLIDS (CONTINUED)
(Classified in Accordance with Appendix B.14)

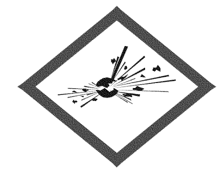
Hazard category	Signal word	Hazard statement
2	Danger	May intensify fire; oxidizer
3	Warning	May intensify fire; oxidizer

Pictogram
Flame over circle

Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat. **Keep/Store away from clothing/…/ combustible materials.** … Chemical manufacturer, importer, or distributor to specify incompatible materials. **Take any precaution to avoid mixing with combustibles/...** …Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... to extinguish.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. - *if water increases risk*.		**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.28 ORGANIC PEROXIDES
(Classified in Accordance with Appendix B.15)

Hazard category	Signal word	Hazard statement	Pictogram Exploding bomb
Type A	Danger	Heating may cause an explosion	

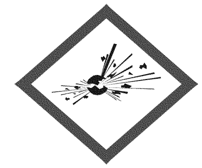
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces.- No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep/Store away from clothing/…/combustible materials.** ... Chemical manufacturer, importer, or distributor to specify incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.		**Store at temperatures not exceeding …°C/…°F. Keep cool.** ... Chemical manufacturer, importer, or distributor to specify temperature. **Protect from sunlight.** **Store away from other materials.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.28 ORGANIC PEROXIDES (CONTINUED)
(Classified in Accordance with Appendix B.15)

Hazard category	Signal word	Hazard statement
Type B	Danger	Heating may cause a fire or explosion

Pictograms

Exploding bomb and flame



Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep /Store away from clothing/.../combustible materials.** ... Chemical manufacturer, importer, or distributor to specify incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.		**Store at temperatures not exceeding …°C/…°F. Keep cool.** Chemical manufacturer, importer, or distributor to specify temperature. **Protect from sunlight.** **Store away from other materials.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.28 ORGANIC PEROXIDES (CONTINUED)
(Classified in Accordance with Appendix B.15)

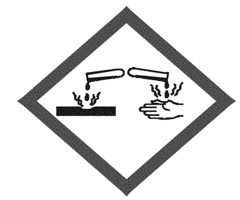
Pictogram
Flame

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

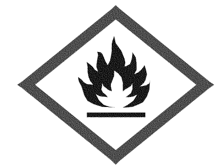
Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep/Store away from clothing/.../ combustible materials** ... Chemical manufacturer, importer, or distributor to specify incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.		**Store at temperatures not exceeding …°C/…°F. Keep cool.** ... Chemical manufacturer, importer, or distributor to specify temperature. **Protect from sunlight.** **Store away from other materials.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.29 CORROSIVE TO METALS
(Classified in Accordance with Appendix B.16)

Hazard category	Signal word	Hazard statement	Pictogram Corrosion
1	Warning	May be corrosive to metals	

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep only in original container.	**Absorb spillage to prevent material damage.**	**Store in corrosive resistant/... container with a resistant inner liner.** ... Chemical manufacturer, importer, or distributor to specify other compatible materials.	

C.4.30 Label elements for OSHA defined hazards

Hazard	Signal word	Hazard statement	Pictogram
Pyrophoric Gas	Danger	Catches fire spontaneously if exposed to air	Flame 
Simple Asphyxiant	Warning	May displace oxygen and cause rapid suffocation	*No Pictogram*
Combustible Dust[2]	Warning	May form combustible dust concentrations in air	*No Pictogram*

[2] *The chemical manufacturer or importer shall label chemicals that are shipped in dust form, and present a combustible dust hazard in that form when used downstream, under paragraph (f)(1); 2) the chemical manufacturer or importer shipping chemicals that are in a form that is not yet a dust must provide a label to customers under paragraph (f)(4) 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) where combustible dust hazards are present.*

BILLING CODE 4510–26–C

Appendix D to § 1910.1200—Safety Data Sheets (Mandatory)

A safety data sheet (SDS) shall include the information specified in Table D.1 under the section number and heading indicated for sections 1–11 and 16. If no relevant information is found for any given subheading within a section, the SDS shall clearly indicate that no applicable information is available. Sections 12–15 may be included in the SDS, but are not mandatory.

TABLE D.1—MINIMUM INFORMATION FOR AN SDS

Heading	Subheading
1. Identification	(a) Product identifier used on the label; (b) Other means of identification; (c) Recommended use of the chemical and restrictions on use; (d) Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party; (e) Emergency phone number.
2. Hazard(s) identification	(a) Classification of the chemical in accordance with paragraph (d) of § 1910.1200; (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) Describe any hazards not otherwise classified that have been identified during the classification process; (d) Where an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥1% and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required.
3. Composition/information on ingredients	Except as provided for in paragraph (i) of § 1910.1200 on trade secrets: For Substances (a) Chemical name; (b) Common name and synonyms; (c) CAS number and other unique identifiers; (d) Impurities and stabilizing additives 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 and concentration (exact percentage) or concentration ranges of all ingredients which are classified as health hazards in accordance with paragraph (d) of § 1910.1200 and (1) Are present above their cut-off/concentration limits; or (2) Present a health risk below the cut-off/concentration limits. (b) The concentration (exact percentage) shall be specified unless a trade secret claim is made in accordance with paragraph (i) of § 1910.1200, when there is batch-to-batch variability in the production of a mixture, or for a group of substantially similar mixtures (*See* A.0.5.1.2) with similar chemical composition. In these cases, concentration ranges may be used. For All Chemicals Where a Trade Secret is Claimed Where a trade secret is claimed in accordance with paragraph (i) of § 1910.1200, a statement that the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret is required.
4. First-aid measures	(a) Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact, and ingestion; (b) Most important symptoms/effects, acute and delayed. (c) Indication of immediate medical attention and special treatment needed, if necessary.
5. Fire-fighting measures	(a) Suitable (and unsuitable) extinguishing media. (b) Specific hazards arising from the chemical (e.g., nature of any hazardous combustion products). (c) Special protective equipment and precautions for fire-fighters.
6. Accidental release measures	(a) Personal precautions, protective equipment, and emergency procedures. (b) Methods and materials for containment and cleaning up.
7. Handling and storage	(a) Precautions for safe handling. (b) Conditions for safe storage, including any incompatibilities.
8. Exposure controls/personal protection	(a) OSHA permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available. (b) Appropriate engineering controls. (c) Individual protection measures, such as personal protective equipment.
9. Physical and chemical properties	(a) Appearance (physical state, color, etc.); (b) Odor; (c) Odor threshold; (d) pH; (e) Melting point/freezing point; (f) Initial boiling point and boiling range; (g) Flash point; (h) Evaporation rate; (i) Flammability (solid, gas); (j) Upper/lower flammability or explosive limits;

TABLE D.1—MINIMUM INFORMATION FOR AN SDS—Continued

Heading	Subheading
	(k) Vapor pressure; (l) Vapor density; (m) Relative density; (n) Solubility(ies); (o) Partition coefficient: n-octanol/water; (p) Auto-ignition temperature; (q) Decomposition temperature; (r) Viscosity.
10. Stability and reactivity	(a) Reactivity; (b) Chemical stability; (c) Possibility of hazardous reactions; (d) Conditions to avoid (e.g., static discharge, shock, or vibration); (e) Incompatible materials; (f) Hazardous decomposition products.
11. Toxicological information	Description of the various toxicological (health) effects and the available data used to identify those effects, including: (a) Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact); (b) Symptoms related to the physical, chemical and toxicological characteristics; (c) Delayed and immediate effects and also chronic effects from short- and long-term exposure; (d) Numerical measures of toxicity (such as acute toxicity estimates). (e) 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.
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 (e.g., Marine pollutant (Yes/No)); (f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code); (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.

Appendix F to § 1910.1200—Guidance for Hazard Classifications Re: Carcinogenicity (Non-Mandatory)

The mandatory criteria for classification of a chemical for carcinogenicity under HCS (§ 1910.1200) are found in Appendix A.6 to this section. This non-mandatory Appendix provides additional guidance on hazard classification for carcinogenicity. Part A of Appendix F includes background guidance provided by GHS based on the Preamble of the International Agency for Research on Cancer (IARC) ''Monographs on the Evaluation of Carcinogenic Risks to Humans'' (2006). Part B provides IARC classification information. Part C provides background guidance from the National Toxicology Program (NTP) ''Report on Carcinogens'' (RoC), and Part D is a table that compares GHS carcinogen hazard categories to carcinogen classifications under IARC and NTP, allowing classifiers to be able to use information from IARC and NTP RoC carcinogen classifications to complete their classifications under the GHS, and thus the HCS.

Part A: Background Guidance [1]

As noted in Footnote 6 of Appendix A.6. to this section, the GHS includes as guidance for classifiers information taken from the Preamble of the International Agency for Research on Cancer (IARC) ''Monographs on the Evaluation of Carcinogenic Risks to Humans'' (2006), providing guidance on the evaluation of the strength and evidence of carcinogenic risks to humans. This guidance also discusses some additional considerations in classification and an approach to analysis, rather than hard-and-fast rules. Part A is consistent with Appendix A.6, and should help in evaluating information to determine carcinogenicity.

Carcinogenicity in humans:

The evidence relevant to carcinogenicity from studies in humans is classified into one of the following categories:

(a) Sufficient evidence of carcinogenicity: A causal relationship has been established between exposure to the agent and human cancer. That is, a positive relationship has been observed between the exposure and cancer in studies in which chance, bias and confounding could be ruled out with reasonable confidence.

(b) Limited evidence of carcinogenicity: A positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence.

In some instances, the above categories may be used to classify the degree of evidence related to carcinogenicity in specific organs or tissues.

Carcinogenicity in experimental animals:

The evidence relevant to carcinogenicity in experimental animals is classified into one of the following categories:

[1] *The text of Appendix F, Part A, on the IARC Monographs, is paraphrased from the 2006 Preamble to the ''Monographs on the Evaluation of Carcinogenic Risks to Humans''; the Classifier is referred to the full IARC Preamble for the complete text. The text is not part of the agreed GHS text on the harmonized system developed by the OECD Task Force-HCL.*

(a) Sufficient evidence of carcinogenicity: A causal relationship has been established between the agent and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms in two or more species of animals or two or more independent studies in one species carried out at different times or in different laboratories or under different protocols. An increased incidence of tumors in both sexes of a single species in a well-conducted study, ideally conducted under Good Laboratory Practices, can also provide sufficient evidence.

Exceptionally, a single study in one species and sex might be considered to provide sufficient evidence of carcinogenicity when malignant neoplasms occur to an unusual degree with regard to incidence, site, type of tumor or age at onset, or when there are strong findings of tumors at multiple sites.

(a) Limited evidence of carcinogenicity: The data suggest a carcinogenic effect but are limited for making a definitive evaluation because, e.g. the evidence of carcinogenicity is restricted to a single experiment; there are unresolved questions regarding the adequacy of the design, conduct or interpretation of the studies; the agent increases the incidence only of benign neoplasms or lesions of uncertain neoplastic potential; or the evidence of carcinogenicity is restricted to studies that demonstrate only promoting activity in a narrow range of tissues or organs.

Guidance on How To Consider Important Factors in Classification of Carcinogenicity (See Reference Section)

The weight of evidence analysis called for in GHS and the HCS (§ 1910.1200) is an integrative approach that considers important factors in determining carcinogenic potential along with the strength of evidence analysis. The IPCS ''*Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogenesis''* (2001), International Life Sciences Institute (ILSI) ''*Framework for Human Relevance Analysis of Information on Carcinogenic Modes of Action''* (Meek, *et al.,* 2003; Cohen *et al.,* 2003, 2004), and Preamble to the IARC Monographs (2006; Section B.6. (Scientific Review and Evaluation; Evaluation and Rationale)) provide a basis for systematic assessments that may be performed in a consistent fashion. The IPCS also convened a panel in 2004 to further develop and clarify the human relevance framework. However, the above documents are not intended to dictate answers, nor provide lists of criteria to be checked off.

Mode of Action

Various documents on carcinogen assessment all note that mode of action in and of itself, or consideration of comparative metabolism, should be evaluated on a case-by-case basis and are part of an analytic evaluative approach. One must look closely at any mode of action in animal experiments, taking into consideration comparative toxicokinetics/toxicodynamics between the animal test species and humans to determine the relevance of the results to humans. This may lead to the possibility of discounting very specific effects of certain types of substances. Life stage-dependent effects on cellular differentiation may also lead to qualitative differences between animals and humans. Only if a mode of action of tumor development is conclusively determined not to be operative in humans may the carcinogenic evidence for that tumor be discounted. However, a weight of evidence evaluation for a substance calls for any other tumorigenic activity to be evaluated, as well.

Responses in Multiple Animal Experiments

Positive responses in several species add to the weight of evidence that a substance is a carcinogen. Taking into account all of the factors listed in A.6.2.5.2 and more, such chemicals with positive outcomes in two or more species would be provisionally considered to be classified in GHS Category 1B until human relevance of animal results are assessed in their entirety. It should be noted, however, that positive results for one species in at least two independent studies, or a single positive study showing unusually strong evidence of malignancy may also lead to Category 1B.

Responses Are in One Sex or Both Sexes

Any case of gender-specific tumors should be evaluated in light of the total tumorigenic response to the substance observed at other sites (multi-site responses or incidence above background) in determining the carcinogenic potential of the substance.

If tumors are seen only in one sex of an animal species, the mode of action should be carefully evaluated to see if the response is consistent with the postulated mode of action. Effects seen only in one sex in a test species may be less convincing than effects seen in both sexes, unless there is a clear patho-physiological difference consistent with the mode of action to explain the single sex response.

Confounding Effects of Excessive Toxicity or Localized Effects

Tumors occurring only at excessive doses associated with severe toxicity generally have doubtful potential for carcinogenicity in humans. In addition, tumors occurring only at sites of contact and/or only at excessive doses need to be carefully evaluated for human relevance for carcinogenic hazard. For example, forestomach tumors, following administration by gavage of an irritating or corrosive, non-mutagenic chemical, may be of questionable relevance. However, such determinations must be evaluated carefully in justifying the carcinogenic potential for humans; any occurrence of other tumors at distant sites must also be considered.

Tumor Type, Reduced Tumor Latency

Unusual tumor types or tumors occurring with reduced latency may add to the weight of evidence for the carcinogenic potential of a substance, even if the tumors are not statistically significant.

Toxicokinetic behavior is normally assumed to be similar in animals and humans, at least from a qualitative perspective. On the other hand, certain tumor types in animals may be associated with toxicokinetics or toxicodynamics that are unique to the animal species tested and may not be predictive of carcinogenicity in humans. Very few such examples have been agreed internationally. However, one example is the lack of human relevance of kidney tumors in male rats associated with compounds causing α2u-globulin nephropathy (IARC, Scientific Publication N° 147 [2]). Even when a particular tumor type may be discounted, expert judgment must be used in assessing the total tumor profile in any animal experiment.

Part B: International Agency for Research on Cancer (IARC) [3]

IARC Carcinogen Classification Categories:

Group 1: The agent is *carcinogenic to humans*

This category is used when there is *sufficient evidence of carcinogenicity* in humans. Exceptionally, an agent may be placed in this category when evidence of carcinogenicity in humans is less than *sufficient* but there is *sufficient evidence of carcinogenicity* in experimental animals and strong evidence in exposed humans that the agent acts through a relevant mechanism of carcinogenicity.

Group 2:

This category includes agents for which, at one extreme, the degree of evidence of carcinogenicity in humans is almost *sufficient,* as well as those for which, at the other extreme, there are no human data but for which there is evidence of carcinogenicity in experimental animals. Agents are assigned to either Group 2A (*probably carcinogenic to humans*) or Group 2B (*possibly carcinogenic to humans*) on the basis of epidemiological and experimental evidence of carcinogenicity and mechanistic and other relevant data. The terms *probably carcinogenic* and *possibly carcinogenic* have no quantitative significance and are used simply as descriptors of different levels of evidence of human carcinogenicity, with *probably carcinogenic* signifying a higher level of evidence than *possibly carcinogenic.*

Group 2A: The agent is *probably carcinogenic to human.*

This category is used when there is *limited evidence of carcinogenicity* in humans and *sufficient evidence of carcinogenicity* in experimental animals. In some cases, an agent may be classified in this category when there is *inadequate evidence of carcinogenicity* in humans and *sufficient evidence of carcinogenicity* in experimental animals and strong evidence that the carcinogenesis is mediated by a mechanism that also operates in humans. Exceptionally, an agent may be classified in this category solely on the basis of *limited evidence of carcinogenicity* in humans. An agent may be assigned to this category if it clearly belongs, based on mechanistic considerations, to a class of agents for which one or more members have been classified in Group 1 or Group 2A.

[2] *While most international agencies do not consider kidney tumors coincident with α2u-globulin nephropathy to be a predictor of risk in humans, this view is not universally held. (See: Doi et al., 2007).*

[3] *Preamble of the International Agency for Research on Cancer (IARC) ''Monographs on the Evaluation of Carcinogenic Risks to Humans'' (2006).*

Group 2B: The agent is *possibly carcinogenic to humans*.

This category is used for agents for which there is *limited evidence of carcinogenicity* in humans and less than *sufficient evidence of carcinogenicity* in experimental animals. It may also be used when there is *inadequate evidence of carcinogenicity* in humans but there is *sufficient evidence of carcinogenicity* in experimental animals. In some instances, an agent for which there is *inadequate evidence of carcinogenicity* in humans and less than *sufficient evidence of carcinogenicity* in experimental animals together with supporting evidence from mechanistic and other relevant data may be placed in this group. An agent may be classified in this category solely on the basis of strong evidence from mechanistic and other relevant data.

Part C: National Toxicology Program (NTP), "Report on Carcinogens", Background Guidance

NTP Listing Criteria [4]*:*

The criteria for listing an agent, substance, mixture, or exposure circumstance in the Report on Carcinogens (RoC) are as follows:

Known To Be A Human Carcinogen: There is sufficient evidence of carcinogenicity from studies in humans [5] that indicates a causal relationship between exposure to the agent, substance, or mixture, and human cancer.

Reasonably Anticipated To Be A Human Carcinogen: There is limited evidence of carcinogenicity from studies in humans that indicates that a causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding factors, could not adequately be excluded,

or

there is sufficient evidence of carcinogenicity from studies in experimental animals that indicates there is an increased incidence of malignant and/or a combination of malignant and benign tumors in multiple species or at multiple tissue sites, or by multiple routes of exposure, or to an unusual degree with regard to incidence, site, or type of tumor, or age at onset,

or

there is less than sufficient evidence of carcinogenicity in humans or laboratory animals; however, the agent, substance, or mixture belongs to a well-defined, structurally-related class of substances whose members are listed in a previous Report on Carcinogens as either known to be a human carcinogen or reasonably anticipated to be a human carcinogen, or there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.

Conclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information. Relevant information includes, but is not limited to, dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive sub-populations, genetic effects, or other data relating to mechanism of action or factors that may be unique to a given substance. For example, there may be substances for which there is evidence of carcinogenicity in laboratory animals, but there are compelling data indicating that the agent acts through mechanisms that do not operate in humans and would therefore not reasonably be anticipated to cause cancer in humans.

Part D: Table Relating Approximate Equivalences Among IARC, NTP RoC, and GHS Carcinogenicity Classifications

The following table may be used to perform hazard classifications for carcinogenicity under the HCS (§ 1910.1200). It relates the approximated GHS hazard categories for carcinogenicity to the classifications provided by IARC and NTP, as described in Parts B and C of this Appendix.

APPROXIMATE EQUIVALENCES AMONG CARCINOGEN CLASSIFICATION SCHEMES

IARC	GHS	NTP RoC
Group 1	Category 1A	Known.
Group 2A	Category 1B	Reasonably Anticipated.
Group 2B	Category 2	(See Note 1).

Note 1:
1. *Limited evidence of carcinogenicity from studies in humans (corresponding to IARC 2A/GHS 1B);*
2. *Sufficient evidence of carcinogenicity from studies in experimental animals (again, essentially corresponding to IARC 2A/GHS 1B);*
3. *Less than sufficient evidence of carcinogenicity in humans or laboratory animals; however:*
c. *The agent, substance, or mixture belongs to a well-defined, structurally-related class of substances whose members are listed in a previous RoC as either "Known" or "Reasonably Anticipated" to be a human carcinogen, or*
d. *There is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.*

***References**

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* * * * *

■ 33. Amend § 1910.1450 as follows:
■ A. Remove the definitions of *Combustible liquid, Compressed gas, Explosive, Flammable, Flashpoint, Organic peroxide, Oxidizer, Unstable (reactive),* and *Water-reactive* from paragraph (b);
■ B. Revise the definitions of *Hazardous chemical, Physical hazard, and Reproductive toxins* in paragraph (b);
■ C. Add definitions of *Health hazard* and *Mutagen* in alphabetical order in paragraph (b);

[4] *See: http://ntp.niehs.nih.gov/go/15209.*

[5] *This evidence can include traditional cancer epidemiology studies, data from clinical studies, and/or data derived from the study of tissues or cells from humans exposed to the substance in question that can be useful for evaluating whether a relevant cancer mechanism is operating in people.*

■ D. In paragraphs (f)(3)(v), (h)(1) introductory text, (h)(1)(ii) and (h)(2)(iii), remove the phrases ''Material Safety Data Sheets'' and ''material safety data sheets'' and add in their place ''safety data sheets'';

■ E. In Appendix A to § 1910.1450, in the Table of Contents (item ''G'') remove ''Material Safety Data Sheets'' and add in its place ''Safety Data Sheets'';

■ F. In Appendix A to § 1910.1450, revise the heading ''G. Material Safety Data Sheets'' and revise the text following the heading.

The revisions read as follows:

§ 1910.1450 Occupational exposure to hazardous chemicals in laboratories.

* * * * *

(b) * * *

Hazardous chemical means any chemical which is classified as health hazard or simple asphyxiant in accordance with the Hazard Communication Standard (§ 1910.1200).

Health hazard means a chemical that 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; carcinogenity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); aspiration hazard. The criteria for determining whether a chemical is classified as a health hazard are detailed in Appendix A of the Hazard Communication Standard (§ 1910.1200) and § 1910.1200(c) (definition of ''simple asphyxiant'').

* * * * *

Mutagen means chemicals that cause permanent changes in the amount or structure of the genetic material in a cell. Chemicals classified as mutagens in accordance with the Hazard Communication Standard (§ 1910.1200) shall be considered mutagens for purposes of this section.

* * * * *

Physical hazard means a chemical that is classified as posing one of the following hazardous effects: Explosive; flammable (gases, aerosols, liquids, or solids); oxidizer (liquid, solid, or gas); self reactive; pyrophoric (gas, liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; in contact with water emits flammable gas; or combustible dust. The criteria for determining whether a chemical is classified as a physical hazard are in Appendix B of the Hazard Communication Standard (§ 1910.1200) and § 1910.1200(c) (definitions of ''combustible dust'' and ''pyrophoric gas'').

* * * * *

Reproductive toxins mean chemicals that affect the reproductive capabilities including adverse effects on sexual function and fertility in adult males and females, as well as adverse effects on the development of the offspring. Chemicals classified as reproductive toxins in accordance with the Hazard Communication Standard (§ 1910.1200) shall be considered reproductive toxins for purposes of this section.

* * * * *

Appendix A to § 1910.1450—National Research Council Recommendations Concerning Chemical Hygiene in Laboratories (Non-Mandatory)

* * * * *

G. Safety Data Sheets

Safety data sheets are presented in ''Prudent Practices'' for the chemicals listed below. (Asterisks denote that comprehensive safety data sheets are provided).

* * * * *

PART 1915—OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR SHIPYARD EMPLOYMENT

■ 34. Revise the authority citation for part 1915 to read as follows:

Authority: Section 41, Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); Sections. 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (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), or 1–2012 (77 FR 3912), as applicable; 29 CFR Part 1911.

Section 1915.100 also issued under 49 U.S.C. 1801–1819 and 5 U.S.C. 553.

Sections 1915.120 and 1915.152 of 29 CFR also issued under 29 CFR part 1911.

Subpart Z—[Amended]

■ 35. Revise § 1915.1001 paragraphs (i)(3), (k)(7), and (k)(8) to read as follows:

§ 1915.1001 Asbestos.

* * * * *

(i) * * *

(3) The employer shall ensure that contaminated clothing is transported in sealed impermeable bags, or other closed, impermeable containers, and labeled in accordance with paragraph (k) of this section.

* * * * *

(k) * * *

(7) *Hazard communication.* (i) Labels shall be affixed to all products containing asbestos and to all containers containing such products, including waste containers. Where feasible, installed asbestos products shall contain a visible label.

(ii) *General.* The employer shall include asbestos in the program established to comply with the Hazard Communication Standard (HCS) (§ 1910.1200). The employer shall ensure that each employee has access to labels on containers of asbestos and safety data sheets, and is trained in accordance with the provisions of the HCS and paragraph (k)(9) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer and lung effects.

(iii) *Labels.* (A) The employer shall ensure that labels of bags or containers of protective clothing and equipment, scrap, waste, and debris containing asbestos fibers bear the following information:

DANGER
CONTAINS ASBESTOS FIBERS
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
DO NOT BREATHE DUST
AVOID CREATING DUST

(B)(*1*) Prior to June 1, 2015, employers may include the following information on raw materials, mixtures or labels of bags or containers of protective clothing and equipment, scrap, waste, and debris containing asbestos fibers in lieu of the labeling requirements in paragraphs (k)(7)(ii) and (k)(7)(iii)(A) of this section:

DANGER
CONTAINS ASBESTOS FIBERS
AVOID CREATING DUST
CANCER AND LUNG DISEASE HAZARD

(*2*) Labels shall also contain a warning statement against breathing asbestos fibers.

(iv) The provisions for labels required in paragraph (k)(7) of this section do not apply where:

(A) Asbestos fibers have been modified by a bonding agent, coating, binder, or other material, provided that the manufacturer can demonstrate that, during any reasonably foreseeable use, handling, storage, disposal, processing, or transportation, no airborne concentrations of asbestos fibers in excess of the permissible exposure limit and/or excursion limit will be released, or

(B) Asbestos is present in a product in concentrations less than 1.0 percent.

(8) *Signs.* (i) Warning signs that demarcate the regulated area shall be provided and displayed at each location where a regulated area is required to be established by paragraph (e) of this section. Signs shall be posted at such a distance from such a location that an

employee may read the signs and take necessary protective steps before entering the area marked by the signs.

(ii) The warning signs required by this paragraph (k)(8) shall bear the following legend:

DANGER
ASBESTOS
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AUTHORIZED PERSONNEL ONLY

(iii) In addition, where the use of respirators and protective clothing is required in the regulated area under this section, the warning signs shall include the following:

WEAR RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING IN THIS AREA

(iv) The employer shall ensure that employees working in and contiguous to regulated areas comprehend the warning signs required to be posted by paragraph (k)(8) of this section. Means to ensure employee comprehension may include the use of foreign languages, pictographs, and graphics.

(v) When a building/vessel owner or employer identifies previously installed PACM and/or ACM, labels or signs shall be affixed or posted so that employees will be notified of what materials contain PACM and/or ACM. The employer shall attach such labels in areas where they will clearly be noticed by employees who are likely to be exposed, such as at the entrance to mechanical room/areas. Signs required by paragraph (k)(6) of this section may be posted in lieu of labels, so long as they contain information required for labeling. The employer shall ensure, to the extent feasible, that employees who come in contact with these signs or labels can comprehend them. Means to ensure employee comprehension may include the use of foreign languages, pictographs, graphics, and awareness training.

(vi) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (k)(8)(ii) of this section:

DANGER
ASBESTOS
CANCER AND LUNG DISEASE HAZARD
AUTHORIZED PERSONNEL ONLY

(vii) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (k)(8)(iii) of this section:

RESPIRATORS AND PROTECTIVE CLOTHING ARE REQUIRED IN THIS AREA

* * * * *

■ 36. Revise § 1915.1026 paragraphs (g)(2)(iv) and (j)(1), to read as follows;

§ 1915.1026 Chromium (VI).

* * * * *

(g) * * *

(2) * * *

(iv) The employer shall ensure that bags or containers of contaminated protective clothing or equipment that are removed from change rooms for laundering, cleaning, maintenance, or disposal are labeled in accordance with the requirements of the Hazard Communication Standard, § 1910.1200.

* * * * *

(j) * * *

(1) *Hazard communication.* The employer shall include chromium (VI) in the program established to comply with the Hazard Communication Standard (HCS) (§ 1910.1200). The employer shall ensure that each employee has access to labels on containers of chromium (VI) and safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (j)(2) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer; skin sensitization; and eye irritation.

* * * * *

PART 1926—SAFETY AND HEALTH REGULATIONS FOR CONSTRUCTION

Subpart D—[Amended]

■ 37. The authority citation for subpart D is revised to read as follows:

Authority: Section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); and 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 31159), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912) as applicable; and 29 CFR part 1911.

Sections 1926.58, 1926.59, 1926.60, and 1926.65 also issued under 5 U.S.C. 553 and 29 CFR part 1911.

Section 1926.61 also issued under 49 U.S.C. 1801–1819 and 6 U.S.C. 553.

Section 1926.62 also issued under section 1031 of the Housing and Community Development Act of 1992 (42 U.S.C. 4853).

Section 1926.65 also issued under section 126 of the Superfund Amendments and Reauthorization Act of 1986, as amended (reprinted at 29 U.S.C.A. 655 Note), and 5 U.S.C. 553.

■ 38. Revise § 1926.60 paragraphs (l)(1) and (l)(2) to read as follows:

§ 1926.60 Methylenedianiline.

* * * * *

(l) * * *

(1) *Hazard communication.* The employer shall include Methylenedianiline (MDA) in the program established to comply with the Hazard Communication Standard (HCS) (§ 1910.1200). The employer shall ensure that each employee has access to labels on containers of MDA and safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (l)(3) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer; liver effects; and skin sensitization.

(2) *Signs and labels*— (i) *Signs.* (A) The employer shall post and maintain legible signs demarcating regulated areas and entrances or access-ways to regulated areas that bear the following legend:

DANGER
MDA
MAY CAUSE CANCER
CAUSES DAMAGE TO THE LIVER
RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING MAY BE REQUIRED IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(B) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (l)(2)(i)(A) of this section:

DANGER
MDA
MAY CAUSE CANCER
LIVER TOXIN
AUTHORIZED PERSONNEL ONLY
RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN THIS AREA

(ii) *Labels.* (A) The employer shall ensure that labels or other appropriate forms of warning are provided for containers of MDA within the workplace. The labels shall comply with the requirements of § 1910.1200(f) and shall include at least the following information for pure MDA and mixtures containing MDA:

DANGER
CONTAINS MDA
MAY CAUSE CANCER
CAUSES DAMAGE TO THE LIVER

(B) Prior to June 1, 2015, employers may include the following information workplace labels in lieu of the labeling requirements in paragraph (l)(2)(ii)(A) of this section:

(*1*) For Pure MDA:

DANGER
CONTAINS MDA
MAY CAUSE CANCER
LIVER TOXIN

(*2*) For mixtures containing MDA:

DANGER
CONTAINS MDA
CONTAINS MATERIALS WHICH MAY CAUSE CANCER

LIVER TOXIN

* * * * *

■ 39. Amend § 1926.62 by revising paragraph (g)(2)(vii), the heading of paragraph (l), paragraph (l)(1)(i), and paragraph (m), and Appendix B to § 1926.62 section XI, to read as follows:

§ 1926.62 Lead.

* * * * *

(g) * * *

(2) * * *

(vii)(A) The employer shall ensure that the containers of contaminated protective clothing and equipment required by paragraph (g)(2)(v) of this section are labeled as follows:

DANGER: CLOTHING AND EQUIPMENT CONTAMINATED WITH LEAD. MAY DAMAGE FERTILITY OR THE UNBORN CHILD. CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM. DO NOT EAT, DRINK OR SMOKE WHEN HANDLING. DO NOT REMOVE DUST BY BLOWING OR SHAKING. DISPOSE OF LEAD CONTAMINATED WASH WATER IN ACCORDANCE WITH APPLICABLE LOCAL, STATE, OR FEDERAL REGULATIONS.

(B) Prior to June 1, 2015, employers may include the following information on bags or containers of contaminated protective clothing and equipment required by paragraph (g)(2)(v) in lieu of the labeling requirements in paragraph (g)(2)(vii)(A) of this section:

Caution: Clothing contaminated with lead. Do not remove dust by blowing or shaking. Dispose of lead contaminated wash water in accordance with applicable local, state, or federal regulations.

* * * * *

(l) *Communication of hazards.*

(1) * * *

(i) *Hazard communication.* The employer shall include lead in the program established to comply with the Hazard Communication Standard (HCS) (§ 1910.1200). The employer shall ensure that each employee has access to labels on containers of lead and safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (l) of this section. The employer shall ensure that at least the following hazards are addressed:

(A) Reproductive/developmental toxicity;

(B) Central nervous system effects;

(C) Kidney effects;

(D) Blood effects; and

(E) Acute toxicity effects.

* * * * *

(m) *Signs.*

(1) *General.*

(i) The employer shall post the following warning signs in each work area where an employee's exposure to lead is above the PEL.

DANGER
LEAD WORK AREA
MAY DAMAGE FERTILITY OR THE UNBORN CHILD
CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM
DO NOT EAT, DRINK OR SMOKE IN THIS AREA

(ii) The employer shall ensure that no statement appears on or near any sign required by this paragraph (m) that contradicts or detracts from the meaning of the required sign.

(iii) The employer shall ensure that signs required by this paragraph (m) are illuminated and cleaned as necessary so that the legend is readily visible.

(iv) The employer may use signs required by other statutes, regulations or ordinances in addition to, or in combination with, signs required by this paragraph (m).

(v) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (m)(1)(i) of this section:

WARNING
LEAD WORK AREA
POISON
NO SMOKING OR EATING

* * * * *

Appendix B to § 1926.62—Employee Standard Summary

* * * * *

XI. Signs—Paragraph (M)

The standard requires that the following warning sign be posted in work areas when the exposure to lead is above the PEL:

DANGER
LEAD WORK AREA
MAY DAMAGE FERTILITY OR THE UNBORN CHILD
CAUSES DAMAGE TO THE CENTRAL NERVOUS SYSTEM
DO NOT EAT, DRINK OR SMOKE IN THIS AREA

Prior to June 1, 2016, employers may use the following legend in lieu of that specified above:

WARNING
LEAD WORK AREA
POISON
NO SMOKING OR EATING

* * * * *

■ 40. Revise § 1926.64 paragraphs (a)(1)(ii) introductory text, (a)(1)(ii)(B), and (d)(1)(vii), and the note following paragraph (d)(1)(vii), to read as follows:

§ 1926.64 Process safety management of highly hazardous chemicals.

* * * * *

(a) * * *

(1) * * *

(ii) A process which involves a Category 1 flammable gas (as defined in § 1910.1200(c)) or flammable liquid with a flashpoint below 100 °F (37.8 °C) on site in one location, in a quantity of 10,000 pounds (4535.9 kg) or more except for:

* * * * *

(B) Flammable liquids with a flashpoint below 100 °F (37.8 °C) stored in atmospheric tanks or transferred that are kept below their normal boiling point without benefit of chilling or refrigeration.

* * * * *

(d) * * *

(1) * * *

(vii) Hazardous effects of inadvertent mixing of different materials that could foreseeably occur.

Note to paragraph (d)(1): Safety data sheets meeting the requirements of § 1910.1200(g) may be used to comply with this requirement to the extent they contain the information required by this paragraph (d)(1).

* * * * *

■ 41. Amend § 1926.65 paragraph (a)(3) by revising the definition of ''Health hazard'' to read as follows:

§ 1926.65 Hazardous waste operations and emergency response.

(a) * * *

(3) * * *

Health hazard means a chemical or a pathogen where acute or chronic health effects may occur in exposed employees. It also includes stress due to temperature extremes. The term *health hazard* includes chemicals that are classified in accordance with the Hazard Communication Standard, § 1910.1200, 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); aspiration toxicity or simple asphyxiant. (*See* Appendix A to § 1910.1200—Health Hazard Criteria (Mandatory) for the criteria for determining whether a chemical is classified as a health hazard.)

* * * * *

Subpart F—[Amended]

■ 42. Revise the authority citation for subpart F to read as follows:

Authority: Section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (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 (62 FR 50017), 5–2002 (67 FR 650008), 5–2007 (72 FR 31159), 4–2010 (75 FR 55355), or 1–2012

(77 FR 3912), as applicable; and 29 CFR part 1911.

* * * * *

■ 43. Amend § 1926.152 as follows:
■ A. Revise the section heading;
■ B. Remove the words ''and combustible'' from the first sentence in paragraph (a)(1), the heading of paragraph (b), and paragraphs (b)(2) introductory text, (b)(4)(viii), (h) introductory text, and (h)(1);
■ C. Remove the words ''or combustible'' wherever it appears in paragraphs (a)(2), (b)(1), (b)(4)(iii), (b)(5), and (c)(3);
■ D. Remove the words ''or combustible'' in paragraphs (d) (the heading), (d)(1), (d)(4), (e)(1), (e)(3), (f)(2), (g)(1), and (g)(8);
■ E. Remove the words ''or combustible'' wherever it appears in paragraphs (i)(1)(i)(D) and (F), (i)(1)(iii)(D), (i)(2)(ii)(A), (D), and (F), (i)(2)(vii)(B)(*2*), (i)(4)(iv)(C), (i)(5)(vi)(A), (D), (G), (V) introductory text, and (i)(5)(vi)(V)(*1*); (j)(1)(i), (j)(2)(ii), (j)(5), and (k)(4);
■ F. Amend the fifth sentence of paragraph (b)(4)(vi) by adding the words ''Category 1, 2, or 3'' before the words ''flammable liquids'';
■ G. Amend paragraphs (e)(2), (e)(5), (g)(7)(i), and (g)(7)(ii), by adding the words ''Category 1, 2, or 3'' before the words ''flammable liquids'' ;
■ H. Amend paragraphs (f)(1) and (f)(3) by removing the words ''Flammable liquids'' and adding in their place the words ''Category 1, 2, or 3 flammable liquids'';
■ I. Revise paragraphs (b)(2)(iii), (b)(3), (h) introductory text, (i)(2)(iv)(F) and (G), (i)(2)(vi)(B), (i)(2)(viii)(E), (i)(3)(i), (i)(3)(iv)(A) and (C), (i)(3)(v)(D), and (i)(4)(iv)(E);
■ J. Revise Table F–19 and paragraph (k)(3)(iv).

The revisions read as follows:

§ 1926.152 Flammable liquids.

* * * * *

(b) * * *

(2) * * *

(iii) Cabinets shall be labeled in conspicuous lettering, ''Flammable-Keep Away from Open Flames.''

(3) Not more than 60 gallons of Category 1, 2 and/or 3 flammable liquids or 120 gallons of Category 4 flammable liquids shall be stored in any one storage cabinet. Not more than three such cabinets may be located in a single storage area. Quantities in excess of this shall be stored in an inside storage room.

* * * * *

(h) *Scope.* This section applies to the handling, storage, and use of flammable liquids with a flashpoint at or below 199.4 °F (93 °C). This section does not apply to:

* * * * *

(i) * * *

(2) * * *

(iv) * * *

(F) Tanks and pressure vessels storing Category 1 flammable liquids shall be equipped with venting devices that shall be normally closed except when venting to pressure or vacuum conditions. Tanks and pressure vessels storing Category 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall be equipped with venting devices that shall be normally closed except when venting under pressure or vacuum conditions, or with approved flame arresters.

Exemption: Tanks of 3,000 bbls (barrels) (84 m(3)) capacity or less containing crude petroleum in crude-producing areas; and, outside aboveground atmospheric tanks under 1,000 gallons (3,785 L) capacity containing other than Category 1 flammable liquids may have open vents. (*See* paragraph (i)(2)(vi)(B) of this section.)

(G) Flame arresters or venting devices required in paragraph (i)(2)(iv)(F) of this section may be omitted for Category 2 flammable liquids or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C) where conditions are such that their use may, in case of obstruction, result in tank damage.

* * * * *

(vi) * * *

(B) Where vent pipe outlets for tanks storing Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), are adjacent to buildings or public ways, they shall be located so that the vapors are released at a safe point outside of buildings and not less than 12 feet (3.658 m) above the adjacent ground level. In order to aid their dispersion, vapors shall be discharged upward or horizontally away from closely adjacent walls. Vent outlets shall be located so that flammable vapors will not be trapped by eaves or other obstructions and shall be at least 5 feet (1.52 m) from building openings.

(viii) * * *

(E) For Category 2 flammable liquids or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), other than crude oils, gasolines, and asphalts, the fill pipe shall be so designed and installed as to minimize the possibility of generating static electricity. A fill pipe entering the top of a tank shall terminate within 6 inches (15.24 cm) of the bottom of the tank and shall be installed to avoid excessive vibration.

* * * * *

(3) * * *

(i) *Location.* Evacuation for underground storage tanks shall be made with due care to avoid undermining of foundations of existing structures. Underground tanks or tanks under buildings shall be so located with respect to existing building foundations and supports that the loads carried by the latter cannot be transmitted to the tank. The distance from any part of a tank storing Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), to the nearest wall of any basement or pit shall be not less than 1 foot (0.304 m), and to any property line that may be built upon, not less than 3 feet (0.912 m). The distance from any part of a tank storing Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids to the nearest wall of any basement, pit or property line shall be not less than 1 foot (0.304 m).

* * * * *

(iv) * * *

(A) Location and arrangement of vents for Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C). Vent pipes from tanks storing Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall be so located that the discharge point is outside of buildings, higher than the fill pipe opening, and not less than 12 feet (3.658 m) above the adjacent ground level. Vent pipes shall discharge only upward in order to disperse vapors. Vent pipes 2 inches (5.08 cm) or less in nominal inside diameter shall not be obstructed by devices that will cause excessive back pressure. Vent pipe outlets shall be so located that flammable vapors will not enter building openings, or be trapped under eaves or other obstructions. If the vent pipe is less than 10 feet (3.04 m) in length, or greater than 2 inches (5.08 cm) in nominal inside diameter, the outlet shall be provided with a vacuum and pressure relief device or there shall be an approved flame arrester located in the vent line at the outlet or within the approved distance from the outlet.

* * * * *

(C) Location and arrangement of vents for Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids. Vent pipes from tanks storing Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids shall terminate outside of the building and higher than the fill pipe opening. Vent outlets shall be above normal snow level. They may be fitted with return bends, coarse screens or other devices to minimize ingress of foreign material.

* * * * *

(v) * * *

(D) For Category 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), other than crude oils, gasolines, and asphalts, the fill pipe shall be so designed and installed as to minimize the possibility of generating static electricity by terminating within 6 inches (15.24 cm) of the bottom of the tank.

* * * * *

(4) * * *

(iv) * * *

(E) For Category 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), other than crude oils, gasolines, and asphalts, the fill pipe shall be so designed and installed as to minimize the possibility of generating static electricity by terminating within 6 inches (15.24 cm) of the bottom of the tank.

* * * * *

(k) * * *

(3) * * *

* * * * *

BILLING CODE 4510–26–P

TABLE F-19 - ELECTRICAL EQUIPMENT HAZARDOUS AREAS - SERVICE STATIONS

Location	Class I Group D division	Extent of classified area
Underground tank:		
Fill opening	1	Any pit, box or space below grade level, any part of which is within the Division 1 or 2 classified area.
	2	Up to 18 inches (45.72 cm) above grade level within a horizontal radius of 10 feet (3.04 m) from a loose fill connection and within a horizontal radius of 5 feet (1.52 m) from a tight fill connection.
Vent - Discharging upward...	1	Within 3 feet (0.912 m) of open end of vent, extending in all directions.
	2	Area between 3 feet (0.912 m) and 5 feet (1.52 m) of open end of vent, extending in all directions.
Dispenser:		
Pits........................	1	Any pit, box or space below grade level, any part of which is within the Division 1 or 2 classified area.
Dispenser enclosure.........	1	The area 4 feet (1.216 m) vertically above base within the enclosure and 18 inches (45.72 cm) horizontally in all directions.
Outdoor.....................	2	Up to 18 inches (45.72 cm) above grade level within 20 feet (6.08 m) horizontally of any edge of enclosure.
Indoor:		
With mechanical ventilation.	2	Up to 18 inches (45.72 cm) above grade level within 20 feet (6.08 m) horizontally of any edge of enclosure.
With gravity ventilation....	2	Up to 18 inches (45.72 cm) above grade or floor level within 25 feet (7.6 m) horizontally of any edge of enclosure.
Remote pump - Outdoor.......	1	Any pit, box or space below grade level if any part is within a horizontal distance of 10 feet (3.04 m) from any edge of pump.
	2	Within 3 feet (0.912 m) of any edge of pump, extending

		in all directions. Also up to 18 inches (45.72 cm) above grade level within 10 feet (3.04 m) horizontally from any edge of pump.
Remote pump - Indoor........	1	Entire area within any pit.
	2	Within 5 feet (1.52 m) of any edge of pump, extending in all directions. Also up to 3 feet (3.04 m) above floor or grade level within 25 feet (6.08 m) horizontally from any edge of pump.
Lubrication or service room.	1	Entire area within any pit.
	2	Area up to 18 inches (45.72 cm) above floor or grade level within entire lubrication room.
Dispenser for Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 ° F (37.8 ° C)	2	Within 3 feet (0.912 m) of any fill or dispensing point, extending in all directions.
Special enclosure inside building per 1910.106(f)(1)(ii).	1	Entire enclosure.
Sales, storage and rest rooms...............	(1)	If there is any opening to these rooms within the extent of a Division 1 area, the entire room shall be classified as Division 1.

(1) Ordinary.

* * * * *

BILLING CODE 4510–26–C

(iv) Piping handling Category 1 or 2 flammable liquids, or Category 3 flammable liquids with a flashpoint below 100 °F (37.8 °C), shall be grounded to control stray currents.

* * * * *

■ 44. Amend § 1926.155 as follows:

■ A. Remove and reserve paragraph (c);

■ B. Revise paragraphs (h) and (i)(1) and (2).

The revisions read as follows:

§ 1926.155 Definitions applicable to this subpart.

* * * * *

(h) *Flammable liquid* means any liquid having a vapor pressure not exceeding 40 pounds per square inch (absolute) at 100 °F (37.8 °C) and having a flashpoint at or below 199.4 °F (93 °C). Flammable liquids are divided into four categories as follows:

(1) Category 1 shall include liquids having flashpoints below 73.4 °F (23 °C) and having a boiling point at or below 95 °F (35 °C).

(2) Category 2 shall include liquids having flashpoints below 73.4 °F (23 °C) and having a boiling point above 95 °F (35 °C).

(3) Category 3 shall include liquids having flashpoints at or above 73.4 °F (23 °C) and at or below 140 °F (60 °C).

(4) Category 4 shall include liquids having flashpoints above 140 °F (60 °C) and at or below 199.4 °F (93 °C).

(i) * * *

(1) The flashpoint of liquids having a viscosity less than 45 Saybolt Universal Second(s) at 100 °F (37.8 °C) and a flashpoint below 175 °F (79.4 °C) shall be determined in accordance with the Standard Method of Test for Flash Point by the Tag Closed Tester, ASTM D–56–69 (incorporated by reference; *See* § 1926.6), or an equivalent method as defined by § 1910.1200 appendix B.

(2) The flashpoints of liquids having a viscosity of 45 Saybolt Universal Second(s) or more at 175 °F (79.4 °C) or higher shall be determined in accordance with the Standard Method of Test for Flash Point by the Pensky Martens Closed Tester, ASTM D–93–69 (incorporated by reference; *See* § 1926.6), or an equivalent method as defined by § 1910.1200 appendix B.

* * * * *

Subpart Z—[Amended]

■ 45. Revise the authority citation for subpart Z to read as follows:

Authority: Section107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3704); Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); and 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 31159), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912) as applicable; and 29 CFR part 1911.

Section 1926.1102 not issued under 29 U.S.C. 655 or 29 CFR part 1911; also issued under 5 U.S.C. 553.

■ 46. Amend § 1926.1101 as follows:

■ A. Redesignate paragraph (k)(1) as (k)(1)(i) and add a new heading to paragraph (k)(1);

■ B. Add new paragraphs (k)(1)(ii), (k)(7)(ii)(C), (k)(7)(ii)(D), and (k)(8)(iv);

■ C. Amend paragraphs (k)(2)(i) and (k)(3)(i) by removing the references to ''(k)(1)'' and adding in their place ''(k)(1)(i)'';

■ D. Revise paragraphs (k)(7)(ii)(A) and (B), and (k)(8)(ii) and (iii);

The revisions read as follows:

§ 1926.1101 Asbestos.

* * * * *

(k) * * *

(1) *Hazard communication.*

* * * * *

(ii) The employer shall include asbestos in the program established to comply with the Hazard Communication Standard (HCS) (§ 1910.1200). The employer shall ensure that each employee has access to labels on containers of asbestos and safety data sheets, and is trained in accordance with the provisions of HCS and paragraphs (k)(9) and (10) of this section. The employer shall provide information on at least the following hazards: Cancer and lung effects.

* * * * *

(7) * * *

(ii) * * *

(A) The warning signs required by paragraph (k)(7) of this section shall bear the following information.

DANGER
ASBESTOS
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AUTHORIZED PERSONNEL ONLY

(B) In addition, where the use of respirators and protective clothing is required in the regulated area under this section, the warning signs shall include the following:

WEAR RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING IN THIS AREA

(C) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (k)(7)(ii)(A) of this section:

DANGER
ASBESTOS
CANCER AND LUNG DISEASE HAZARD
AUTHORIZED PERSONNEL ONLY

(D) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (k)(7)(ii)(B) of this section:

RESPIRATORS AND PROTECTIVE CLOTHING ARE REQUIRED IN THIS AREA

* * * * *

(8) * * *

(ii) The employer shall ensure that such labels comply with paragraphs (k) of this section.

(iii) The employer shall ensure that labels of bags or containers of protective clothing and equipment, scrap, waste, and debris containing asbestos fibers bear the following information:

DANGER
CONTAINS ASBESTOS FIBERS
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
DO NOT BREATHE DUST
AVOID CREATING DUST

(iv) (A) Prior to June 1, 2015, employers may include the following information on raw materials, mixtures or labels of bags or containers of protective clothing and equipment, scrap, waste, and debris containing asbestos fibers in lieu of the labeling requirements in paragraphs (k)(8)(ii) and (k)(8)(iii) of this section:

DANGER
CONTAINS ASBESTOS FIBERS
AVOID CREATING DUST
CANCER AND LUNG DISEASE HAZARD

(B) Labels shall also contain a warning statement against breathing asbestos fibers.

* * * * *

■ 47. Revise § 1926.1126 paragraphs (g)(2)(iv) and (j)(1) to read as follows:

§ 1926.1126 Chromium (VI).

* * * * *

(g) * * *

(2) * * *

(iv) The employer shall ensure that bags or containers of contaminated protective clothing or equipment that are removed from change rooms for laundering, cleaning, maintenance, or disposal shall be labeled in accordance with the requirements of the Hazard Communication Standard, § 1910.1200.

* * * * *

(j) * * *

(1) *Hazard communication.* The employer shall include chromium (VI) in the program established to comply with the Hazard Communication Standard (HCS) (§ 1910.1200). The employer shall ensure that each employee has access to labels on containers of chromium and safety data sheets, and is trained in accordance with the provisions of § 1910.1200 and paragraph (j)(2) of this section. The employer shall provide information on at least the following hazards: Cancer; eye irritation; and skin sensitization.

* * * * *

■ 48. Revise § 1926.1127 paragraphs (i)(2)(iv), (k)(7), and (m)(1), (m)(2), and (m)(3), to read as follows:

§ 1926.1127 Cadmium.

* * * * *

(i) * * *

(2) * * *

(iv) The employer shall ensure that containers of contaminated protective clothing and equipment that are to be taken out of the change rooms or the workplace for laundering, cleaning, maintenance or disposal shall bear labels in accordance with paragraph (m)(3)(ii) of this section.

(k) * * *

(7) Waste, scrap, debris, bags, and containers, personal protective equipment and clothing contaminated with cadmium and consigned for disposal shall be collected and disposed of in sealed impermeable bags or other closed, impermeable containers. These bags and containers shall be labeled in accordance with paragraph (m)(3)(ii) of this section.

* * * * *

(m) * * *

(1) *Hazard communication.* The employer shall include cadmium in the program established to comply with the Hazard Communication Standard (HCS) (§ 1910.1200). The employer shall ensure that each employee has access to labels on containers of cadmium and safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (m)(4) of this section. The employer shall provide information on at least the following hazards: Cancer; lung effects; kidney effects; and acute toxicity effects.

(2) *Warning signs.* (i) Warning signs shall be provided and displayed in regulated areas. In addition, warning signs shall be posted at all approaches to regulated areas so that an employee may read the signs and take necessary protective steps before entering the area.

(ii) Warning signs required by paragraph (m)(2)(i) of this section shall bear the following legend:

DANGER
CADMIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS AND KIDNEYS
WEAR RESPIRATORY PROTECTION IN THIS AREA
AUTHORIZED PERSONNEL ONLY

(iii) The employer shall ensure that signs required by this paragraph (m)(2) are illuminated, cleaned, and maintained as necessary so that the legend is readily visible.

(iv) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (m)(2)(ii) of this section:

DANGER
CADMIUM
CANCER HAZARD
CAN CAUSE LUNG AND KIDNEY DISEASE
AUTHORIZED PERSONNEL ONLY
RESPIRATORS REQUIRED IN THIS AREA

(3) *Warning labels.* (i) Shipping and storage containers containing cadmium or cadmium compounds shall bear appropriate warning labels, as specified in paragraph (m)(1) of this section.

(ii) The warning labels for containers of cadmium-contaminated protective clothing, equipment, waste, scrap, or debris shall include at least the following information:

DANGER
CONTAINS CADMIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS AND KIDNEYS
AVOID CREATING DUST

(iii) Where feasible, installed cadmium products shall have a visible label or other indication that cadmium is present.

(iv) Prior to June 1, 2015, employers may include the following information on shipping and storage containers containing cadmium, cadmium compounds, or cadmium-contaminated clothing, equipment, waste, scrap, or debris in lieu of the labeling requirements specified in paragraphs (m)(3)(i) and (m)(3)(ii) of this section:

DANGER
CONTAINS CADMIUM
CANCER HAZARD
AVOID CREATING DUST
CAN CAUSE LUNG AND KIDNEY DISEASE

* * * * *

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