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), Department of Labor.

ACTION: Proposed rule; request for comments.

SUMMARY: OSHA is proposing to modify its existing Hazard Communication Standard (HCS) to conform with the United Nations' (UN) Globally Harmonized System of Classification and Labelling of Chemicals (GHS). OSHA has made a preliminary determination that the proposed modifications 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 may be exposed, and in reducing the incidence of chemical-related occupational illnesses and injuries.

The proposed 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, requirements for employee training on labels and safety data sheets. OSHA is also proposing to modify provisions of a number 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.

DATES: *Written comments.* Written comments, including comments on the information collection determination described in Section VIII of the preamble (OMB Review under the Paperwork Reduction Act of 1995), must be submitted by the following dates:

Hard copy: Comments must be submitted (postmarked or sent) by December 29, 2009.

Facsimile and electronic transmissions: Comments must be sent by December 29, 2009.

Informal public hearings. The Agency will schedule an informal public hearing on the proposed rule. The location and date of the hearing, procedures for interested parties to notify the Agency of their intention to participate, and procedures for participants to submit their testimony and documentary evidence will be announced in the **Federal Register.**

ADDRESSES: *Written comments.* You may submit comments by any of the following methods:

Electronically: You may submit comments electronically at *http://www.regulations.gov,* which is the Federal e-Rulemaking Portal. Follow the instructions on-line for making electronic submissions.

Fax: If your submissions, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger or courier service: You must submit three copies of your comments to the OSHA Docket Office, Docket No. OSHA–H022K–2006–0062, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210. Deliveries (hand, express mail, messenger and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m.–4:45 p.m., E.T.

Instructions: All submissions must include the Agency name and the docket number for this rulemaking (Docket No. OSHA–H022K–2006–0062). All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at *http://www.regulations.gov.* Therefore, OSHA cautions you about submitting personal information such as social security numbers and birthdates.

Docket: To read or download comments submitted in response to this **Federal Register** notice, go to Docket No. OSHA–H022K–2006–0062 at *http://www.regulations.gov* or to the OSHA Docket Office at the address above. All comments are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through that Web page. All comments, including copyrighted material, are available for inspection and copying at the OSHA Docket Office.

Electronic copies of this **Federal Register** document are available at *http://regulations.gov.* Copies also are available from the OSHA Office of Publications, Room N–3101, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–1888. This document, as well as news releases and other relevant information, are also available at OSHA's Web page at *http://www.osha.gov.*

FOR FURTHER INFORMATION CONTACT: For general information and press inquiries, contact Jennifer Ashley, Office of Communications, Room N–3647, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–1999. For technical information, contact Maureen O'Donnell, 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:

I. Introduction

The preamble to the proposal to modify the Hazard Communication Standard includes a review of the events leading to the proposal, a discussion of the reasons why OSHA believes these modifications are necessary, the preliminary economic and regulatory flexibility analysis for the proposal, and an explanation of the specific provisions set forth in the proposed standard. The discussion follows this outline:

In the preamble, OSHA references a number of 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*). The documents are also available at the OSHA Docket Office (see **ADDRESSES** section above). For further information about accessing documents referenced in this **Federal Register** notice, *see* Section XIV (Public Participation—Notice of Hearing).

II. Issues

OSHA requests comment on all relevant issues, including economic impact and feasibility, environmental impact, effects on small entities, proposed revisions to the HCS, and subsequent modifications to other standards. OSHA has received many comments on the issues raised in the Advance Notice of Proposed Rulemaking (ANPR) (71 FR 53617, September 12, 2006), and the Agency has considered those comments in the development of this proposal. This section identifies issues on which the Agency seeks additional information and comment to supplement that received in response to the ANPR, as well as new topics related to this proposal. While new comments are welcome, OSHA requests that comments submitted in response to the ANPR not be resubmitted as they are retained in the rulemaking record and reconsidered throughout the process.

OSHA is including these issues at the beginning of the document to assist readers as they consider the comments they plan to submit. However, to fully understand the questions and provide substantive input in response to them, the parts of the preamble that address these issues in detail should be read and reviewed. These include Section VII, which addresses the impacts of the NPRM, and thus provides the background related questions 2 through 5. Section XV provides the Summary and Explanation of the proposed regulatory text, and Section XVII is the text itself. These are key to understanding questions 6 through 26. It should be noted that the Federal Register's required format for a modification of an existing standard does not allow the Agency to provide the full text of the rule, *i.e.,* the regulatory text in this document only addresses those paragraphs that OSHA is proposing to change. Therefore, the Agency is putting a marked up version of the text of the current rule on its web page to help readers understand the proposed changes in context. The marked up text will be found on *www.osha.gov* under Hazard Communication in the subject index.

OSHA requests that comments be organized, to the extent possible, around the following issues and numbered questions. Submitting comments in an organized manner and with clear reference to the issue raised will enable all participants to easily see what issues the commenter addressed and how they were addressed. This is particularly important in a rulemaking such as GHS which affects many diverse industries. Many commenters, especially small businesses, are likely to confine their interest (and comment) to the issues that affect them, and they will benefit from being able to quickly identify comment on their issues in others' submissions. Of course, OSHA also welcomes relevant comments concerning the proposal that fall outside the issue questions raised in this section. However, the Agency is particularly interested in receiving public responses, supported by evidence and reasons, to the following questions:

Need and Support for the Standard

1. OSHA has made a preliminary determination that the proposed modifications to the HCS would increase the quality and consistency of information provided to employers and employees. Specifically, OSHA believes that 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. Is this assessment correct? OSHA requests information that reflects on the effectiveness of the proposed modifications to the HCS in protecting employees from chemical hazards in the workplace.

Economic Impacts and Economic Feasibility

2. The preliminary economic analysis in Section VII raises a variety of specific questions and issues with respect to the preliminary economic analysis. OSHA would appreciate it if you could place answers to these issues as heading 2 in your comments and further organize comments on the preliminary economic analysis (PEA) as follows:

a. *Industrial profiles.* This covers issues concerning how many employees, establishments and products would be affected by the proposed standard. OSHA welcomes comments on all aspects of the industrial profile and is particularly interested in comments on the number of affected employees, and the number of SDSs that would need revision, by industry.

b. *Issues with respect to estimated benefits of the proposed standard.* OSHA considers three kinds of benefits in this preliminary analysis: Benefits associated with preventing injuries, illnesses, and fatalities through clearer and more accessible information; benefits associated with reducing the time that safety and health managers and logistics and emergency response personnel spend on hazardous chemicals through clearer and easier-to-find information; and benefits associated with reducing the time needed to develop and review SDSs because of international harmonization. OSHA is particularly interested in comments on the scope of these benefits; the extent to which they are already being achieved by existing practices; and the extent to which they depend on other countries following the harmonization effort.

c. *Issues with respect to the costs and range of costs of the proposed standard.* OSHA preliminarily estimated the principal costs of the standard to chemical producers for reclassification of chemicals; remaking SDS's; and redoing labels; and to chemical users for familiarization and program changes for managers and for training exposed employees. OSHA welcomes comments on all aspects of the costs, and is particularly interested in comments on the extent to which chemical producers may have already met some of the requirements of the standard and the time and professional skills needed for the activities the standard would require.

d. *Issues with respect to economic impacts and feasibility of the proposed standard, including the sensitivity of OSHA's economic feasibility determination with respect to various assumptions.* OSHA welcomes comments on all aspects of the economic impact and economic feasibility analyses.

e. *All other issues with respect to the PEA.*

Effects on Small Entities

3. OSHA has certified that the proposed standard will not have a

significant impact on a substantial number of small entities. Nevertheless, because of the number of small entities affected, OSHA has prepared a voluntary initial regulatory flexibility analysis, the results of which are described in Section VII of the proposed rule. Do you consider the estimated costs and impacts on small entities presented there to be reasonable? Why or why not?

4. Are there alternatives to the rule as a whole or specific requirements of the rule that reduce impacts on small entities while still protecting the health of employees and meeting the broad goal of a globally harmonized system?

Environmental Impacts

5. OSHA has preliminarily determined that the proposed standard will not have any adverse effects on the environment, and may have positive effects on the environment. OSHA welcomes comments on this determination.

Hazard Classification

6. OSHA is proposing to adopt all of the physical and health hazard classes in the GHS. Among the physical and health hazard classes, OSHA is proposing to include all hazard categories in the GHS except Acute Toxicity Category 5 for oral, dermal, or inhalation exposures; Skin Corrosion/Irritation Category 3; and Aspiration Hazard Category 2. If you believe that the exclusion of these hazard categories is not consistent with the scope and/or level of protection provided by the current HCS, please describe any recommended changes to this proposal and the reasons you think these changes are necessary.

7. OSHA has proposed a definition for unclassified hazards be added to the HCS to ensure that all hazards currently covered by the HCS—or new hazards that are identified in the future—are included in the scope of the revised standard until such time as specific criteria for the effect are added to the GHS and subsequently adopted by OSHA. Will this approach provide sufficient interim coverage for hazards such as combustible dust? Are there other hazards for which criteria should be developed and added to the GHS? Please provide information regarding these hazards, and the information available to characterize them.

8. OSHA believes it may be more appropriate to add specific coverage for simple asphyxiants to the standard in the final rule to ensure everyone properly addresses their coverage rather than addressing them under the unclassified hazard definition. This effect is simple and straightforward, and could be addressed in a definition that does not involve extensive criteria. OSHA is requesting comment on this approach. A possible definition would be 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 would also like to solicit comments on specific label elements for simple asphyxiants. 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.

All other requirements of the standard that apply to hazardous chemicals would also apply to chemicals that meet this definition. These substances would generally be covered already under the proposed rule as compressed gases, and may also pose other effects such as flammability that would have to be addressed as well. They are also already covered under the existing HCS. Is the definition suggested by OSHA sufficient to cover this effect? Do you have suggestions for modifying this definition? Are the label elements suggested appropriate?

9. In order to help to ensure that health hazard determinations are properly conducted under a performance-oriented approach, the HCS includes a ''floor'' of chemicals that are to be considered hazardous based on several cited reference lists. In addition, the existence of one toxicological study indicating a possible adverse effect is considered sufficient for a finding of hazard for any health effect. Under the GHS, there is no floor of chemicals cited, nor is there an across-the-board provision such as the one-study criterion. Instead, specific, detailed criteria are provided for each type of health hazard to guide the evaluation of relevant data and subsequent classification of the chemical. The proposed modifications to the HCS would align the standard to the GHS approach, and thus do not include the floor of chemicals nor the universal one-study rule. Would the proposed detailed criteria provide sufficient guidance for a thorough hazard evaluation?

10. OSHA has edited the chapters in the GHS for classification of physical and health hazards to remove material not directly related to classification and to otherwise streamline the text. OSHA anticipates providing the decision logics separately to serve as guidance, but has not included them in the regulatory text. Are there any additions, subtractions, or clarifications of the classification criteria from the GHS that OSHA needs to consider?

11. Certain physical hazard classification criteria (*i.e.,* for self-reactive chemicals, organic peroxides, self-heating chemicals, explosives) either directly reference packaging or quantity, or rely on test methods that reference packaging or quantity. The criteria were developed for transport concerns. Clearly, quantity and packaging can greatly affect safe transport of chemicals that pose hazards such as those listed above. However, OSHA seeks comments on whether the criteria as stated in the GHS are appropriate for the workplace. Does use of these criteria present any obstacles to classification or create any difficulties for suppliers or users of chemicals? Describe any difficulties these criteria may present and any suggestions for addressing these issues, particularly recommendations that would be consistent with the GHS and maintain the GHS level of safety for these chemicals.

12. The GHS gives countries guidance on a cut-off or concentration limit for chemical mixtures containing target organ toxicity hazards. In Appendix A, Section A.8.3, OSHA is proposing to make the suggested 20% concentration limit mandatory so that label preparers are clear on what needs to be done. Please comment on whether this mandatory concentration limit is appropriate. If you have an alternative, please provide it along with the rationale.

Labels

13. The proposal would require pictograms to have a red frame. As discussed in Section V, OSHA believes that use of the color red will make warnings more noticeable and will aid in communicating the presence of a hazard. However, the GHS gives competent authorities such as OSHA the discretion to allow use of a black frame when the pictogram appears on a label for a package which will not be exported. For packages that will not be exported, should the modified standard allow black frames on pictograms, or should the pictogram frame be required to be presented in red?

14. In addition to the pictograms, signal word and hazard statements, GHS labels must include precautionary statements. OSHA is proposing to require the text in the precautionary statements in the GHS to be on HCS labels. As discussed in Section XV Summary and Explanation of the Proposed Standard, these statements are codified under the GHS, meaning that numbers have been assigned to them. In addition, the appropriate statements to use for each hazard class and category have been indicated in the GHS annexes. This means that label preparers will know exactly what precautionary statements to apply once they complete their hazard classification, and chemical users will see consistent language on labels to indicate the necessary precautionary measures. However, the statements are not yet considered to be part of the harmonized text like hazard statements are; rather they are included in the GHS as an suggested language. OSHA expects that other countries may adopt the codified precautionary statements when they put GHS in place. For example the EU has required that labels use the GHS codified precautionary statement text in adapting the GHS. Since OSHA did not previously require the use of precautionary statements, and had no such recommended statements to provide, the Agency is proposing to use those currently in the GHS as the mandatory requirements with the option of consolidating statements where appropriate (*See* Appendix C). OSHA anticipates this approach will provide the maximum benefit. OSHA is also seeking comment on whether any of these statements should be modified or if other precautionary statements should be included.

In addition, as discussed in Section IV, OSHA has presented other alternatives with regards to precautionary statements, and OSHA is soliciting comment on these options as well. Specifically, OSHA is seeking feedback on whether the Agency should include the GHS precautionary statements as nonbinding examples, through a non mandatory appendix or guidance, rather than as required statements, or whether OSHA should allow label preparers to develop their own precautionary statements rather than specifying the text to be used.

15. OSHA has not proposed to require the exploding bomb pictogram or specific precautionary statements for Division 1.4S ammunition and ammunition components because the specified GHS label elements may not accurately reflect the hazards of these materials. Is this sufficiently protective? Are any adjustments to the label elements for Division 1.4S ammunition and ammunition components necessary? Describe any requested changes and explain why such revisions are necessary.

16. In the current HCS, OSHA has a provision that requires labels to be updated within three months of obtaining new and significant information about the hazards. The Agency has not been enforcing this provision for many years, and there has been an administrative stay on enforcement. OSHA is including the provision in this proposal, and inviting comment on it with the intention of including it in the final rule and lifting the stay. Is three months the appropriate time interval for updating? Are there any practical accommodations that need to accompany this limit (for example, related to stockpiles of chemicals)? Provide any alternatives you consider appropriate, as well as documentation to support them.

Safety Data Sheets (SDSs)

17. As discussed in Section XV, the Agency is proposing to require that OSHA permissible exposure limits (PELs) be included on the SDS, as well as any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet. OSHA welcomes comments on this approach, along with an explanation of the basis for your position.

18. OSHA is proposing that Section 15 of the SDS be non-mandatory. As indicated in Appendix D, Section 15 addresses regulatory information concerning the chemical. OSHA is considering requiring the substance specific standards be referenced in this section, which would make Section 15 mandatory. Would employers and employees benefit from having this information in this section of the SDS?

Other Standards Affected

19. OSHA is proposing 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 HCS or provide information pertinent to the Safety Data Sheets (SDSs). In most cases OSHA has modified the standards to maintain scope and protection. However, the changes in definitions for flammable liquids Category 1 and 2 and flammable aerosols appear to be more than simply rounding to the nearest significant number.

○ *Flammable liquids Category 1 and 2:* The boiling point cut-off for Category 1 is reduced from 100 deg F (37.8 deg C) or less to 95 deg F (35 deg C) or less, which could shift some liquids from Category 1 to Category 2.

○ *Flammable aerosols:* OSHA is proposing to adopt the GHS method to determine flammability rather than the method defined by the Consumer Product Safety Commission (CPSC).

OSHA's decision to change these definitions to be consistent with the GHS is based not only upon harmonizing its standards with those of other countries that have adopted or may adopt the GHS, but OSHA is also concerned with making its standards internally consistent. OSHA believes the methods used to classify these physical hazards are similar enough so 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. Would the proposed changes have any impact on your operations? If so, describe the anticipated effects.

20. OSHA is proposing 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 °F. To reflect consistency with the revised HCS where appropriate, OSHA is proposing to add the specific flashpoint criteria. This will maintain equivalent protection. Are there other standards that OSHA should update with the new terminology?

21. OSHA is proposing to modify the language required on signs in substance-specific health standards. The Agency developed the proposed language to reflect the terminology of the revised HCS while, at the same time, providing adequate warning through language that is consistent with the current sign requirements for these chemicals. An added benefit is the hazard warnings on signs specified for these standards will now be consistent throughout OSHA standards. For example, all carcinogens will now bear the hazard statement ''MAY CAUSE CANCER''. OSHA believes that providing language that is consistent on both signs and labels will improve comprehension for employees. Does the proposed language on signs accurately convey the hazards?

22. OSHA is proposing to revise the substance-specific health standards' provisions on labeling for producers and importers of chemicals and substances. Currently in the substance-specific standards OSHA requires specific language on labels for certain chemicals. OSHA is proposing to change these labeling requirements by referring those responsible for labeling to the modified HCS and including in each substance-

specific standard a list of health effects that must be considered for hazard classification. The modified HCS will dictate the specific language (*i.e.,* signal word, hazard statement(s), and precautionary statement(s)) that is required on labels through the classification process. However, OSHA is proposing to maintain specific language for labels on contaminated clothing and waste/debris containers to ensure adequate hazard communication for the downstream recipients. How would the removal of required language for labels from substance-specific standards affect your work place? Are there hazard warnings that will be lost that do not have an equivalent hazard or precautionary statement? Are there alternatives to OSHA's approach for the substance-specific standards that will assure information is disseminated in a manner that is consistent with the modified HCS labeling requirements?

23. In determining the health hazards that need to be considered by manufacturers, importers and distributors when classifying chemicals regulated by the substance-specific standards, OSHA is proposing to primarily rely on the determinations made by the Agency in each rulemaking, the *NIOSH Pocket Guide to Chemical Hazards* (2005) and the International Chemical Safety Cards, and use as a secondary source the health effects identified by the European Commission (2007). OSHA is proposing to include a health hazard only if it is identified as such by two or more of these organizations. Are there other sources of information that OSHA should consult?

24. As detailed in the Summary and Explanation section of this document, OSHA is not proposing in this rulemaking to update 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). 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]). OSHA believes that these standards could be updated when the referenced external organizations adopt applicable GHS elements. If OSHA were to change these standards to comply with the GHS, how would this impact your operations?

Effective Dates

25. OSHA has proposed to require that employers train employees regarding the new labels and safety data sheets within two years after publication of the final rule to ensure they are familiar with the new approach when they begin to see new labels and SDSs in their workplaces. Is the proposed time appropriate?

26. OSHA has proposed that chemical manufacturers, importers, distributors, and employers be required to comply with all provisions of the modified final rule within three years after its publication. Does this allow adequate time to review hazard classifications and amend them as necessary, and to revise labels and safety data sheets to reflect the new requirements? Would a shorter time frame be sufficient?

27. Are there any other factors that should be considered in establishing the phase-in period?

Compliance Assistance and Outreach

28. OSHA received many comments in response to the questions in the ANPR regarding compliance assistance and outreach and is seeking additional comment in this proposal. However, comments already submitted need not be resubmitted. Please refer to the discussion in Section XV. Specifically, OSHA is interested in your responses to the following: What types of materials or products would best assist employers in understanding and complying with the modified HCS? OSHA seeks input to identify the tools that would be most useful to employers and employees, the subjects of greatest interest (*e.g.,* classification criteria, labels, safety data sheets), and the best means of distributing these materials.

29. OSHA received a number of comments that suggested that a data base of chemical classifications should be developed and maintained to assist chemical manufacturers and importers in performing hazard classifications. This approach has been adopted in some other countries. Would such a data base be helpful? Who would be responsible for doing the classifications and maintaining them? How would the data base be kept aligned with other countries' classifications?

Alternative Approaches

30. OSHA has described alternatives to the scope and application of the proposed rule in the preamble, Section IV. These include consideration of allowing voluntary implementation of the GHS; exemptions based on size of the business; adopting some components of the GHS but not others; and not adopting all of the required label elements. The Agency requests comments on these alternatives, with data to support the views expressed. Suggestions and support for other alternatives are requested as well.

III. Events Leading to the Proposed Modifications to the Hazard Communication Standard

OSHA's Hazard Communication Standard (HCS) (29 CFR 1910.1200; 1915.1200; 1917.28; 1918.90; and 1926.59) was first issued in 1983 and covered the manufacturing sector of industry (48 FR 53280, November 25, 1983). In 1987, the Agency expanded the scope of coverage to all industries where employees are potentially exposed to hazardous chemicals (52 FR 31852, August 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 covered by OSHA since March 17, 1989 (54 FR 6886, February 15, 1989). In 1994, OSHA made a number of minor changes and technical amendments to the HCS to help ensure full compliance and achieve better protection of employees (59 FR 6126, February 9, 1994). The development of the HCS is discussed in detail in the preambles to the original and revised final rules (see 48 FR 53280–53281; 52 FR 31852–31854; and 59 FR 6127–6131). This discussion will focus on the sequence of events leading to the development of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and the modifications to the HCS included in this proposed rule.

The HCS requires chemical manufacturers and importers to evaluate the chemicals they produce or import to determine if they are hazardous. The rule 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 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. (**Note:** The HCS uses the term ''material safety data sheet'' or ''MSDS'', while the GHS uses ''safety data sheet'' or ''SDS''. For convenience and for consistency with the GHS, safety data sheet or SDS is being used throughout this document and that term would replace MSDS in the modified HCS.)

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 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's HCS, 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 having other authority over labeling under the Toxic Substances Control Act. Each of these regulatory authorities operates under different statutory mandates, and has adopted distinct hazard communication requirements.

Tracking 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 may 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 issued in 1983. The preamble to the final rule included a commitment by OSHA to review the standard regularly to address international harmonization of hazard communication requirements. OSHA was asked to include this commitment 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:

> * * * [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 53287)

OSHA has actively participated in a number of 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 also 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 Labor Organization (ILO) to develop a convention and recommendations on safety in the use of chemicals at work (55 FR 2166, January 22, 1990). On a closely related matter, OSHA published an 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 SDS 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 labelling 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 to complete. 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 Subcommittee 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, there were a number of other agencies

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 e-mail 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, April 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. The GHS will be updated as necessary to reflect new technology and scientific developments, or provide additional explanatory text. This proposed rule is based on Revision 3 of the GHS, published in 2009.

Countries have been encouraged to implement the GHS as soon as possible, and established a goal to 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. While much progress was made by the U.S. and other countries by the end of 2008, most are still in the process of implementing the GHS.

OSHA published an Advance Notice of Proposed Rulemaking (ANPR) on the GHS in September of 2006 (71 FR 53617, September 12, 2006). 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 this proposed rule. At the same time the ANPR was published, OSHA made a document summarizing the GHS available on its Web site (*http://www.osha.gov).*

OSHA remains engaged in a number of activities related to the GHS. The U.S. is a member of both the United Nations Committee of Experts on the Transport of Dangerous Goods and the Globally Harmonized System of Classification and Labeling of Chemicals, as well as the Subcommittee of Experts on the Globally Harmonized System of Classification and Labeling of Chemicals. 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 and EPA also 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 also continues to be involved 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.

IV. Overview and Purpose of the Proposed Modifications to the Hazard Communication Standard

The intent of the HCS is to ensure that the hazards of all chemicals are 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 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.

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, 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.

OSHA believes that the comprehensive approach adopted in the HCS—requiring evaluation of chemicals and the transmittal of information through labels, SDSs, and training—is sound. The proposed modifications to the rule do not alter that approach. Rather, the proposed modifications to the rule are 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 modifying the requirements of the standard to conform with the more specific and detailed provisions of the GHS for classification,

labeling, and SDSs. OSHA's rationale for this belief is summarized below. The evidence supporting this preliminary conclusion is presented in Section V of this preamble, and the proposed revisions to the HCS are discussed in detail in Section XV.

HCS Provisions for Classification, Labeling, and SDSs

The 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 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. 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 provided as 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 HCS also recognizes that risk may remain at concentrations below these cut-offs, and where there is evidence that is the case, the mixtures are considered hazardous under the standard.

The current definitions of physical hazards in the HCS were derived from other OSHA standards that address such chemicals (*e.g.,* flammable chemicals), or from the DOT criteria for physical hazards at the time OSHA promulgated the HCS. DOT subsequently changed their criteria to be consistent with the internationally harmonized transport requirements, and the HCS criteria for classification of physical hazards are generally not consistent with current DOT requirements.

The 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 HCS was issued in 1983, the public record strongly supported this performance-oriented approach (*see* 48 FR 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. In recognition of the work that had been voluntarily completed, OSHA decided to allow labels and SDSs to be presented in any format desired, as long as the minimum information requirements of the standard were met.

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 a new system.

The GHS is designed to allow regulatory authorities to choose provisions that are appropriate to their particular 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.

Regulatory authorities such as OSHA adopt the provisions of the GHS that are appropriate for their particular regulatory sector, but do not need to adopt all of the criteria and provisions of the GHS. For example, the GHS includes criteria for classifying chemicals for aquatic toxicity. Since OSHA does not have the regulatory authority to address environmental concerns, OSHA would not adopt the GHS criteria for aquatic toxicity. The building block approach may also be applied to the criteria for defining hazards. For example, the acute toxicity criteria in the GHS are much broader than those currently found in the HCS. This is to allow consumer product authorities the ability to address the protection of children and other vulnerable populations. OSHA would not need to adopt all of the acute toxicity categories to maintain protection of employees in the workplace.

The building block approach can also be applied when a regulatory authority decides which parts of the system to adopt. For example, the GHS includes classification criteria and provisions for labels and SDSs. While OSHA is proposing to adopt all of these elements because the current HCS cover labels and SDSs, consumer product and transportation authorities are not expected to require SDSs.

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. The definitions of hazards are more specific and detailed than those currently in the HCS. For example, under the HCS, a chemical is either an explosive or it is not. Under the GHS, there are seven categories of explosives, and assignment to these categories is based on the classification criteria provided.

The GHS generally applies a tiered approach to evaluation of 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 which is used for classification. The approach is generally consistent with the current requirements of the 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) are 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 of severity of the hazard. Precautionary statements are also required on GHS labels. The GHS provides example precautionary statements, but they are not yet

considered formally harmonized. In other words, it would be possible for regulatory authorities to use different language for the precautionary statements. However, it appears likely that the language in the examples will become the harmonized text of the GHS on precautionary statements in the near future. The most recent revision to 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 reference to them 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 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 later. 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).

Advantages of the Proposed Modifications to the Standard

OSHA believes that the detailed and specific classification requirements of the GHS would result in better, more consistent information being provided to employers and employees. Classification under the revised criteria would not only indicate the type of hazard, but would generally give an indication of the degree of severity of the hazard as well. This information would be helpful to both employers and employees in understanding chemical hazards and identifying and implementing protective measures. The detailed criteria for classification are also expected to result in greater accuracy in hazard classification and more consistency among classifiers. By following the detailed criteria, classifiers are less likely to reach different interpretations of the same data.

OSHA also believes that standardized presentation of information on labels and safety data sheets would improve the comprehensibility of chemical hazard information. Employers and employees would be given the same core information on a chemical regardless of the supplier. Use of standardized pictograms would complement and reinforce the information provided through signal words and hazard statements. Pictograms are also anticipated to improve communication for those who are not functionally literate, or who are not literate in the language used on the label. The standardized format for SDSs is expected to make the information easier for users to find, with the information employees and emergency responders need most appearing in the beginning of the document for easy identification and reference.

Standardized requirements for labels and SDSs are also expected to increase the accuracy of chemical hazard information. With consistent presentation of information, the task of reviewing SDSs and labels to assure accuracy would be simplified. Individuals preparing and reviewing these documents should find it easier to identify any missing elements, and OSHA enforcement personnel should be able to more efficiently examine SDSs and labels when conducting inspections.

Another advantage that will result from adopting a system that has harmonized hazard statements in it relates to the use of ''control banding,'' a guidance approach to recommending control measures for chemical exposures. The approach uses information that is readily available to small and medium-sized employers with chemicals in their workplaces to provide them with workplace-specific control recommendations. Basically, the system uses such information to estimate the degree of severity of the hazard and the amount of chemical present, and relates that to the degree of control needed. The control banding approach relies on harmonized hazard statements to allow the system to estimate the degree of severity of the hazard. Initially based on the European hazard classification system, it has now been converted to the GHS phrases. 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 U.S. to help small and medium-sized employers select and implement appropriate control measures. For more information on control banding, please *see http://www.cdc.gov/niosh/topics/ctrlbanding/.*

OSHA is proposing modifications to the HCS that are necessary for consistency with the GHS. The GHS does not include requirements for a written hazard communication program or for employee training. OSHA is not proposing any substantive changes to the requirements for a written hazard communication program. However, OSHA believes that additional training would be necessary to ensure that employees understand some elements of the new system. In particular, some training and familiarization would be needed for pictograms to be effective. The Agency is therefore proposing modified training requirements to address the new label elements and SDS format that would be required under the revised standard.

The GHS leaves certain matters to the competent authority (*i.e.,* the regulatory authority with jurisdiction over that sector) to determine. OSHA would maintain its current approaches in these situations. For example, the scope and application provisions in the HCS address the interface of the OSHA requirements with requirements of other agencies. These scope provisions would remain unchanged under the proposed rule.

The proposed modifications to the HCS primarily affect manufacturers and importers of hazardous chemicals. Chemical manufacturers and importers would be required to re-evaluate chemicals according to the new criteria in order to ensure they are classified appropriately. For health hazards, this will necessitate placing the chemical in the appropriate hazard category as well as the hazard class. For physical hazards, however, the 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 for physical hazards for purposes of complying with DOT's transport requirements. This should minimize the additional work required for classification of physical hazards. Preparation and distribution of modified labels and safety data sheets by chemical manufacturers and importers would also be required. Those chemical manufacturers and importers already following the ANSI Z400.1 standard for safety data sheets should already have the appropriate format, and would only be required to make some small modifications to the content of the sheets to be in compliance.

Compliance requirements for chemical users would be limited. Workplaces where chemicals are used would need to integrate the new

approach into their hazard communication program, assuring that employees understand the pictograms and other information provided on labels and SDSs. Employers who use chemicals, and exposed employees, would benefit from receiving labels and safety data sheets presented in a consistent format. The information should be easier to find and comprehend, allowing it to be used more effectively for the protection of employees.

Changing the HCS to make it conform to the GHS will also make it necessary to modify a number of other OSHA standards. Modifications are proposed 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. A modification to the Process Safety Management standard (29 CFR 1910.119) is proposed to ensure that the scope of the standard is not changed by the proposed modifications to the HCS. In addition, modifications to most of OSHA's substance-specific health standards are proposed to ensure that requirements for signs and labels are consistent with the modified HCS.

OSHA's preliminary determination to modify the HCS is based on its assessment of the potential to improve employee safety and health by adopting the GHS approach to hazard communication. However, GHS implementation is also expected to accomplish a number of other objectives, and produce additional benefits. By providing an internationally comprehensible system for hazard communication, the GHS is anticipated to enhance the protection of the environment and of human health in all sectors, not only the workplace. The GHS provides a framework for developing a hazard communication system for those countries without an existing system, thus protecting employees around the world and helping to ensure that the appropriate information is received with chemicals imported into American workplaces. Implementation of the GHS is also expected to reduce the need for testing and evaluation of chemicals, since classification would be based on existing data and would only need to be performed once for each substance. In addition, implementation of the GHS is expected to facilitate international trade in chemicals, as the need to identify and comply with diverse and complex hazard communication requirements in different countries would be reduced or eliminated.

Alternative Approaches

In this section OSHA presents several alternatives to the proposed GHS modification to the HCS to respond to concerns raised by commenters through the ANPR. OSHA provides the following discussion of these alternatives and their potential impacts and requests comments regarding their relative costs, benefits, feasibility, impact on small businesses, impact on worker safety and health, and any other issues on which commenters may wish to provide feedback.

This rulemaking seeks to improve employee protections by adopting an internationally harmonized approach to hazard communication issues. While the current HCS provides protections for exposed workers by disseminating information about chemicals in their workplaces, OSHA believes, as discussed in Section V, that the adoption of GHS strengthens and refines the system, and gives OSHA the opportunity to improve worker safety by improving hazard communications. The GHS has the same general concept of an integrated, comprehensive process of identifying and communicating hazards, but provides more extensive criteria to define the hazards in a consistent manner, as well as standardizes label elements and SDS formats to help to ensure that the information is conveyed consistently.

Additionally, the Agency believes that adoption of the GHS as proposed will simplify implementation insofar as OSHA's preferred alternative would clearly be considered ''harmonized'' with other regulatory authorities in the world, and thereby acquire the full benefits of harmonization.

This is in line with the GHS, which anticipates that countries will adopt the hazard classification criteria and required label elements, as well as SDS requirements in workplaces. As stated in the introduction to the GHS (3rd revision):

> 1.1.3.1.3 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.

As addressed in Section XV, many commenters supported the concept of OSHA moving forward to adopt the GHS (Document ID #s 0003, 0007, 0047, 0050, 0052, 0062, 0106, 0011, 0033, 0038, 0123, 0130, 0151, 0163, and 0171). While others objected to adoption, OSHA has identified and responded to their concerns in Section XV as well. In addition, there were several commenters who noted that small chemical manufacturers that are not in international trade of chemicals would have a large burden associated with adopting the GHS, and questionable benefits due to their lack of international trade. (Document ID # 0022). Others simply noted that they believed there would be high costs and limited benefits for such employers, or that it would be costly and difficult to adopt (*Document ID #s* 0015, 0026, 0178, and 0144). There was no discussion in any of these comments about potential alternatives.

It should be noted that it appears that all of these commenters assumed the primary benefits of adopting the GHS would be in facilitating international trade. As has been addressed in Section VII, OSHA has based the benefits of this action on improved communication to workers and has provided initial estimates of a range of benefits that would be achieved in this area; trade benefits which, while recognized, have not been quantified. Therefore, grandfathering or other exemptions related to this rule might result in workers in those facilities receiving lower benefits of increased comprehensibility relative to workers in other types and sizes of workplaces; OSHA considers this a serious concern that could potentially exclude a group of workers exposed to hazardous chemicals from the increased benefits associated with clearer and more specific classification criteria, as well as standardized label elements.

Alternatives:

In order to respond to the concerns raised in these comments, OSHA solicits comment on several options:

1. The first option is designed to facilitate voluntary adoption of GHS within the existing HCS framework. Specifically, this approach would involve recognition and adoption of the GHS, with minimal changes to the current HCS. Under this approach, entities could opt to adopt GHS or continue to follow their current practice under HCS.

Therefore, companies would decide whether they would continue complying with the existing standard, or comply with the GHS. This would reduce the costs for those companies that choose to remain in compliance with the existing HCS, and allow those companies that foresee the benefits of GHS compliance from a trade perspective to adopt its provisions. Another version of this option would be to exempt small chemical producers from complying.

2. A second option that OSHA is seeking to solicit comment on would

make modifications to the current HCS in order to improve hazard communication through adoption of components of the GHS. Under this option OSHA would add requirements for standardized hazard statements, signal words, and precautionary statements being added to the current HCS, but otherwise would follow the approach outlined in Alternative 1 above.

Since the standardized labels are relatively inexpensive to implement, while reviewing classifications is more costly, this has the potential to reduce the overall cost of implementation of the revised rule.

A variation on this alternative would entail incorporation of some, but not all, of the label elements. In particular, the Agency would not adopt the precautionary statements since these are not yet considered to be ''harmonized'' under the GHS—they are provided for guidance and reference, but competent authorities may choose to implement other statements. The precautionary statements could be adopted later when they are harmonized under the GHS. Or, alternatively, OSHA could either allow label preparers to use whatever precautionary statements they deem appropriate or develop its own set of statements to require.

From OSHA's perspective, a key issue regarding the alternative approaches presented is that the classification criteria in the GHS are different from the hazard definitions in the current HCS. In general, as discussed in Section XV, they cover the same scope of hazard so these differences do not result in significant differences in the chemicals covered. But the GHS criteria divide most of the hazard classes into hazard categories that convey the severity of the effect, while few of the hazard classes in the current HCS take this approach. The standardized label elements are associated with these specific hazard categories, *i.e.,* the harmonized pictograms, signal words, and hazard statements are assigned by hazard category and reflect the degree of hazard it presents to those exposed. Likewise, the precautionary statements assigned are also reflective of the degree of hazard, with responses related to these presumed hazard levels.

Additionally, with regard to the first alternative, there will be chemicals that will be classified in different hazards classes under the GHS classification scheme versus the HCS hazard determination step. In addition, these chemicals will also be assigned to hazard categories under GHS where there are none now. This is particularly true for the classification of mixtures for all hazards, except the chronic health hazards, since the hazard determination scheme in the current HCS is based solely on concentration limits and the GHS classification scheme is based on bridging principles. Under the alternatives presented workers might be given different hazard information when exposed to a chemical purchased from two different suppliers. OSHA notes that this would be similar to the situation under the current performance-oriented HCS, but this approach may forego an opportunity to make the system more consistent.

OSHA is interested in comments related to the alternatives addressing the extent to which differences in classification between the GHS and HCS might create confusion or otherwise result in problems. OSHA is further interested in comments addressing the classification of mixtures under the alternatives discussed, given the differences in classification under HCS and GHS applicable to mixtures.

Given the current variability in MSDS and labels under the performance based HCS, OSHA believes that this approach might not have a negative impact on safety and health relative to our current HCS. However, the Agency anticipates that components of the GHS would confer benefits external to producers (*e.g.,* the benefits associated with clearer and more specific classification criteria, as well as labels or other changes that could potentially make easier for users to locate and understand the information they are seeking), adoption of this alternative could result in foregone benefits. In addition, a small number of chemicals or mixtures might be labeled differently due to differing categorization results between the existing HCS and GHS.

OSHA is generally seeking comment on the possible cost impacts associated with the alternatives on the chain of chemical suppliers. OSHA notes that large and small producers are not mutually exclusive so that a large business or distributers engaged in international trade cannot simply and straightforwardly choose to implement the GHS regardless of their suppliers. Small businesses sell to large businesses. If small businesses do not adopt the GHS, then the large businesses or the distributor would either have to generate GHS classifications for chemicals they buy from them 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 unknown to the original producer. Thus knowing whether or not a product will wind up in international trade may be questionable in some situations. A producer may provide a substance to another company, who then formulates it into a product that is sold internationally—thus the original producer is involved in international trade without necessarily realizing it. In theses cases, costs would be incurred for the conversion to GHS. This issue was raised in comments regarding the effective dates for the rule, when many suggested it was not appropriate to differentiate dates based on the size of the business. For example, ORC Worldwide, Inc. stated (Document ID # 0123):

> OSHA should consider a company's place in the manufacturing supply chain, not size, in determining how the phase-in is implemented. It would be sensible to start with producers of raw materials and basic chemicals. The technical information, classification and categorization they perform will be useful downstream for the intermediate chemical producers and specialty chemical manufacturers. Lastly, the end user will benefit from the influx of information developed by the upstream professionals.

OSHA solicits comment on whether a voluntary system, or a system based on business size, could be successfully implemented given the structure of the supply system.

OSHA seeks comment on how companies that use chemicals, but don't produce them, would be affected under an alternative approach. Rather than potentially simplifying compliance and improving comprehensibility, the user of chemicals would continue to see variation in labels on purchased chemicals. This would be further complicated by the fact that the underlying criteria for these labels may be different as well, and thus the warnings would be too. If there is no requirement for such employers to be familiar with the new system, and train their employees, then there will be new pictograms and signal words with no structure for ensuring they are understood and the appropriate precautions are implemented.

Regarding Alternative 2, under OSHA's proposed approach the label provisions are relatively cost-efficient to adopt given that the GHS assigns the various required elements by hazard class and category and once the classification or re-classification has been accomplished, the GHS provides the specific information for the label.

OSHA solicits comment on whether requiring this standardized approach to labeling under the HCS, without the infrastructure of the GHS will be burdensome for the chemical

manufacturer to accomplish OSHA further solicits comment on whether confusion may result from labels that may look the same but which actually reflect different classification criteria. Under this approach, chemical producers will have to assess their current determinations and attempt to relate them to the established hazard classes and categories. Alternatively, OSHA could create a regulatory system assigning HCS categories to each GHS label elements; comments are welcomed on the impact on benefits and costs, and the feasibility of such an approach. OSHA believes it is unlikely that this component of Alternative 2 would provide significant savings over reviewing classifications for purposes of putting the chemicals into GHS classes and categories.

OSHA is concerned that chemical producers following this approach might not be able to use their labels in other countries where the GHS has been adopted. OSHA is further concerned that adopting only some elements of the GHS label may be confusing and may fail to provide useful information regarding the possible hazardous effects of exposure. Delaying adoption of the precautionary statements may also reduce the effectiveness of the labels significantly, and reduce the appropriate information on the SDSs as well. A variation on this alternative—to simply require precautionary statements, but not to specify what they are, may generate significant variation due to the performance-oriented approach that allows the label preparer to determine what they are or if they are included. One communication advantage of providing the information in the same language from label-to-label is that workers and other users can be assured that the same action is required. If you take a simple preventive measure such as ''wash your hands,'' but convey it in several different ways, the reader of the label will think you mean something different. This is one of the advantages of providing the text for these statements in the revised HCS. In addition, since these precautionary statements will be translated, this should make it easier for those participating in international trade to produce and use labels.

Thus, OSHA solicits comment on a range of alternative approaches to regulatory adoption of GHS and welcomes comments on these options. The costs and benefits are further addressed in Section VII.

V. Need and Support for the Proposed 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 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 HCS was issued in 1983 (48 FR 53282–53284). 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.

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). 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; Leigh *et al.,* 1997; Landrigan and Markowitz, 1989).

The HCS currently serves to ensure that information concerning chemical hazards and associated protective measures is provided to employers and employees. However, OSHA's experience, along with information acquired since the HCS was issued, indicates that modifications to the standard may be appropriate. The Agency believes that the proposed changes, based on the GHS, will substantially improve the quality and consistency of the information provided to employers and employees. OSHA further believes the proposed revisions to the HCS will enhance workplace protections, because better information will enable employers and employees to take measures that would result in a reduction in 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 issue 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.''

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. Prepared by researchers at the University of Maryland, the document entitled ''Hazard Communication: A Review of the Science Underpinning the Art of Communication for Health and Safety'' (Sattler *et al.,* 1997) has also long been available to the public on OSHA's Hazard Communication web page. More recently, 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).

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 related to comprehensibility testing (see GHS Annex 6, Comprehensibility Testing Methodology) (United Nations, 2009). 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.

Also among the agreed principles that were established to guide development of the GHS was that the level of protection offered by an existing hazard communication system should not be reduced. 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 32 member nations as well as 17 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. A number of United States-based scientific and professional associations have endorsed adoption of the GHS. The American Chemical Society indicated its support for the GHS, stating: ''The American Chemical Society (ACS) 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). In comments submitted in response to the ANPR, 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). The American Society of Safety Engineers also indicated its support for the GHS rulemaking (Document ID #0139). 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'' (SOT, 2007). 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). The positions taken by these organizations point to wide support for the GHS among the scientific and professional communities.

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

This evidence was obtained from a number of sources. OSHA has commissioned several studies to examine the quality of information on SDSs (Karstadt, 1988; Kearney/Centaur 1991a, 1991b; Lexington Group, 1999); the General Accounting Office (GAO) has issued two reports based on its evaluation of certain aspects of the HCS (GAO 1991, 1992); 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); 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). An updated review was published in 2007 (ERG, 2007). In addition, OSHA conducted a review of the requirements of the HCS and published its findings in March of 2004 (OSHA, 2004). Key findings derived from these sources are discussed below.

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 that 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 provide a brief, conspicuous hazard summary at the work site where a chemical is used. Labels serve as an immediate visual reminder of chemical hazards, and complement the information presented in training and on SDSs.

The HCS currently 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.

OSHA is proposing a requirement that labels include four new, standardized elements: a signal word; hazard statement(s); pictogram(s); and precautionary statement(s) (see Section XV for a detailed discussion of the proposed requirements). The appropriate label elements for a chemical would be determined by the hazard classification. OSHA believes that these standardized label elements would better convey critically important hazard warnings, and provide useful information regarding precautionary measures that would serve to better protect employees.

A great deal of literature has been developed that examines the effectiveness of warnings on labels. However, some important limitations must be recognized in applying this information to workplace labels for hazardous chemical products. Most studies have examined labels for prescription and non-prescription medications, alcoholic beverages, or consumer products. Relatively few studies pertain specifically to labels for hazardous chemicals in the workplace. Much of the literature is also characterized by the use of research subjects such as college students or consumers. Such subjects may not be representative of workplace populations, as these subjects may differ from typical employees in terms of product knowledge, hazard perception, perceptual abilities, and safety motivation. In addition, some studies involve non-U.S. populations that may not be representative of the U.S. workforce.

Nevertheless, the literature provides a substantial body of information applicable 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. Relevant finding from the literature are presented in the sections that follow.

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.

The proposal prescribes 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 order of descending severity (ANSI, 2006).

A number of recent 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 in 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). 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). 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).

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). 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). 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). 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). 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). 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). 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).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). 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). 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 have 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.

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 includes 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 that are required on a label would be determined based on the hazard classification of the substance in question.

OSHA believes that the proposed pictograms would make warnings on labels more noticeable and easier for employees to understand. In particular, symbols are expected to improve comprehension among people with low literacy and those who are not literate in the English language. It should be remembered that pictograms would be used not only in conjunction with other label elements, but in the context of the hazard communication program as a whole. Training that includes an explanation of labels (included in the proposed rule) would ensure that pictograms are understood by employees.

A considerable amount of evidence supports the belief that pictograms can serve as useful and effective communication tools. In reviewing this evidence, it should be noted that some sources offer distinct definitions for ''pictogram,'' ''pictorial,'' ''symbol,'' and other terms describing graphical elements. For example, Rogers *et al.* state that: ''Pictorials refer to pictures that represent the concept of interest (*e.g.,* a picture of a fire extinguisher). Symbols are more abstract representations of a concept, the meaning of which must be learned (*e.g.,* the use of a skull and crossbones to denote poison)'' (Rogers *et al.,* 2000). ANSI and others combine these terms in the definition of ''symbol,'' however, and for the purposes of discussing the literature on this subject, these terms are used interchangeably.

Symbols serve several important functions in warning labels. As Wogalter *et al.* explain, 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 (Wogalter *et al.,* 2006).

Symbols also can bolster a text message and improve label comprehension among individuals with low literacy, and those who do not understand the language in which the label text is written (Parsons *et al.,* 1999).

Several researchers have sought to evaluate how people comprehend symbols, including those symbols that are incorporated in the proposed rule. Some studies have found that the skull and crossbones icon—one of the symbols included in the proposed rule—is among the most recognizable safety symbols. For example, Wogalter *et al.* asked 112 undergraduates and community volunteers to rank various label elements (Wogalter *et al.,* 1998). 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). The skull was rated significantly higher than all other symbols.

Some research has examined other pictograms included in the proposed 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 proposed rule (Akerboom and Trommelen, 1998). 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). The authors recommend that labels present the hazard phrase [statement] and symbol together, along with corresponding precautions, as would be required under the proposed rule.

Banda and Sichilongo tested comprehension of labels that included the proposed pictograms among 364 workers in four sectors in Zambia (transport, agriculture, industrial, and household consumers) (Banda and Sichilongo, 2006). 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). ''Exploding bomb'' was correctly comprehended by 44 to 71 percent of each sector. 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 well comprehended symbol.

These findings indicate that some of the pictograms included in the proposed rule are already widely recognized by a general audience. Others, however, are not commonly understood. Therefore, simply adding some of the proposed 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). These results emphasize the need to train employees on the meaning of the pictograms that would 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). 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). 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). 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).

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). 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). 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.

As far as chemical labels are concerned, London found that symbols tend to be the most easily recalled label elements (London, 2003). 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. Overall, the author concludes that ''Symbols are therefore key to attracting attention, and informing risk perception regarding a chemical.''

Wogalter *et al.* found less encouraging evidence on pictorials, however (Wogalter *et al.,* 1993). 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). 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 recent 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). 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). 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). A group of 96 adults were less confused, more satisfied, 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, 1993). 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.

In addition to the evidence pertaining to the other graphical elements in pictograms, research indicates that the use of the color red in pictograms will serve to make warnings more noticeable. Red is also generally perceived to reflect the greatest degree of hazard, and is thus well-suited to identifying serious chemical hazards in the workplace.

In their review of the literature on warning effectiveness on behavioral compliance, Kalsher and Williams summarize several studies that examined the effects of adding color to warnings (Kalsher and Williams, 2006). Overall, Kalsher and Williams suggest that adding color can influence both the noticeability and effectiveness of warnings.

In a test on the noticeability of warnings, Swindell measured the amount of time it took subjects to locate warning text that had been embedded in medication instructions (Swindell, 1999). Warnings were found significantly faster when the icon and signal word were presented in either red or blue, causing the warning to stand out from the black text. 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). While these studies involve color on label elements other than the pictogram border, they provide a general indication that color attracts the attention of label users.

A number of researchers have investigated the hazard connotations of different colors. These investigations indicate that red is generally perceived to reflect the greatest degree of hazard. Yellow, orange, and black reflect a lesser degree of hazard. In a review of the literature, Parsons *et al.* suggest that the red-orange-yellow hierarchy generally matches people's perceptions of risk, including perceptions among native Spanish speakers (Parsons *et al.*, 1999). Experimental results that support the conclusion that red generally connotes the highest degree of hazard include:

■ Smith-Jackson and Wogalter asked English-speaking community members to rate the perceived hazard of ten ANSI safety colors (Smith-Jackson and Wogalter, 2000). 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).

■ Wogalter *et al.* asked Spanish speakers to rank the perceived hazard of ANSI safety colors (Wogalter *et al.,* 1997b). 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). 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). 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).

■ Banda and Sichilongo asked workers in Zambia to rate the perceived hazard of various colors used in chemical labels (Banda and Sichilongo,

2006). 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).

These reports are consistent in indicating that red is commonly understood to be associated with a high level of hazard—the highest of any color. OSHA anticipates that by using the color red on labels for hazardous chemicals, labels will be more effective in communicating hazards to employees—both by drawing the attention of employees and indicating the presence of a hazard through non-verbal means.

Hazard 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. The HCS currently includes a performance-oriented requirement for ''appropriate hazard warnings'' on labels. The proposed rule would require specific hazard statements and precautionary statements on labels. The statements would be determined based on the hazard classification of the chemical.

Standardized requirements for hazard and precautionary statements would provide a degree of consistency that is currently lacking among chemical labels. This lack of consistency makes it difficult in some instances for users to understand the nature and degree of hazard associated with a chemical, and to compare chemical hazards. For example, Beach relates experiences from the perspective of a doctor treating occupationally exposed patients (Beach, 2002). 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 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, the ANSI approach has not been adopted by all chemical manufacturers and importers. As a result of the diverse formats and language used, consistent and understandable presentation of information has not been fully achieved.

A preference for hazard statements was shown in EPA's Consumer Labeling Initiative (Abt Associates, 1999). 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 can provide 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). 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 have indicated 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). 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).

Explicit precautionary statements may 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). 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 proposed rule would eliminate the need for users to infer protective actions.

Some evidence indicates that using key label elements together can improve warning performance, compared with labels that only contain a subset of these elements. This is the approach taken in the proposed rule, which would require 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); and warnings with text only (Meingast, 2001). 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). 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). 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). Laughery *et al.* tested warnings to determine which elements influenced noticeability. 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.

These findings support the belief that the proposed label elements, in combination, would likely be 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 included in the proposed 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 may improve understanding. OSHA therefore believes that this evidence substantiates its belief that the proposed labeling requirements will result in more effective transmittal of information to employees.

Overall, 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 #s 0054, 0032, 0124, 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.

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

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. The HCS does not require this information to be presented in any particular order or to follow a specific format.

Since the HCS was adopted in 1983, access to chemical information has improved dramatically due to the availability of SDSs. 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.

OSHA is proposing a requirement that the information on SDSs be presented using consistent headings in the sequence specified in the GHS (see Section XV for a detailed discussion of the proposed requirements). The Agency believes that a standardized order of information would improve the utility of SDSs by making it easier for users to locate and understand the information they are seeking. A standardized format would also be expected to improve the accuracy of the information presented on SDSs.

A number of studies have demonstrated the benefits provided by SDSs. In May 1992, the General Accounting Office (GAO) issued a report presenting the findings of an examination of difficulties small employers were said to experience in complying with the HCS, as well as issues relating to the costs of compliance (GAO, 1992). 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. For example, in a survey of 160 workers at a large national laboratory, more than 90 percent of respondents said that SDSs are satisfactory or very satisfactory in providing protective information and answering questions (Phillips *et al.,* 1999).

Conklin demonstrated the utility of SDSs among employees of a multinational petrochemical company (Conklin, 2003). 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, however, that this sample did not include any workers with low literacy.

A number of investigations have raised concerns that, in some cases, 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, 1991). 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.

A similar result was reported by Conklin in a study involving employees of a multinational petrochemical company (Conklin, 2003). 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.

A study that examined the comprehensibility of SDS to master printers was reported by the Printing Industries of America in 1990 (PIA, 1990). 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). 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). 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). 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 also 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:

> * * * 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 (Hanson, 2004).

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.

OSHA established a voluntary format for SDSs in 1985 to assist manufacturers

and importers who desired some guidance in organizing SDS information. This 2-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. An updated version of the ANSI standard published in 2004 is consistent with the GHS format that is included in the proposed rule.

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). 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 (Niemeier, 1997). 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). 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). 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 was better than the ANSI format regarding carcinogenic potential.

In a separate comparison, Conklin also found similarities in the overall performance of several standard SDS formats (Conklin, 2003). 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).

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). 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 1991). 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 would improve the effectiveness of SDSs. The primary basis for this belief is very simple: A consistent format would make it easier for users to find information on an SDS. Headings for SDS sections would be standardized, so SDS users would know which section to consult for the information they desire. The sections would be 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) would be presented in the beginning of the document for easy reference. More technical information (*e.g.,* Stability and Reactivity; Toxicological Information) would be presented later.

By segregating more complex information on an SDS from the information that is generally easier to understand, the standardized format included in the proposed rule has the potential to address many of the concerns that have been raised regarding the comprehensibility of information on SDSs. The standardized order of information will allow SDS users who desire only basic information about a hazardous chemical to find that information 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.

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 proposed 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, a number of researchers have 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). 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 (Kearnet/Centaur, 1991). The study examined information presented in five areas considered crucial to the health of workers potentially exposed to hazardous substances. These 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). 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). 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 assure accuracy would 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 would be able to more efficiently examine SDSs when conducting inspections. The detailed entries proposed for the SDS are particularly noteworthy in this regard. The sub-headings would 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 proposed rule would provide a list of 18 properties for Section 9 of the SDS. The party preparing the SDS would either include the relevant information for these entries, or indicate that the information is not available or not applicable. This approach would provide 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.

OSHA anticipates that the classification criteria included in the proposed rule would also improve the accuracy and precision of information on SDSs. The detailed criteria provided would 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 would also play an important role in increasing the usefulness of SDSs under the proposed rule. By including the classification of the substance on the SDS, employers would 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 believe that the proposed rule would result in more effective use of the SDS as an instrument for identifying less hazardous substitutes for hazardous chemicals.

Support for a standard SDS format has been expressed consistently by a variety of stakeholders for a long period of time. 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. As noted previously, ANSI Z400.1 was updated in 2004 to include the same sections and sequence as the proposed rule. Responses to OSHA's Request for Information in the **Federal Register** of May 17, 1990 (55 FR 20580) indicated widespread support for a standard SDS format, with many specifically supporting the ANSI format.

In its report of its evaluation of the HCS, the GAO included several recommendations. Among these was a recommendation that OSHA clearly specify the language and presentation of information on SDSs (GAO, 1991). 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).

Comments received in response to the ANPR also indicate widespread support for a standard format for SDS (*e.g.,* Document ID #s 0054, 0064, 0030, 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). Based on the information in the record, OSHA thus believes not only that the proposed standardized SDS format would improve the quality of information provided on SDSs, but that stakeholders generally prefer a standardized format.

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 to follow. The proposed rule includes a relatively minor revision to the HCS training requirements, intended to ensure that labels and SDSs are adequately explained to employees (see Section XV for a detailed discussion of the proposed requirements). In light of the evidence previously discussed relating to label and SDS comprehension, the importance of training should not be underestimated.

Training is necessary to ensure that employees understand the standardized heading and sequence of information on SDSs. Likewise, employees must be able to understand the meaning of the proposed 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'' already 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 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, contains a test method for determining the effectiveness of a pictogram. The criterion for success 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. 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). 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; 2003). 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). 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 proposed 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. A similar result was reported by Banda and Sichilongo 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). 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 symbols that may

generate critical confusion (London, 2003).

These reports serve to 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), for example, recommends training on the meaning of standard safety symbols and signal words, and ANSI Z535.4 contains similar guidance.

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 (FR 53:29826; FR 59:6126). 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 cannot occur. By ensuring that emergency responders, physicians, nurses, industrial hygienists, safety engineers and other professionals have the information they need to devise protections, the HCS serves to reduce the likelihood of chemical source illnesses and injuries. Selection of appropriate engineering controls, work practices, and personal protective equipment is predicated knowing the chemicals that are present, the form they are present in, and their hazardous properties.

OSHA believes that the proposed requirements would 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, easier to understand, and 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, these revisions would serve to more adequately inform employees of chemical hazards, and lead to better protections in the workplace.

OSHA's preliminary determination to modify the HCS is based on its assessment of the potential to improve employee safety and health. While enhancing protection of employees is the Agency's objective in this rulemaking, implementation of the GHS is also anticipated to provide other benefits. As indicated in Section IV, modification of the HCS is expected to promote a range of objectives.

Many countries do not currently have regulatory requirements addressing chemical hazard communication. Those countries that do not have the resources to develop a regulatory system can use the GHS as a basis for establishing such requirements. Implementation in these countries will thus lead to dissemination of information about chemical hazards and protective measures to individuals who would not otherwise be afforded this benefit.

Transmittal of information provides a basis for the sound management of chemicals, which is beneficial not only to the country where it is practiced, but to neighboring countries as well. For example, uncontrolled releases of hazardous chemicals are not confined by national borders. A coordinated and harmonized approach to developing and providing chemical hazard information is beneficial to all.

The United Nations Institute for Training and Research (UNITAR) and the International Labor Organization (ILO) have initiated a program to support GHS implementation. The program provides assistance regarding development of national GHS implementation strategies, legislation, and other topics. UNITAR is supporting national GHS implementation and capacity building projects in Cambodia, Indonesia, Laos, Nigeria, Senegal, Slovenia, Thailand, the Gambia, and the Philippines, and has supported meetings, workshops, and regional activities as well. Over 80 countries have requested assistance from UNITAR/ILO, indicating widespread interest in GHS adoption throughout the world.

Adoption of the GHS is also expected to reduce the amount of testing performed to identify hazardous properties of chemicals. The HCS does not currently require testing of chemicals, and will not require testing with adoption of the GHS. However, testing is often performed to determine how a chemical will be classified under the various systems currently in place. By harmonizing definitions of hazards, such testing would be minimized, saving unnecessary use of test animals and associated costs.

Implementation of the GHS is expected to lessen the regulatory burden associated with classification of chemical hazards and labeling of hazardous chemicals. In the U.S., regulatory authorities with jurisdiction over the workplace, environment, consumer and transport sectors (*i.e.,* OSHA, EPA, CPSC, and DOT) are not currently harmonized with regard to definitions of hazards and other requirements related to classification and labeling of chemicals. Widespread adoption of the GHS among the agencies would simplify the process of classifying chemicals and developing labels. For example, most chemicals are produced in a workplace and shipped elsewhere. As a result, manufacturers must comply with at least two sets of requirements that are currently not harmonized. Adoption of the GHS would simplify this process. Thus every chemical manufacturer would be likely to experience some benefits from harmonization, even if they are not involved in international trade.

For those who are involved in international trade in hazardous chemicals, the expected benefits would be even greater. As discussed in Section III, different countries have established requirements for chemical hazard classification, labeling, and SDSs that vary with regard to the scope of chemicals covered, definitions of hazards, the specificity of requirements, and the use of symbols and pictograms. Tracking the requirements of different regulatory authorities and developing different labels and SDSs is a burden for all manufacturers, importers, distributors, and transporters. Chemical manufacturers that do not have the resources to identify and comply with the requirements of regulatory authorities in different countries are precluded from engaging in trade with those countries. Small businesses are particularly affected. Implementation of the GHS would alleviate this burden and simplify the provision of chemical hazard information in international commerce.

VI. 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 the 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 a 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. *Industrial Union Dep't* v. *American Petroleum Institute,* 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 workplaces in question would be ''unsafe'' in the sense that employees would be threatened with a significant risk of harm. *Id.*

OSHA's Hazard Communication Standard (''HCS'') is a health standard promulgated under the authority of sections 6(b)(5) and 6(b)(7) of the Act. *Associated Builders & Contractors, Inc.* v. *Brock,* 862 F.2d 63, 67–68 (3d Cir. 1988); *United Steelworkers of America* v. *Auchter,* 763 F.2d 728, 738 (3d Cir. 1985); *United Steelworkers of America* v. *Auchter,* 819 F.2d 1263, 1267 (3d Cir. 1987). Authority for the HCS may also be found in section 8(c) and 8(g) of the Act. Section 8(c)(1) of the Act empowers the Secretary to require employers to make, keep, and preserve records regarding activities related to the Act and to make such records available to the Secretary. 29 U.S.C. 657(c)(1). Section 8(g)(2) of the Act empowers 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).

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 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 * * * place[d] worker health above all other considerations save those making attainment of this benefit unachievable.'' *American Textile Manufacturers Institute, Inc.* v. *Donovan,* 452 U.S. 490, 509 (1981) (''*Cotton Dust*''). Where, however, OSHA is confronted with two feasible methods of reducing risk to the appropriate level, OSHA must chose the cheaper method. *Id.* at 513 n.32; *International 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 medical 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 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 § 6(b)(7) to uphold the imposition of exposure and medical monitoring requirements at exposures to benzene below the permissible exposure limit. *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 workers before they suffered any permanent damage. *Id.* at 657–58.

In making the determinations required by the Act, OSHA's conclusions must be ''supported by substantial evidence in the record considered as a whole.'' OSH Act § 6(f), 29 U.S.C. 655(f). OSHA must use the ''best available evidence,'' which 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 ''with anything approaching scientific certainty,'' and that the determination of whether a 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), 29 U.S.C. 655(b). 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. Automobile Ins. Co.,* 463 U.S. 29, 42 (1983) (internal quotation marks and citations omitted).

A. Significant Risk. Most OSHA health standards protect employees by imposing requirements when employees are exposed 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 measuring the exposure an employee may be expected to incur when dealing with these substances to determine 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. Rather than attempting to assess the exposure—and therefore the risk—associated with the use of each hazardous chemical in each industry to determine if that chemical posed a significant risk in that industry,

OSHA took a more general approach. It relied on NIOSH data showing that about 25 million or about 25% of American employees were potentially exposed to one or more of 8,000 NIOSH-identified chemical hazards and that for the years 1977 and 1978, more than 174,000 illnesses were likely caused by exposure to hazardous chemicals. 48 FR 53282. 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. 48 FR 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.

48 FR 53321. The U.S. Court of Appeals for the Third Circuit has on several occasions upheld this determination of significant risk as sufficient to justify the HCS under OSH Act § 6(b). *See Associated Builders & Contractors,* 862 F.2d at 67 (discussing the history of its review of the issue).

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, are 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. *See* 48 FR 53306, 53322. Therefore, they 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 53295–96, 53307; 59 FR 6132.

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 these 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. 49 FR 53295–96; 59 FR 6132. Further, it is only by the provision of hazard information that downstream employers and employees can determine how to use the chemical so that exposure and risk may be minimized. *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. *Durez Div. of Occidental Chemical Corp* v. *OSHA,* 906 F.2d 1, 4 (D.C. Cir. 1990); *General Carbon Co.* v. *OSHRC,* 860 F.2d 479, 485 (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, 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.'' 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 assures that employers and employees have the information they need to avoid situations of exposure in the work place even before the employee is exposed to a hazardous chemical.

The current proposal makes no conceptual or theoretical change in this approach. It still imposes the same general requirements: Hazard identification, labeling, safety data sheets, a written hazard communication program, and employee training. OSHA's determination that inadequate communication about hazardous chemicals constitutes a significant risk supports the incorporation of the GHS into the HCS, just as it supported the promulgation of the original HCS and its subsequent modifications. Further, the data discussed in parts V and VII of this preamble show that the significant risk continues to exist even under the current standard. OSHA estimates that over 40 million employees are potentially exposed to hazardous chemicals. BLS data show that in 2007, there were approximately 54,000 illnesses related to hazardous chemical exposure and 125 chemically-related fatalities. These new statistics probably represent only a small portion of the illnesses experienced by exposed employees because many illnesses are not reported as being related to workplace exposures, due to long latency periods, and other factors. For all the reasons detailed in Section V, the agency believes that adoption of the GHS will improve communication of the hazards associated with the use of chemicals, and reduce significant risk.

B. Section 6(b)(7) Authority. With respect to labels and employee warnings, the last sentence of section 6(b)(7) provides that:

> The Secretary, in consultation with the Secretary of Health and Human Services, may by rule promulgated pursuant to section 553 of title 4, 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).

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 (January 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 33458. 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 the survival rates for semi-annual x-rays were not higher than annual exams. 63 FR 33458–59. 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 (August 4, 2004); *see generally* 29 CFR 1910.134 App. A, Pt. II.

OSHA's proposal to revise the HCS fits well within the authority granted by the last sentence of § 6(b)(7). Adoption of GHS provisions would constitute 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 to be ''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* Part III above and 71 FR 53618–19. Indeed, OSHA noted the possibility of a future internationally harmonized standard in the preamble accompanying the original rule. 48 FR 53287.

The last sentence of section 6(b)(7) also requires consultation with the Secretary of Health and Human Services. OSHA briefed NIOSH on this proposal as a part of the October 2008 OSHA–NIOSH Issues Exchange meeting, which was attended by NIOSH's Acting Director, and NIOSH expressed its support. OSHA has also briefed NIOSH on the GHS in previous Issues Exchange meetings. In addition, NIOSH has actively supported the GHS during its development and has been involved in the development of control banding, international chemical safety cards, and employee training for the GHS. NIOSH has submitted a comment supporting OSHA's proposal, (Ex. 2–46–1), and reviewed a draft of both this NPRM and the ANPR before it was published. NIOSH has stated that it

> supports OSHA in its proposal to update the HCS and to address the changes in hazard criteria, to include all 16 physical hazard criteria, and to adopt the specific labeling requirements and the safety data sheet (SDS) order of information in the Globally Harmonized System of Classification and Labelling of Chemicals.

(Document ID # 0082) These consultations coupled with OSHA's on-going relationship with NIOSH are more than sufficient to satisfy the requirement. 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).

C. 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 part V of this preamble. Section 6(b)(5) also requires a finding that the proposed standard is 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 America* 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. *See Lead I,* 647 F.2d 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 6133. OSHA has repeatedly found that the requirements of the HCS are technologically feasible. *See* 52 FR 31855–57; 59 FR 6133. While the GHS modifications to HCS impose more specific requirements for hazard classification, labeling, and safety data sheets, employers may use the same methods to meet these requirements as they are already utilizing to comply with the requirements of HCS.

The most important resource employers will need 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 53296–99. OSHA believes that the availability of professionals with this expertise has only increased in the intervening time. At least one professional organization provides training in hazard communication to professionals and businesses. (Document ID #s 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 # 0082.) OSHA received numerous comments in response to its September 12, 2006 ANPR 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 #s 0042, 0046, 0050, 0053, 0072, 0077, 0015, 0024, 0026, 0036, 0038, 0107, 0108, 0116, 0123, 0128, 0141, 0144, 0145, 0154, 0155, and 0163.) The Agency has been engaged on several fronts to facilitate the transition from the current standard to the GHS modifications, if ultimately adopted. For instance, the United Nations Institute for Training and Research (UNITAR) is developing basic and more advanced training courses for the GHS, and OSHA has been involved with and committed resources to this effort. NIOSH's comment also discussed the development of the WHO/IPCS International Chemical Safety Cards, which includes the GHS pictograms and signal words. (Document ID # 0082.) OSHA believes that adopting the GHS modifications as proposed poses no technological feasibility issues.

Likewise, for the reasons more fully discussed in the Preliminary Regulatory Analysis, OSHA believes that there is nothing about the adoption of GHS that will pose economic feasibility issues. Again, OSHA has found that the implementation of HCS in the first instance would have no such effect. *See* 52 FR 31855–57; 59 FR 6133. Most commenters agreed 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. (Document ID #s 0046, 0047, 0080, 0103, 0104, 0105, 0179,

0119, 0123, 0129, 0135, 0139, 0145, 0147, and 0163.) 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.

Finally, OSHA is not proposing to ''delegate[e] power to an international body'' through the adoption of the GHS or justifying this proposal as a means to reduce ''potential barriers to international trade,'' as suggested in the comments. (Document ID #s 0065 and 0026). OSHA recognizes, however, that there are potential benefits to international trade by adopting the GHS, and these are discussed in section VII of this preamble, OSHA is proposing to comply with the OSH Act's mandate to assure as far as possible safe and healthful working conditions in this country by incorporating the GHS's improved hazard communications requirements into the HCS through the process authorized by section 6 of the OSH Act. Adoption of the GHS modifications into the HCS would not place any new obligations on OSHA to comply with the requirements of any foreign or international body.

VII. Preliminary Economic Analysis and Initial Regulatory Flexibility Screening 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 Order 12866, 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.

Accordingly, OSHA has prepared this Preliminary Economic Analysis (PEA), including an Initial Regulatory Flexibility Screening Analysis (IRFSA), for the proposed modifications to the Hazard Communication Standard (HCS). The OSHA PEA is based largely on research conducted for this purpose by Policy, Planning, and Evaluation, Inc. (PP&E), as presented in their report, ''Data and Analysis in Support of an Economic Analysis of Proposed Changes to the OSHA Hazard Communication Standard,'' prepared under contract to OSHA. The PP&E report is 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 assure 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 proposed changes would create a uniformity standard for the presentation of risk information and, as such, would 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 V of the 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 proposed revisions to the OSHA HCS would 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 proposed revisions would harmonize the U.S. system with international norms, they would facilitate international trade.

Affected Industries

The proposal would affect employers and employees in many different industries across the economy. Based on the PP&E report, OSHA estimates in Table VII–2 that the HCS covers over five million workplaces in which employees are potentially exposed to hazardous chemicals.

For establishments with employees whose exposures to hazardous chemicals results from their use of the chemical products, the proposed 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 preliminarily judged that SDSs for imported chemicals would normally be produced in the country of origin, and thus would not represent expenses for importers. OSHA welcomes comment on this judgment.

Benefits, Net Benefits, and Cost-Effectiveness

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 estimates probably only reflect a small percentage of occupational illnesses (48 FR 53284) 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. 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.[1]

Section V of the preamble describes some of the incidents that may have been related to the non-standardized approach to SDSs in the current HCS,

[1] 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. Underlying studies are to appear in forthcoming publications.

including xylene exposure at a hospital when an employee was unable to find critical information on an SDS in an emergency spill situation (Hanson, 2004). As a result, twelve employees required emergency room treatment. Another example is the explosion at a manufacturing plant in Corbin, KY, which resulted in the death of 7 workers and injuries to another 37 workers. A Federal investigation into the explosion concluded that the cause was the inability to effectively identify and respond to the inherent explosive hazards of phenolic resin and specifically referenced the MSDS for phenolic resin dust (U.S. Chemical Safety and Hazard Investigation Board, February 2005). Were the information on SDSs more uniformly formatted and comprehensible, as required under the proposed modifications to HCS, incidents such as those described above would be less likely to occur.

In general, the proposed 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 proposed revisions to the HCS. The benefits associated with the existing HCS may indirectly help provide a general sense of the potential magnitude of the benefits of the proposed revisions to the HCS. OSHA preliminarily estimates that if the proposed rule could capture one percent of the benefits estimated for the original 1983 and 1987 HCS rules, the proposed 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 $266 million on an annualized basis.

The harmonization of hazard classifications, safety data sheet formats, and warning labels for affected chemicals and products would also involve 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 proposed modifications.

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 proposed revisions to the HCS and analyzed the potential savings that would be realized as a result of adopting these revisions. Based on PP&E's research, OSHA has concluded that the annual cost savings for these companies would be an estimated $585 million.

As an additional benefit, the modification of the HCS by the inclusion of the globally harmonized system (GHS) of classification and labelling 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.

The proposed revisions may also result in reductions in the costs associated with providing training for employees as required by the existing OSHA HCS.

Finally, the proposed GHS modifications to the OSHA HCS would meet the international goals for adoption and implementation of the GHS that were 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 (*see http://www.chem.unep.ch/saicm/*).

Table VII–1 provides a summary of the costs and benefits of the proposed modifications to the OSHA HCS, and it shows the net benefits of the modifications to the standard, which are estimated to be $754 million annually. Because compliance with the proposed 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 a factor of eight.

BILLING CODE 4510–26–P

Table VII-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 and invites comments on the estimates. OSHA provides a Sensitivity Analysis on these estimates in the final section of the PEA.

Annualized Costs	
Reclassification of Chemical Hazards and Revision of SDSs and Labels	$11 million
Employee Training	$44 million
Management Familiarization and Other Costs	$42 million
Total Annualized Costs:	$97 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	$266 ($133-$1,318) million
Cost Reductions and Productivity Gains	$585 million
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:	$851 ($738-$1,903) million
Net Annual Monetized Benefits (Benefits Minus Costs):	$754 ($641-1,806) million

Note: Costs and benefits are expressed in 2007 dollars.

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Compliance Costs

The estimated compliance costs for the proposed 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 with regard to the new requirements; 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 costs associated with compliance with the proposed revisions to the HCS would generally be incurred by the affected industries as one-time transition costs over the phase-in period of three years. Aside from the transition costs, the ongoing annual compliance costs associated with the proposed revisions to the HCS generally are expected to be the same or lower than under the existing standard.

The compliance costs are expressed as an annualized cost for purposes of assessing the cost-effectiveness of the proposed 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. The annualized cost was calculated by annualizing the one-time costs over a period of 20 years and applying a discount rate of 7 percent, as recommended by the Office of Management and Budget.

The total annualized cost of compliance with the proposed standard is estimated to be about $97 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 ($11 million); training for employees to become familiar with new warning symbols and the revised safety data sheet format ($44 million); and management familiarization and other management-related costs as may be necessary ($42 million).

Economic Impacts

To assess the nature and magnitude of the economic impacts associated with compliance with the proposed rule, OSHA developed quantitative estimates of the potential economic impact of the 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 revised standard 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 proposed revisions. As described in section D of this PEA, 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 G of this PEA, the costs of compliance with the proposed 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 0.0004 percent of revenues and about 0.007 percent of profits, on average, across all entities; compliance costs do not represent more than 0.02 percent of revenues or more than 0.3 percent of profits in any individual affected industry sector.

The economic impact of achieving compliance with the proposal, without considering the associated benefits, is most likely to consist of an extremely small increase in prices of about 0.0004 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 proposal 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 0.0004 percent were not possible, profits in the affected industries would be reduced by an average of about 0.007 percent.

Given the minimal potential impact on prices or profits in the affected industries, OSHA has preliminarily concluded that compliance with the requirements of the proposed 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 preliminarily concludes that the effect of the proposed standard 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.

Initial Regulatory Flexibility Screening Analysis

OSHA has analyzed the potential impact of the proposed rule on small entities, and has prepared an Initial Regulatory Flexibility Screening Analysis (IRFSA) in conjunction with this rulemaking to describe the potential effects on small entities. The IRFSA is included as a part of this PEA in section H.

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, an Initial Regulatory Flexibility Analysis (IRFA) is not required for this rulemaking. Nevertheless, OSHA has voluntarily provided the elements of the IRFA as part of the IRFSA presented in Section H. In proceeding with this rulemaking, OSHA will fulfill 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 PEA includes the following sections:

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

B. Market Failure and the Need for Regulation

Employees in work environments addressed by the 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 assure that employers and employees are provided the information they need about the chemical hazards in chemical products both to make informed purchases and to provide for safe use. In the existing HCS, OSHA developed a set of requirements for chemical products, to include mandatory classification, labeling, and detailed information provision (in safety data sheets). OSHA believes that the improvements in the proposed rule would make the hazard communication system more worker-protective and more efficient and effective. In addition, the improvements would have the effect of harmonizing

hazard communication to facilitate international trade—replacing a plethora of national rules with a single international system.

The proposed standard, through conformance with GHS (as explained in Section IV of the 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, p. 8). And much like other uniformity standards, such as driving on the right side of the road (in the U.S.), screw threads for fire hose connectors, ''handshake'' protocols for communication between computers, and, for that matter, language, GHS would provide significant efficiencies and economies.[2] In the case of GHS, manufacturers would be able to produce SDSs at lower cost, and users of SDSs would 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.[3]

Since publication of the existing HCS, there has been some movement by industry toward standardization, consistent with the proposed revisions. However, OSHA does not believe that full and comprehensive standardization, as required under the proposed revisions, or that the goal of harmonizing the U.S. system with the international one could 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 existing 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 will 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.[4]

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 assure 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 presence of positive GHS externalities would prevent the private market, without regulation, from achieving the socially optimal adoption of GHS.

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 provide pressure to 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 will not see these types of trade benefits if they do not engage in exporting chemicals. 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 illnesses, injuries, fatalities, and accidents due to a more consistent, comprehensible, and clearer system that does not require English literacy to obtain some minimal hazard information;
- Greater ease of use of SDSs; and
- Reduced training requirements for 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

[2] 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. Note that an engineering standard would generally not provide efficiencies or economies to the regulated community. On the contrary, an engineering standard would impose additional costs on some firms, in that they could effectively protect workers using an alternative approach, if it 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 technological or strategic considerations, the possible costs of uniformity here would be non-existent or minuscule.

[3] On the ability of individuals to more fully and effectively utilize knowledge when uniformity requirements are present, see Hemenway, *1975,* pp. 34–35.

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

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 proposed 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 proposed revisions to the HCS are not anticipated to either increase or decrease the scope of affected industries or establishments. The proposed revisions define and revise specific classifications and categories of hazards, but the scope of the requirements under which a chemical, substance, or mixture becomes subject to the requirements of the standard are not substantially different from the current HCS. Therefore, the proposed revisions should have little or no effect on whether an entire establishment falls within the scope of the standard. OSHA requests comments from the public regarding this preliminary determination.

For establishments with employees exposed to hazardous chemicals, the proposed revisions to the HCS would 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, the revisions to the standard would 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 preliminary determination that all production employees in manufacturing would be covered, and that, in addition, employees in other industries working in any of the occupations specified in the PP&E report would also be exposed to hazardous chemicals.

Table VII–2 provides an overview of the industries and estimated numbers of employees potentially affected by the HCS. OSHA welcomes additional information and data that may help improve the accuracy of these estimates.

The industries and establishments affected by the proposed 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, OSHA has preliminarily judged that SDSs for imported chemicals would normally be produced in the country of origin, and thus would not represent expenses for importers or other US firms.

As shown in Table VII–2, approximately 75,000 firms, in over 90,000 establishments, create hazardous chemicals (*i.e.*, products, substances, or mixtures) for which a label and an SDS are required in accordance with the OSHA HCS. Approximately 880,000 SDSs and corresponding container labels would be potentially affected by the proposed revisions to the HCS. OSHA estimates that the adoption of GHS through this proposal would not significantly change the numbers of labels and SDSs produced. OSHA welcomes comment on this issue.

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 proposed revisions to the OSHA HCS would 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.

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Table VII-2
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	12,301	12,301	12,509	12,509	75,822	20,752	0
114	Fishing, Hunting and Trapping	2,368	1,086	2,385	1,103	9,244	2,184	0
115	Support Activities for Ag & Forestry	11,165	5,021	11,658	5,487	96,096	11,738	0
211	**Oil and Gas Extraction**							
211111	Crude petroleum & natural gas extraction	6,238	6,238	7,135	7,135	76,794	47,962	55,825
211112	Natural gas liquid extraction	113	113	494	494	11,486	9,691	10,700
212	Mining (except Oil & Gas)	4,669	4,669	7,205	7,205	194,174	155,834	0
213	Support Activities for Mining	7,587	7,587	9,037	9,037	183,321	135,602	0
22	**Utilities**							
2211	Electric Power Gen, Trans & Distrib	1,756	1,756	9,493	9,493	515,769	251,589	0
2212	Natural Gas Distribution	631	631	2,897	2,897	86,890	37,492	0
2213	Water, Sewage, & Other Systems	5,296	5,296	6,042	6,042	45,595	24,769	0
23	**Construction**							
236	Construction of Buildings	224,416	224,416	226,394	226,394	1,585,717	1,088,995	0
237	Heavy Construction	38,610	38,610	39,949	39,949	856,312	520,365	0
238	Special Trade Contractors	438,835	438,835	443,982	443,982	3,865,341	3,047,666	0
31	**Manufacturing**							
311	Food Manufacturing	21,384	21,384	25,698	25,698	1,443,766	1,121,846	0
312	Beverage &Tobacco Prod. Manuf.	2,721	2,721	3,232	3,232	163,395	95,319	0
313	Textile Mills	3,398	3,398	4,045	4,045	261,655	221,502	0
314	Textile Product Mills	6,956	6,956	7,332	7,332	190,209	154,672	0
315	Apparel Manufacturing	12,862	12,862	13,359	13,359	350,439	275,995	0
316	Leather & Allied Product Manufac.	1,481	1,481	1,549	1,549	47,795	37,996	0
321	Wood Product Manufacturing	15,198	15,198	17,052	17,052	534,011	434,987	0
322	Paper Manufacturing	3,538	3,538	5,546	5,546	495,990	385,229	0

Table VII-2
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
323	Printing and Related Support	35,174	35,174	36,902	36,902	706,419	516,676	0
324	**Petroleum & Coal Prod. Manufac.**							
324110	Petroleum refineries	202	202	349	349	62,132	37,744	31,790
324121	Asphalt paving mixture & block mfg	494	494	1,303	1,303	12,664	9,436	120,140
324122	Asphalt shingle & coating materials mfg	132	132	234	234	13,142	9,635	18,620
324191	Petroleum lubricating oil & grease mfg	275	275	330	330	9,605	5,142	15,860
324199	All other petroleum & coal products mfg	68	68	80	80	2,860	2,156	4,650
325	**Chemical Manufacturing**							
325110	Petrochemical mfg	39	39	58	58	10,449	5,153	4,704
325120	Industrial gas mfg	87	87	551	551	9,557	4,182	4,878
325131	Inorganic dye & pigment mfg	59	59	78	78	7,649	5,334	754
325132	Synthetic organic dye & pigment mfg	94	94	120	120	6,983	3,924	2,807
325181	Alkalies & chlorine mfg	25	25	38	38	4,483	3,139	286
325182	Carbon black mfg	11	11	25	25	1,708	1,139	214
325188	All other basic inorganic chemical mfg	367	367	611	611	49,845	30,634	17,350
325191	Gum & wood chemical mfg	41	41	54	54	2,139	1,280	2,540
325192	Cyclic crude & intermediate mfg	37	37	46	46	5,074	2,944	645
325193	Ethyl alcohol mfg	60	60	66	66	1,735	1,279	835
325199	All other basic organic chemical mfg	443	443	640	640	73,342	41,633	26,582
325211	Plastics material & resin mfg	443	443	695	695	59,840	37,775	82,570
325212	Synthetic rubber mfg	137	137	163	163	10,389	7,677	2,027
325221	Cellulosic organic fiber mfg	10	10	19	19	2,365	1,846	33
325222	Noncellulosic organic fiber mfg	65	65	92	92	24,214	19,015	0
325311	Nitrogenous fertilizer mfg	130	130	157	157	4,949	3,142	209

Table VII-2
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
325312	Phosphatic fertilizer mfg	35	35	50	50	6,288	4,724	82
325314	Fertilizer (mixing only) mfg	362	362	520	520	9,009	5,569	4,890
325320	Pesticide & other agricultural chemical mfg	198	198	235	235	14,021	7,607	5,282
325411	Medicinal & botanical mfg	326	326	353	353	22,496	11,153	3,440
325412	Pharmaceutical preparation mfg	727	727	891	891	144,577	62,540	11,060
325413	In-vitro diagnostic substance mfg	175	175	205	205	42,239	15,531	24,179
325414	Biological product (except diagnostic) mfg	242	242	330	330	28,593	13,660	3,084
325510	Paint & coating mfg	1,107	1,107	1,363	1,363	47,329	19,989	90,250
325520	Adhesive mfg	468	468	603	603	21,058	12,961	25,885
325611	Soap & other detergent mfg	671	671	735	735	25,983	15,930	16,200
325612	Polish & other sanitation good mfg	591	591	647	647	20,751	11,322	14,845
325613	Surface active agent mfg	149	149	178	178	7,301	3,234	6,370
325620	Toilet preparation mfg	726	726	794	794	56,647	36,416	17,986
325910	Printing ink mfg	226	226	501	501	12,001	5,882	54,145
325920	Explosives mfg	61	61	92	92	6,304	4,786	2,463
325991	Custom compounding of purchased resin	563	563	660	660	22,909	14,239	5,881
325992	Photographic film, paper, plate, & chemical mfg	348	348	379	379	30,322	18,734	2,841
325998	Miscellaneous chemical product & preparation mfg	986	986	1,147	1,147	34,881	20,235	49,165
326	Plastics and Rubber Products Man.	12,223	12,223	15,462	15,462	925,607	721,853	38,927
327	Nonmetallic Mineral Prod. Manufac.	11,395	11,395	16,674	16,674	475,476	372,842	41,536
331	Primary Metal Manufacturing	5,154	5,154	6,229	6,229	501,038	392,944	15,187
332	Fabricated Metal Prod. Manufac.	57,398	57,398	61,652	61,652	1,582,399	1,175,989	0
333	Machinery Manufacturing	25,245	25,245	27,941	27,941	1,166,221	719,025	0
334	Computer & Electronic Prod Man.	13,833	13,833	15,883	15,883	1,300,411	573,517	0

Table VII-2
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
335	Electric Equipment, Appliance Man.	5,546	5,546	6,601	6,601	502,400	363,433	0
336	Transportation Equip. Manufacturing	10,114	10,114	12,202	12,202	1,578,707	1,129,194	0
337	Furniture & Related Product Man.	21,194	21,194	22,083	22,083	575,128	454,344	0
339	Miscellaneous Manufacturing	28,269	28,269	29,507	29,507	664,710	418,422	42,543
42	**Wholesale Trade**							
423	Durable Goods	221,357	221,357	282,959	282,959	3,443,697	969,852	0
424	Nondurable Goods	124,758	124,758	153,941	153,941	2,416,559	905,759	0
44-45	**Retail Trade**							
441	Motor vehicle & parts dealers	96,890	96,890	126,644	126,644	1,890,916	644,840	0
442	Furniture & home furnishings stores	49,846	49,334	66,360	64,447	551,567	119,718	0
443	Electronics & appliance stores	34,012	13,483	49,600	28,152	418,725	37,305	0
444	Building material & garden equipment & dealers	68,829	68,829	94,109	94,109	1,270,736	262,840	0
445	Food & beverage stores	119,448	69,593	155,677	104,851	2,883,997	389,366	0
446	Health & personal care stores	42,643	42,643	82,574	82,574	988,347	391,312	0
447	Gasoline stations	64,068	37,909	117,100	89,367	895,983	97,373	0
448	Clothing & clothing accessories stores	69,030	6,877	151,895	25,061	1,408,948	25,061	0
451	Sporting goods, hobby, book, & music stores	43,888	11,841	65,933	32,301	617,726	32,937	0
452	General merchandise stores	9,681	3,240	41,069	34,521	2,546,094	174,860	0
453	Miscellaneous store retailers	104,458	46,758	129,997	70,126	822,992	88,788	0
454	Nonstore retailers	37,115	29,791	44,735	37,076	523,873	108,388	0
48-49	**Transportation & Warehousing**							
481	Air transportation	2,762	1,706	5,512	4,405	548,258	77,355	0
483	Water transportation	1,418	1,418	1,902	1,902	64,268	40,259	0
484	Truck transportation	98,645	98,645	111,308	111,308	1,333,342	1,076,215	0

Table VII-2
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
485	Transit & ground passenger transportation	14,770	7,300	17,073	9,586	387,325	33,467	0
486	Pipeline transportation	244	244	2,701	2,701	50,362	24,691	0
487	Scenic & sightseeing transportation	2,429	1,694	2,503	1,761	19,333	4,740	0
488	Support activities for transportation	26,501	26,501	33,342	33,342	475,466	229,856	0
492	Couriers & messengers	8,385	8,385	13,173	13,173	553,250	357,439	0
493	Warehousing & storage	4,917	4,917	7,629	7,629	149,409	91,373	0
51	**Information**							
511	Publishing industries	24,761	18,068	32,577	25,693	1,019,976	150,623	0
512	Motion picture & sound recording industries	19,129	3,414	23,021	7,182	278,399	11,123	0
513	Broadcasting & telecommunications	17,013	5,562	58,712	46,958	1,698,408	65,743	0
514	Information services & data processing services	17,137	3,392	24,280	9,961	539,337	11,302	0
52	**Finance & Insurance**							
521	Monetary authorities - central bank	12	12	58	58	23,367	666	0
522	Credit intermediation & related activities	58,662	5,588	196,160	14,860	3,006,084	14,860	0
523	Securities intermediation & related activities	48,121	1,912	81,690	4,890	1,008,867	4,890	0
524	Insurance carriers & related activities	129,959	13,454	168,976	46,190	2,342,005	48,311	0
525	Funds, trusts, & other financial vehicles	2,531	443	3,538	1,082	34,260	1,127	0
53	**Real Estate & Rental and Leasing**							
531	Real estate	226,318	193,393	257,195	221,358	1,351,973	419,807	0
532	Rental & leasing services	31,575	31,575	63,645	63,645	641,322	184,804	0
533	Lessors of intangibles, except copyrighted works	2,077	737	2,184	827	24,052	1,279	0
54	**Professional, Scientific, & Technical**							
5411	Legal services	170,427	4,520	178,692	5,128	1,138,451	5,128	0
5412	Accounting, tax, bookkeeping, & payroll services	99,149	10,697	110,844	20,331	1,241,269	25,461	0

Table VII-2
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
5413	Architectural, engineering, & related services	95,966	25,079	108,061	36,624	1,236,939	55,328	0
5414	Specialized design services	30,426	10,024	30,711	10,240	131,546	14,419	0
5415	Computer systems design & related services	92,606	5,490	102,872	9,329	1,089,497	9,329	0
5416	Management, scientific, & tech consulting services	110,393	21,006	117,008	27,042	820,439	51,064	0
5417	Scientific R&D Serv.	11,418	4,829	13,944	7,258	399,213	27,349	0
5418	Advertising & related services	34,459	12,734	37,930	16,016	411,819	34,876	0
5419	Other professional, scientific, & technical services	64,480	64,480	72,303	72,303	577,032	205,945	0
55	**Management of Companies**							
551111	Offices of bank holding companies	1,218	948	1,496	1,225	38,730	3,989	0
551112	Offices of other holding companies	8,821	4,977	9,820	5,937	206,973	21,318	0
551114	Corporate, subsidiary, & regional managing offices	19,382	18,420	38,067	37,051	2,668,095	274,811	0
56	**Adm and Support & Waste Management**							
561	Administrative and Support Serv.	275,183	275,183	325,846	325,846	7,998,637	3,812,211	0
562	Waste management & Remediation Serv.	14,184	14,184	17,698	17,698	300,580	210,428	0
61	**Educational Services**							
6111	Elementary & secondary schools	18,547	15,601	20,894	17,934	793,638	66,609	0
6112	Junior colleges	624	447	931	754	95,015	5,475	0
6113	Colleges, universities, & profesional schools	2,593	2,147	3,377	2,929	1,403,085	165,494	0
6114	Business schools, & computer & mgmt training	6,766	630	7,285	758	58,275	758	0
6115	Technical & trade schools	6,063	2,190	7,076	3,110	84,048	4,454	0
6116	Other schools & instruction	27,002	3,420	28,988	3,916	216,593	3,916	0
6117	Educational support services	4,541	689	5,150	1,183	51,021	1,293	0

Table VII-2
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
62	**Healthcare and Social Assistance**							
621	Ambulatory health care services	424,694	424,694	487,747	487,747	4,917,156	2,893,916	0
622	Hospitals	4,548	4,548	7,569	7,569	5,121,584	3,596,545	0
623	Nursing & residential care facilities	32,720	32,720	67,900	67,900	2,770,665	1,767,442	0
624	Social assistance	102,620	78,761	140,324	115,863	2,090,743	282,495	0
71	**Arts, Entertainment & Recreation**							
711	Performing arts, spectator sports, etc.	37,545	12,987	38,191	13,563	370,329	44,899	0
712	Museums, historical sites, & similar institutions	6,135	3,432	6,633	3,883	116,123	13,453	0
713	Amusement, gambling, & recreation industries	59,437	47,924	65,551	53,870	1,314,539	228,698	0
72	**Accommodation & Food Services**							
721	Accommodation	51,168	51,168	61,795	61,795	1,696,701	585,937	0
722	Food services & drinking places	376,637	62,931	503,354	110,106	8,352,174	110,106	0
81	**Other Services (except Public Adm.)**							
811	Repair & maintenance	215,083	215,083	233,234	233,234	1,334,875	917,266	0
812	Personal & laundry services	169,042	128,242	206,884	163,406	1,314,320	259,362	0
813	Religious/grantmaking/civic/professional & similar	291,212	122,918	300,000	131,069	2,770,892	225,286	0

Table VII-2
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
99	**State and Local Government** (about half covered by OSHA standards)							
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 for firms producing SDSs	**74,507**	**74,507**	**90,801**	**90,801**	**3,558,730**	**2,463,420**	**880,260**
	Total for firms not producing SDSs	**5,672,219**	**3,911,083**	**7,060,667**	**4,952,525**	**116,746,665**	**38,165,395**	**0**
	Total	**5,746,726**	**3,985,590**	**7,151,468**	**5,043,326**	**120,305,395**	**40,628,815**	**880,260**

Source: Office of Regulatory Analysis, OSHA, based on PP&E (2008)

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OSHA requests comments from the public regarding these preliminary conclusions and requests information on the number and type of labels and

SDSs that would be affected or produced as a result of this proposal.

The second category of industries and establishments affected by the proposed revisions contains those that do not produce 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 would generally involve promoting employee awareness of and management familiarization with the revisions to SDSs and labels.

As shown in Table VII–2, an estimated 38 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 SDSs, a total of 41 million employees would potentially need to become familiar with the proposed revisions to SDSs and labels. As also shown in Table VII–2, OSHA estimates that there are over five million workplaces where employees may be potentially exposed to hazardous chemicals. OSHA requests comments and information from the public regarding these estimates.

D. Benefits, Net Benefits, and Cost-Effectiveness

OSHA estimates that the promulgation of the proposed revisions would 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; reductions in costs for producers of hazardous chemicals; increased efficiencies in the handling and use of hazardous chemicals; and other benefits as described in this section. OSHA requests comments and information from the public regarding the nature and extent of any benefits that may be associated with the proposed revisions.

OSHA expects the proposed revisions to the HCS would result in an increased degree of safety and health for the affected employees and to reduce the number of accidents, fatalities, injuries, and illnesses associated with exposure to hazardous chemicals.

As explained in detail in Section V of the 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. As a result of this research, OSHA is confident that the GHS revisions to the HCS standard for labeling and safety data sheets would 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 proposal. 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 reduce property damage.

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

The existing 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, November 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, August 24, 1987).

For both of these final rules, OSHA conducted research specifically 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 the 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, November 25, 1983 and 52 FR 31872, August 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. According to the inflation calculator provided by the Bureau of Labor Statistics, the buying power of $18.2 billion in 1985 is equivalent to the buying power of about $35.3 billion in 2007 after adjusting for inflation of 94 percent over the period.[5]

Based on the material presented in this preamble, OSHA expects that the proposed revisions to the HCS would result in incremental improvements in employee health and safety above that already achieved under the existing HCS. For purposes of this proposal, OSHA has selected an estimate of 1 percent of the health and safety benefits due to the existing HCS as the benefits that could be attributed to compliance with the proposed revisions. 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 believes actual benefits may be larger, perhaps several times larger.[6] [7]

[5] *http://data.bls.gov/cgi-bin/cpicalc.pl.* BLS inflation calculator used on September 23, 2008.

[6] For example, one commenter on the ANPR, representing an organization whose membership includes first response and emergency management, wrote the following: ''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.'' (Document ID # 0033.)

[7] OSHA believes that a reasonable range for the magnitude of the health and safety benefits resulting from the proposed revisions would be equal to between 0.5 percent and 5 percent of the benefits associated with the existing HCS. These ranges are considered in the sensitivity analysis presented in Section VII.K.

If the 1 percent estimate is correct, then once all requirements take effect, they 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 these health and safety benefits is an estimated $353 million annually.

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 (Leigh *et al.,* 1997). OSHA believes these more recent data from 1992–2007 show that it is plausible that 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 GHS.

OSHA requests information and data from the public that could assist the agency in more accurately determining the safety and health benefits associated with the proposed revisions.

The annual benefits associated with the proposed revisions to the OSHA HCS would generally begin after full implementation of the changes and associated employee training. The phase-in period is expected to take about three years. Thus, in order to calculate the estimated annualized benefits over a twenty-year period associated with this proposed 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 annual benefits beginning three years after the effective date of the revisions were multiplied by 0.7523 to calculate the annualized benefits over a twenty-year period beginning with the effective date of the final rule.[8] Thus, the annualized monetized benefit associated with the reduction in safety and health risks attributable to the proposed revisions is an estimated $266 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 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 proposed revisions for many businesses that purchase or use hazardous chemicals. The current non-uniformity of SDSs and labels received by establishments in practically all industries requires employees and managers in numerous positions to spend additional time on a daily basis to ascertain the appropriate way to handle and store the hazardous chemicals in their workplace. 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.

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 proposed revisions to the HCS and analyzed the potential savings that would be realized as a result of adopting these revisions.

Based on the PP&E report, OSHA developed estimates of the cost reductions that the affected companies would expect to obtain as a result of the proposed revisions to the OSHA HCS. Among the various benefits expected to be realized as a result of the implementation of the proposed revisions, as described in this section, OSHA quantified two general categories of cost savings. First, 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.[9] OSHA further estimated that this time reduction, and the associated cost savings, would apply to about 7,000 health and safety supervisors and 52,000 logistics personnel in the manufacturing sector and would yield annualized benefits of approximately $569 million.[10] Similar potential time and cost savings as a result of the proposed revisions to the OSHA HCS were not quantified for the non-manufacturing sectors.

Second, OSHA estimated that, for the manufacturing sectors, the costs associated with the creation and revision of SDSs in future years would be reduced by the proposed revisions. The creation and revision of individual SDSs would 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

[8] The formula for annualizing the benefits is equal to:

$$[(1.07)^{-3}] * [(1-(1.07)^{-17})/0.07] * [0.07/((1-(1.07)^{-20})],$$

where the first term in brackets reflects the three year delay until annual benefits are realized; the second term in brackets reflects the present value of seventeen years of annual benefits (from years 4 through 20), and the third term in brackets annualizes the present value of benefits over a 20-year period.

[9] For example, as described by PP&E, 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 proposed 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.

[10] These estimates assume 2,000 hours of work a year for 7,070 health and safety supervisors and 52,280 logistics personnel specializing in handling hazardous chemicals in the manufacturing sector; an hourly wage of $47; and a time savings of 3 percent and 15 percent, respectively, for health and safety supervisors and logistics personnel. The resulting annual savings of $757 million was multiplied by 0.7523 to annualize the savings over a twenty-year period with savings not accruing until three years after the effective date of the revisions.

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 $16 million.[11]

Combining the improved productivity of personnel who use SDSs and the improved efficiency of those who revise SDSs and labels, OSHA concluded that the annual cost savings for companies in the manufacturing sector would be an estimated $585 million.

A secondary 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. 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.

The proposed revisions may also result in reductions in the costs associated with providing training for employees as required by the existing OSHA HCS. Companies would save considerable time and effort in training new employees in the future. The potential savings would 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.

Finally, the proposed GHS modifications to the OSHA HCS would meet the international goals for adoption and implementation of the GHS that were 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.

Table VII–1 provides a summary of the costs and benefits of the proposed 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 $754 million annually. The cost-effectiveness of the standard can be expressed as more than eight 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 Advance Notice for Proposed Rulemaking (ANPR) published by OSHA in the **Federal Register** on September 12, 2006 (71 FR 53617). There was widespread (but not unanimous) support among the commenters for the adoption of GHS in the United States. This included commenters who provided some of the largest estimates of the costs of the proposed revisions. (Document IDs # 0032 and # 0050).[12]

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. In fulfillment of this requirement, OSHA has reviewed the requirements that would be imposed by the proposal, and has assessed their technological feasibility. As a result of this review, OSHA has determined that compliance with the requirements of the proposal is technologically feasible for all affected industries. OSHA requests comments and information from the public with regard to this preliminary determination.

The proposal would require employers producing 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.

The proposal 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.

Compliance with all of the proposed requirements 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 and adding some training to ensure employee familiarization with the changes made. Therefore, there are no new technologies required for compliance with the modifications. In addition, some businesses in the affected industries have already implemented many of the requirements of the proposed standard to varying degrees. OSHA believes that there are no technological constraints associated with compliance with any of the proposed requirements, and welcomes comments regarding this conclusion.

F. Costs of Compliance

Introduction

This section presents the estimated costs of compliance for the proposed revisions to the OSHA HCS. The estimated costs of compliance represent the additional costs necessary for employers to achieve full compliance. They do not include costs associated with current compliance with the new requirements.

The compliance costs associated with the proposal generally consist of the one-time transition costs to adopt the modified criteria for classifications and formats as required under the new system. Ongoing annual costs associated with compliance with the existing OSHA HCS are not expected to increase. As discussed in the benefits section, the adoption of the new system is expected to reduce some of the ongoing costs associated with compliance with the HCS after the completion of the transition period.

The costs of compliance with the proposed revisions consist of three main categories: the cost of reclassification and revision of SDSs and labels, the cost of training employees, and the cost of management familiarization and other management costs associated with the administration of hazard communication programs.

[11] These estimates assume ⅓ of the estimated 880,260 SDSs are reviewed each year; savings per SDS is between 2½ 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 $47; 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 $21 million was multiplied by 0.7523 to annualize the savings over a twenty-year period with savings not accruing until three years after the effective date of the revisions.

[12] One of these commenters is an international trade association for the institutional and industrial cleaning industry that represents over 4,600 manufacturer, distributor, building service contractor, and in-house service provider members worldwide. The other is a trade association representing some 400 manufacturers of paints, coatings, adhesives, sealants, and caulks, raw materials suppliers to the industry, and product distributors.

The estimated compliance costs associated with the proposed revisions are based on a preliminary determination that the revisions would not significantly change the number of chemicals or products for which an SDS will be required, which also means that there will be no change in the number of establishments required to implement a hazard communication program. OSHA requests comments and information from the public regarding this preliminary 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 preliminarily determined that such effects, if any, will not be significant, and requests comments and information from the public regarding this determination.

In addition to the proposed revisions to the HCS, the proposed rulemaking also includes related proposed 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 GHS. OSHA has preliminarily determined that the proposed revisions to the other standards would not impose significant costs beyond those reflected in the preliminary compliance cost estimates for this rulemaking, and requests comments and information from the public regarding this determination.

In order to have compliance costs presented on a consistent and comparable basis across various regulatory activities, the costs of compliance for this proposed rule are expressed in annualized terms. Annualized costs represent the more appropriate measure for assessing the longer-term potential impacts of the rulemaking. The estimated annualized cost of compliance is also provided 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. The annualized cost was calculated by annualizing the one-time transition costs over a period of 20 years and applying a discount rate of 7 percent.

Table VII–3 shows the estimated annualized compliance cost by cost category and by industry sector. As shown in Table VII–3, the total annualized cost of compliance with the proposed rulemaking is estimated to be about $97 million. Of this amount, the cost of chemical hazard reclassification and revision of SDSs and labels is an estimated $11 million, the cost of training employees is an estimated $44 million, and the cost of management familiarization and other management costs is an estimated $42 million.

As shown in Table VII–3, most of the compliance cost associated with chemical hazard reclassification and revision of SDSs and labels would be borne by the chemical manufacturing industry. Table VII–3 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.

OSHA expects that the compliance costs would be incurred over a period of three years, as the proposal would incorporate a three-year transition period into the compliance schedule for the standard. Specifically, for purposes of estimating the annualized compliance costs, OSHA assumed that the compliance costs associated with employee training would be incurred in the two-year period following the effective date of the final standard, and that other compliance costs would be incurred in the three-year period following the effective date of the final standard.

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Table VII-3
Annualized Costs of Compliance

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Cost of Training Employees	Management Familiarization and Other Costs	Total Annualized Costs
11	**Agriculture, Forestry, Fishing & Hunting**				
113	Forestry & Logging	$0	$29,629	$66,608	$96,237
114	Fishing, Hunting and Trapping	$0	$3,149	$6,008	$9,157
115	Support Activities for Ag & Forestry	$0	$14,795	$29,735	$44,529
211	**Oil and Gas Extraction**				
211111	Crude petroleum & natural gas extraction	$1,129,838	$73,379	$216,427	$1,419,643
211112	Natural gas liquid extraction	$87,288	$13,405	$6,744	$107,438
212	Mining (except Oil & Gas)	$0	$100,026	$57,793	$157,819
213	Support Activities for Mining	$0	$65,809	$68,413	$134,222
22	**Utilities**				
2211	Electric Power Gen, Trans & Distrib	$0	$344,711	$374,809	$719,520
2212	Natural Gas Distribution	$0	$52,068	$105,791	$157,859
2213	Water, Sewage, & Other Systems	$0	$41,577	$197,830	$239,408
23	**Construction**				
236	Construction of Buildings	$0	$1,205,553	$1,815,955	$3,021,507
237	Heavy Construction	$0	$463,487	$320,439	$783,927
238	Special Trade Contractors	$0	$2,679,900	$3,561,275	$6,241,175
31	**Manufacturing**				
311	Food Manufacturing	$0	$1,495,454	$790,376	$2,285,830
312	Beverage &Tobacco Prod. Manuf.	$0	$128,884	$95,417	$224,301
313	Textile Mills	$0	$293,482	$126,408	$419,890
314	Textile Product Mills	$0	$210,427	$234,752	$445,179
315	Apparel Manufacturing	$0	$377,113	$437,550	$814,664
316	Leather & Allied Product Manufac.	$0	$51,294	$50,034	$101,328

Table VII-3
Annualized Costs of Compliance
(Continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Cost of Training Employees	Management Familiarization and Other Costs	Total Annualized Costs
321	Wood Product Manufacturing	$0	$581,987	$540,546	$1,122,533
322	Paper Manufacturing	$0	$506,853	$155,360	$662,213
323	Printing and Related Support	$0	$718,586	$1,181,913	$1,900,499
324	**Petroleum & Coal Prod. Manufac.**				
324110	Petroleum refineries	$277,907	$49,701	$8,650	$336,257
324121	Asphalt paving mixture & block mfg	$1,124,381	$13,799	$31,126	$1,169,305
324122	Asphalt shingle & coating materials mfg	$192,106	$12,836	$6,156	$211,098
324191	Petroleum lubricating oil & grease mfg	$206,941	$7,022	$10,774	$224,737
324199	All other petroleum & coal products mfg	$57,721	$2,883	$2,440	$63,043
325	**Chemical Manufacturing**				
325110	Petrochemical mfg	$47,004	$6,769	$1,595	$55,368
325120	Industrial gas mfg	$37,517	$5,824	$9,964	$53,305
325131	Inorganic dye & pigment mfg	$8,753	$7,080	$2,735	$18,569
325132	Synthetic organic dye & pigment mfg	$39,284	$5,209	$4,196	$48,689
325181	Alkalies & chlorine mfg	$3,752	$4,156	$1,165	$9,073
325182	Carbon black mfg	$2,302	$1,516	$630	$4,449
325188	All other basic inorganic chemical mfg	$176,238	$40,322	$17,808	$234,368
325191	Gum & wood chemical mfg	$31,123	$1,773	$1,845	$34,741
325192	Cyclic crude & intermediate mfg	$5,868	$3,912	$1,143	$10,922
325193	Ethyl alcohol mfg	$13,334	$1,746	$2,709	$17,788
325199	All other basic organic chemical mfg	$259,837	$55,396	$19,304	$334,537
325211	Plastics material & resin mfg	$707,424	$50,325	$21,483	$779,231

Table VII-3
Annualized Costs of Compliance
(Continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Cost of Training Employees	Management Familiarization and Other Costs	Total Annualized Costs
325212	Synthetic rubber mfg	$20,540	$10,258	$5,562	$36,361
325221	Cellulosic organic fiber mfg	$540	$2,429	$735	$3,704
325222	Noncellulosic organic fiber mfg	$0	$24,944	$4,470	$29,413
325311	Nitrogenous fertilizer mfg	$3,840	$4,208	$5,183	$13,230
325312	Phosphatic fertilizer mfg	$1,046	$6,243	$1,399	$8,688
325314	Fertilizer (mixing only) mfg	$62,333	$7,904	$20,062	$90,299
325320	Pesticide & other agricultural chemical mfg	$69,890	$10,291	$8,021	$88,203
325411	Medicinal & botanical mfg	$60,974	$13,529	$12,884	$87,388
325412	Pharmaceutical preparation mfg	$161,887	$82,575	$31,357	$275,819
325413	In-vitro diagnostic substance mfg	$226,000	$20,570	$7,172	$253,741
325414	Biological product (except diagnostic) mfg	$38,689	$18,185	$10,665	$67,539
325510	Paint & coating mfg	$973,959	$27,512	$51,081	$1,052,551
325520	Adhesive mfg	$322,231	$17,681	$22,140	$362,051
325611	Soap & other detergent mfg	$219,482	$21,582	$29,265	$270,329
325612	Polish & other sanitation good mfg	$179,028	$15,403	$25,896	$220,327
325613	Surface active agent mfg	$72,265	$4,396	$6,161	$82,822
325620	Toilet preparation mfg	$236,999	$48,504	$31,272	$316,775
325910	Printing ink mfg	$542,497	$8,233	$16,565	$567,295
325920	Explosives mfg	$25,046	$6,354	$2,838	$34,238
325991	Custom compounding of purchased resin	$72,395	$19,269	$24,258	$115,922
325992	Photographic film, paper, plate, & chemical mfg	$49,261	$25,041	$14,292	$88,594
325998	Miscellaneous chemical product & preparation mfg	$610,628	$27,783	$44,045	$682,456

Table VII-3
Annualized Costs of Compliance
(Continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Cost of Training Employees	Management Familiarization and Other Costs	Total Annualized Costs
326	Plastics and Rubber Products Man.	$647,997	$952,337	$463,703	$2,064,037
327	Nonmetallic Mineral Prod. Manufac.	$665,958	$507,151	$462,737	$1,635,846
331	Primary Metal Manufacturing	$254,453	$520,840	$197,245	$972,539
332	Fabricated Metal Prod. Manufac.	$0	$1,598,857	$1,982,933	$3,581,790
333	Machinery Manufacturing	$0	$970,598	$880,371	$1,850,969
334	Computer & Electronic Prod Man.	$0	$770,886	$499,370	$1,270,256
335	Electric Equipment, Appliance Man.	$0	$483,140	$202,957	$686,097
336	Transportation Equip. Manufacturing	$0	$1,489,516	$420,019	$1,909,535
337	Furniture & Related Product Man.	$0	$617,923	$719,241	$1,337,163
339	Miscellaneous Manufacturing	$968,837	$586,567	$944,939	$2,500,342
42	**Wholesale Trade**				
423	Durable Goods	$0	$671,978	$1,321,567	$1,993,545
424	Nondurable Goods	$0	$482,598	$766,034	$1,248,632
44-45	**Retail Trade**				
441	Motor vehicle & parts dealers	$0	$642,325	$929,538	$1,571,863
442	Furniture & home furnishings stores	$0	$101,482	$255,941	$357,422
443	Electronics & appliance stores	$0	$34,982	$90,094	$125,076
444	Building material & garden equipment & dealers	$0	$191,341	$423,215	$614,556
445	Food & beverage stores	$0	$287,094	$539,050	$826,143
446	Health & personal care stores	$0	$565,575	$662,344	$1,227,918
447	Gasoline stations	$0	$157,996	$406,892	$564,888
448	Clothing & clothing accessories stores	$0	$29,602	$76,234	$105,835

Table VII-3
Annualized Costs of Compliance
(Continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Cost of Training Employees	Management Familiarization and Other Costs	Total Annualized Costs
451	Sporting goods, hobby, book, & music stores	$0	$40,680	$104,765	$145,445
452	General merchandise stores	$0	$166,744	$325,838	$492,582
453	Miscellaneous store retailers	$0	$80,156	$206,426	$286,582
454	Nonstore retailers	$0	$86,473	$167,010	$253,483
48-49	**Transportation & Warehousing**				
481	Air transportation	$0	$58,720	$31,275	$89,995
483	Water transportation	$0	$21,900	$14,727	$36,627
484	Truck transportation	$0	$445,419	$613,334	$1,058,753
485	Transit & ground passenger transportation	$0	$41,964	$65,702	$107,665
486	Pipeline transportation	$0	$14,981	$21,417	$36,398
487	Scenic & sightseeing transportation	$0	$4,642	$8,174	$12,816
488	Support activities for transportation	$0	$141,061	$210,661	$351,722
492	Couriers & messengers	$0	$110,087	$73,017	$183,104
493	Warehousing & storage	$0	$69,331	$61,194	$130,525
51	**Information**				
511	Publishing industries	$0	$119,240	$150,895	$270,135
512	Motion picture & sound recording industries	$0	$12,128	$31,235	$43,363
513	Broadcasting & telecommunications	$0	$114,351	$294,491	$408,841
514	Information services & data processing services	$0	$20,174	$51,953	$72,128
52	**Finance & Insurance**				
521	Monetary authorities - central bank	$0	$302	$465	$767
522	Credit intermediation & related activities	$0	$18,831	$48,496	$67,327

Table VII-3
Annualized Costs of Compliance
(Continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Cost of Training Employees	Management Familiarization and Other Costs	Total Annualized Costs
523	Securities intermediation & related activities	$0	$6,967	$17,943	$24,910
524	Insurance carriers & related activities	$0	$132,569	$341,415	$473,984
525	Funds, trusts, & other financial vehicles	$0	$2,323	$5,984	$8,307
53	**Real Estate & Rental and Leasing**				
531	Real estate	$0	$393,854	$866,516	$1,260,369
532	Rental & leasing services	$0	$171,609	$380,927	$552,537
533	Lessors of intangibles, except copyrighted works	$0	$2,065	$5,190	$7,254
54	**Professional, Scientific, & Technical**				
5411	Legal services	$0	$4,398	$11,326	$15,724
5412	Accounting, tax, bookkeeping, & payroll services	$0	$44,617	$114,904	$159,521
5413	Architectural, engineering, & related services	$0	$83,688	$206,442	$290,130
5414	Specialized design services	$0	$21,328	$49,796	$71,124
5415	Computer systems design & related services	$0	$15,861	$40,844	$56,705
5416	Management, scientific, & tech consulting services	$0	$70,810	$158,932	$229,742
5417	Scientific R&D Serv.	$0	$33,839	$52,066	$85,905
5418	Advertising & related services	$0	$41,369	$89,100	$130,468
5419	Other professional, scientific, & technical services	$0	$365,777	$579,958	$945,735
55	**Management of Companies**				
551111	Offices of bank holding companies	$0	$4,286	$8,190	$12,476
551112	Offices of other holding companies	$0	$22,562	$42,400	$64,962
551114	Corporate, subsidiary, & regional managing offices	$0	$223,505	$277,197	$500,702

Table VII-3
Annualized Costs of Compliance
(Continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Cost of Training Employees	Management Familiarization and Other Costs	Total Annualized Costs
56	**Adm and Support & Waste Management**				
561	Administrative and Support Serv.	$0	$2,758,953	$2,212,042	$4,970,996
562	Waste management & Remediation Serv.	$0	$144,778	$141,959	$286,737
61	**Educational Services**				
6111	Elementary & secondary schools	$0	$78,791	$128,331	$207,122
6112	Junior colleges	$0	$4,416	$5,719	$10,135
6113	Colleges, universities, & profesional schools	$0	$152,382	$22,163	$174,545
6114	Business schools, & computer & mgmt training	$0	$887	$2,286	$3,173
6115	Technical & trade schools	$0	$6,217	$15,545	$21,762
6116	Other schools & instruction	$0	$6,722	$17,310	$24,032
6117	Educational support services	$0	$3,111	$8,013	$11,125
62	**Healthcare and Social Assistance**				
621	Ambulatory health care services	$0	$4,436,104	$3,912,323	$8,348,427
622	Hospitals	$0	$4,528,720	$60,713	$4,589,433
623	Nursing & residential care facilities	$0	$2,237,815	$544,640	$2,782,456
624	Social assistance	$0	$442,933	$818,388	$1,261,322
71	**Arts, Entertainment & Recreation**				
711	Performing arts, spectator sports, etc.	$0	$40,492	$64,763	$105,255
712	Museums, historical sites, & similar institutions	$0	$11,630	$20,294	$31,924
713	Amusement, gambling, & recreation industries	$0	$196,571	$284,569	$481,140

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Table VII-3
Annualized Costs of Compliance
(Continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Cost of Training Employees	Management Familiarization and Other Costs	Total Annualized Costs
72	**Accommodation & Food Services**				
721	Accommodation	$0	$503,411	$463,257	$966,669
722	Food services & drinking places	$0	$132,627	$341,559	$474,186
81	**Other Services (except Public Adm.)**				
811	Repair & maintenance	$0	$1,099,257	$1,870,459	$2,969,716
812	Personal & laundry services	$0	$502,938	$1,106,751	$1,609,689
813	Religious/grantmaking/civic/professional	$0	$285,216	$657,996	$943,212
99	**State and Local Government** (about half covered by OSHA standards)				
9992	State Government	$0	$294,840	$102,270	$397,110
9993	Local Government	$0	$1,487,564	$85,466	$1,573,030
	Total	**$10,895,391**	**$44,372,500**	**$41,820,672**	**$97,088,564**

Note: Costs are expressed in 2007 dollars
Source: Office of Regulatory Analysis, OSHA, based on PP&E (2008)

In order to make the compliance cost estimates comparable with the corresponding benefits estimates, the expected timing of these costs was taken

into account. 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 $97 million annualized costs.

In the appendix to this cost section, Table VII–4 shows, by industry and by cost element, total non-annualized (non-discounted) compliance costs of about $1.1 billion estimated to be incurred during the three-year phase-in of the proposed revisions.

Estimation of Compliance Costs

The remainder of this section explains how the compliance costs 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 PP&E report.

The major elements of the proposed revisions that involve compliance costs include (1) the classification of chemicals in accordance with the proposed criteria and the revisions to the safety data sheets and labels corresponding to the affected hazardous chemicals; (2) 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 proposed revisions; and in addition, (3) even though it is not directly a result of any specific requirement included in the proposed revisions, 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.

The estimated compliance costs presented in this analysis of the proposed revisions to the HCS are largely based on research conducted by PP&E. PP&E 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, possible revisions that may be made to the OSHA HCS in order to implement the GHS.

The estimated costs of compliance with many of the provisions of the proposed standard 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 proposed revisions to the OSHA HCS would 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 after a manufacturer or employer becomes aware of any significant new information about the hazards of a chemical.

The proposed revisions to the standard would require 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 would 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 proposed revisions may require a 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 proposed revisions. In addition, the format required by the proposed revisions for SDSs is consistent with the format already adopted by the American National Standards Institute (ANSI) and therefore has already been implemented by many of the affected businesses.

Based on the PP&E report, OSHA developed estimates of the costs that would be associated with the classification of chemicals in accordance with the proposed criteria and with the revisions to the corresponding SDSs and labels for those chemicals. The estimated compliance costs represent the incremental costs that would need to be incurred to achieve compliance with the proposed revisions; 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 proposed revisions would allow for a transition period of three 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 proposed revisions 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 proposed reclassification of hazards and changes to SDSs and labels are based on the numbers of SDSs affected. Based on the PP&E report, 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 VII–2). Downstream users, distributors, and wholesalers are 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. OSHA requests comments and information from the public regarding this aspect of compliance with the standard.

The costs of compliance associated with the classification of chemicals in accordance with the proposed criteria and with the revisions to the corresponding SDSs and labels for those chemicals were based on PP&E industry interviews and estimated as follows.

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 the PP&E report, OSHA estimated the cost of hourly compensation for a professional for this purpose to be $47. 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 $6,580 (7 hours times 20 SDSs times $47).

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. Based on the PP&E report, OSHA estimated the hourly compensation for a professional for this purpose to be $47.

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.

Second, 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 transition to the GHS, and that their products and services are or will be adapted to enable compliance with the proposed revisions. In addition, some firms may purchase custom or proprietary software from private vendors to achieve compliance with existing or proposed revisions to hazard communication requirements and for other purposes.

Regardless of the particular approach individual companies may choose to most efficiently fulfill their obligations under the existing or proposed HCS, OSHA expects that a part of the costs associated with achieving compliance with the proposed revisions 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 $200, on average.

Based on the PP&E report, OSHA estimated the numbers of SDSs produced in each industry that would potentially need to be revised under the proposed standard, as shown in Table VII–2. A total of about 880,000 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 proposed 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 proposed OSHA standard 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 proposed 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 proposed OSHA standard 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 proposed OSHA standard, 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.

Research conducted by PP&E indicates that all of these factors contribute to a substantial degree of current compliance with the proposed rule, even if the existing OSHA standard remains unchanged.[13] Based on the PP&E report, OSHA estimates that, on average, about 53 percent of the gross costs that would otherwise be associated with the proposed 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 proposed revisions—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

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

to 99 employees; and 1 percent for firms with fewer than 20 employees. OSHA used these percentages to reduce the number of firms reported in Table VII–2 for purposes of estimating the costs for affected firms to comply with the proposed revisions (again, with the exception of employee training).

Based on the preceding analysis, OSHA estimates an annualized cost of approximately $11 million for the classification of chemicals in accordance with the proposed criteria and for revisions to the corresponding SDSs and labels for those chemicals.[14]

OSHA requests data and information from the public that would assist the Agency in ensuring that any costs associated with the proposed revisions are accurately estimated. For example, OSHA would appreciate data from individual companies on the number of actively distributed SDSs; the number that would be affected by the GHS proposal; the time required to revise SDSs; the occupation and hourly cost of the individuals working on the revisions; and whether software would need to be modified or purchased and the costs of the modification or purchase.

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 Advance Notice for Proposed Rulemaking (ANPR) published by OSHA in the **Federal Register** on September 12, 2006 (71 FR 53617). 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 preliminary 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. OSHA requests that, in submitting any data or information on compliance costs, commenters distinguish between the costs attributable to compliance with existing requirements, costs already incurred voluntarily or in compliance with another standard, and the incremental costs attributable to the new requirements associated with this rulemaking. The rationale or basis for assigning these compliance costs would also assist OSHA in developing accurate cost estimates.

One commenter, the Fragrance Materials Association of the United States, stated that its 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. (Document ID # 0061). Another commenter, the Flavor and Extract Manufacturers Association of the United States, also reported that it would take from two to eight hours to review the necessary information and produce new labels and safety data sheets for each hazardous chemical. (Document ID # 0062).

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

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.

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 #s 0015, 0018, 0024, 0036, 0079, 0105, 0107, 0116, 0128, 0141, and 0145, 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

[14] This annualized estimate of $11 million reflects software costs of $32 million and labor costs of $100 million multiplied by 0.082573 to annualize these costs (incurred over the first three years) over a 20-year period. The $32 million in software costs is the result of about 160,000 modified SDSs [(574,000 SDSs for large establishments × 25% not in existing compliance × 95% requiring modification) + (128,000 SDSs for establishments with 100–500 employees × 75% not in existing compliance × 25% requiring modification)] at a cost of $200 per SDS. The $100 million in labor cost is the result of about 413,000 affected SDSs multiplied by an average of 5.14 hours per SDS (from 3 to 7 hours per SDS) multiplied by $47 per hour.

The annualization factor, 0.082573, is equal to:

$[(1/3) * [(1—(1.07)^{-3})/0.07] * [0.07/((1—(1.07)^{-20})]$,

where the first term in brackets reflects the fact that these costs are assumed to be spread equally over the first three 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.

standard rather than just the incremental costs associated with the proposed modifications. 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 proposed revisions, as discussed above.

OSHA requests additional comments and information from affected establishments and from the public regarding the nature of the incremental costs of classifying chemicals and modifying SDSs and labels associated with the proposed revisions. Comments would be most helpful to the Agency if they included the underlying data and methodology used to develop the cost estimates.

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 proposed revisions.

Although it would not be explicitly required by the proposed revisions, 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 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 GHS; 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 costs could be considered discretionary in that they would not be explicitly required by the proposed 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. The particular circumstances that would cause these costs to be incurred partly 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 proposed revisions. 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. An 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.

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 proposed revisions to the OSHA standard were estimated to be 2 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 $42 million for management familiarization and other related management activities in response to GHS.[15]

OSHA requests additional comments and information from affected establishments and from the public regarding the nature of the incremental management familiarization costs associated with the proposed revisions.

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 proposed 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 standard. In these establishments, the incremental employee training costs associated with the proposed revisions to the OSHA standard 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 order to adequately reflect the opportunity costs of devoting time and resources to the necessary training, and in order to ensure that the estimated compliance costs reflect an adequate emphasis on the familiarization with the proposed new hazard communication system, a more substantial training cost was estimated.

An estimated 30 minutes of training, in addition to training that would otherwise be received, would provide adequate time for employees to become familiar with the new system. For some occupations for which the use of hazardous chemicals is minimal and the number of hazards for which training is needed is small, OSHA estimated that 15 minutes of training would be sufficient. For some occupations in the transportation sector, where GHS pictograms are already in use, OSHA estimated that only 5 minutes of training would be needed. A complete occupation-by-occupation review of OSHA's estimates is provided in the PP&E report.

[15] This annualized estimate of $42 million reflects total costs of $490 million multiplied by 0.085332 to annualize these costs (incurred over the first two years) over a 20-year period. The $490 million is equal to $5.9 million for health and safety managers (5,900 affected managers × $1000 per manager) plus $16.4 million for logistics personnel in manufacturing (43,600 affected logistics persons × 8 hours × $47 per hour) plus $116 million for health and safety supervisors in manufacturing (309,000 affected health and safety supervisors in manufacturing × 8 hours × $47 per hour) plus $351.7 million for health and safety supervisors in non-manufacturing (3,740,000 affected H&S supervisors in non-manufacturing × 2 hours × $47 per hour).

The annualization factor, 0.085332, is equal to:

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

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.

The training costs associated with the proposed revisions are expected to be incurred during the transition to the new hazard communication system. Compliance with the proposed revisions is not expected to involve any additional training costs after the transition period.

Based on the preceding analysis, OSHA estimates that the annualized cost of training employees in response to GHS would be approximately $44 million.[16]

The proposed revisions 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 associated with the proposed revisions.

[16] This annualized estimate of $44 million reflects total costs of $519 million multiplied by 0.085332 to annualize these costs (incurred over the first two years) over a 20-year period. The $519 million is equal to $444 million in employee hours to receive training (40.6 million affected employees × 0.42 hours × $26 per hour) plus $75 million in management hours to provide the training (3.8 million managers × 0.42 hours × $47 per hour). The 0.42 hours is the average estimated training time for all affected employees, with most receiving 30 minutes of training, some receiving 15 minutes of training, and a very few receiving 5 minutes of training. The total number of managers providing training (3.8 million) would, on average, be equal to approximately 9.4 percent of the number of employees receiving training in response to GHS.

OSHA requests additional comments and information from affected establishments and from the public regarding the nature of the incremental training costs associated with the proposed revisions.

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 proposed revisions to the standard. Except for employee training, these costs would apply only to those businesses not already in compliance with the proposed revisions. OSHA requests comments and information from the public regarding these estimates.

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 $200 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 $200 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:

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

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

Table VII–4 shows the total non-annualized (non-discounted) compliance costs by industry and by cost element that are estimated to be incurred during the three-year phase-in of the proposed revisions. Except for employee training, these estimates include no costs for businesses already in compliance with the proposed revisions.

As shown in Table VII–4, the total cost of compliance with the proposed rulemaking over the course of the transition period of three years is estimated to be about $1.14 billion. This amount also represents the total non-annualized cost of compliance for the proposed rule. Of this amount, the cost of chemical hazard reclassification and revision of SDSs and labels is an estimated $132 million, the cost of training employees is an estimated $519 million, and the cost of management familiarization and other costs such as updates to hazard communication programs is an estimated $490 million.

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Table VII-4
Total Costs of Compliance During Transition Period

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Cost of Training Employees	Management Familiarization and Other Costs	Total Costs During Transition Period
11	**Agriculture, Forestry, Fishing & Hunting**				
113	Forestry & Logging	$0	$347,222	$780,576	$1,127,798
114	Fishing, Hunting and Trapping	$0	$36,903	$70,406	$107,309
115	Support Activities for Ag & Forestry	$0	$173,376	$348,458	$521,834
211	**Oil and Gas Extraction**				
211111	Crude petroleum & natural gas extraction	$13,683,017	$859,919	$2,536,288	$17,079,223
211112	Natural gas liquid extraction	$1,057,112	$157,096	$79,037	$1,293,245
212	Mining (except Oil & Gas)	$0	$1,172,200	$677,270	$1,849,470
213	Support Activities for Mining	$0	$771,214	$801,726	$1,572,940
22	**Utilities**				
2211	Electric Power Gen, Trans & Distrib	$0	$4,039,642	$4,392,355	$8,431,997
2212	Natural Gas Distribution	$0	$610,180	$1,239,756	$1,849,936
2213	Water, Sewage, & Other Systems	$0	$487,243	$2,318,357	$2,805,600
23	**Construction**				
236	Construction of Buildings	$0	$14,127,779	$21,281,036	$35,408,815
237	Heavy Construction	$0	$5,431,571	$3,755,206	$9,186,777
238	Special Trade Contractors	$0	$31,405,551	$41,734,308	$73,139,859
31	**Manufacturing**				
311	Food Manufacturing	$0	$17,525,112	$9,262,352	$26,787,464
312	Beverage &Tobacco Prod. Manuf.	$0	$1,510,378	$1,118,186	$2,628,564
313	Textile Mills	$0	$3,439,290	$1,481,366	$4,920,656
314	Textile Product Mills	$0	$2,465,977	$2,751,043	$5,217,020
315	Apparel Manufacturing	$0	$4,419,364	$5,127,616	$9,546,981
316	Leather & Allied Product Manufac.	$0	$601,109	$586,348	$1,187,457

Table VII-4
Total Costs of Compliance During Transition Period
(Continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Cost of Training Employees	Management Familiarization and Other Costs	Total Costs During Transition Period
321	Wood Product Manufacturing	$0	$6,820,265	$6,334,612	$13,154,877
322	Paper Manufacturing	$0	$5,939,770	$1,820,658	$7,760,428
323	Printing and Related Support	$0	$8,421,055	$13,850,754	$22,271,809
324	**Petroleum & Coal Prod. Manufac.**				
324110	Petroleum refineries	$3,365,616	$582,441	$101,363	$4,049,420
324121	Asphalt paving mixture & block mfg	$13,616,926	$161,706	$364,760	$14,143,392
324122	Asphalt shingle & coating materials mfg	$2,326,520	$150,427	$72,138	$2,549,086
324191	Petroleum lubricating oil & grease mfg	$2,506,180	$82,290	$126,265	$2,714,736
324199	All other petroleum & coal products mfg	$699,030	$33,783	$28,594	$761,407
325	**Chemical Manufacturing**				
325110	Petrochemical mfg	$569,248	$79,327	$18,692	$667,267
325120	Industrial gas mfg	$454,353	$68,254	$116,764	$639,371
325131	Inorganic dye & pigment mfg	$106,009	$82,972	$32,052	$221,033
325132	Synthetic organic dye & pigment mfg	$475,748	$61,046	$49,177	$585,971
325181	Alkalies & chlorine mfg	$45,443	$48,701	$13,649	$107,792
325182	Carbon black mfg	$27,884	$17,764	$7,389	$53,036
325188	All other basic inorganic chemical mfg	$2,134,353	$472,526	$208,694	$2,815,573
325191	Gum & wood chemical mfg	$376,919	$20,781	$21,622	$419,322
325192	Cyclic crude & intermediate mfg	$71,062	$45,842	$13,389	$130,293
325193	Ethyl alcohol mfg	$161,482	$20,459	$31,742	$213,684
325199	All other basic organic chemical mfg	$3,146,780	$649,182	$226,223	$4,022,185
325211	Plastics material & resin mfg	$8,567,325	$589,753	$251,756	$9,408,833

Table VII-4
Total Costs of Compliance During Transition Period
(Continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Cost of Training Employees	Management Familiarization and Other Costs	Total Costs During Transition Period
325212	Synthetic rubber mfg	$248,758	$120,218	$65,183	$434,159
325221	Cellulosic organic fiber mfg	$6,539	$28,466	$8,609	$43,614
325222	Noncellulosic organic fiber mfg	$0	$292,312	$52,378	$344,690
325311	Nitrogenous fertilizer mfg	$46,499	$49,312	$60,735	$156,546
325312	Phosphatic fertilizer mfg	$12,665	$73,158	$16,396	$102,218
325314	Fertilizer (mixing only) mfg	$754,884	$92,632	$235,101	$1,082,617
325320	Pesticide & other agricultural chemical mfg	$846,416	$120,601	$94,001	$1,061,017
325411	Medicinal & botanical mfg	$738,431	$158,550	$150,991	$1,047,972
325412	Pharmaceutical preparation mfg	$1,960,544	$967,694	$367,473	$3,295,710
325413	In-vitro diagnostic substance mfg	$2,736,993	$241,055	$84,047	$3,062,095
325414	Biological product (except diagnostic) mfg	$468,550	$213,109	$124,982	$806,640
325510	Paint & coating mfg	$11,795,224	$322,408	$598,611	$12,716,243
325520	Adhesive mfg	$3,902,405	$207,199	$259,456	$4,369,060
325611	Soap & other detergent mfg	$2,658,060	$252,917	$342,952	$3,253,929
325612	Polish & other sanitation good mfg	$2,168,139	$180,504	$303,476	$2,652,119
325613	Surface active agent mfg	$875,171	$51,511	$72,202	$998,884
325620	Toilet preparation mfg	$2,870,202	$568,419	$366,471	$3,805,093
325910	Printing ink mfg	$6,569,964	$96,486	$194,126	$6,860,576
325920	Explosives mfg	$303,322	$74,459	$33,264	$411,045
325991	Custom compounding of purchased resin	$876,749	$225,811	$284,282	$1,386,842
325992	Photographic film, paper, plate, & chemical mfg	$596,584	$293,452	$167,487	$1,057,522
325998	Miscellaneous chemical product & preparation mfg	$7,395,067	$325,592	$516,165	$8,236,824

Table VII-4
Total Costs of Compliance During Transition Period
(Continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Cost of Training Employees	Management Familiarization and Other Costs	Total Costs During Transition Period
326	Plastics and Rubber Products Man.	$7,847,631	$11,160,366	$5,434,099	$24,442,096
327	Nonmetallic Mineral Prod. Manufac.	$8,065,150	$5,943,265	$5,422,776	$19,431,191
331	Primary Metal Manufacturing	$3,081,580	$6,103,687	$2,311,505	$11,496,772
332	Fabricated Metal Prod. Manufac.	$0	$18,736,880	$23,237,842	$41,974,721
333	Machinery Manufacturing	$0	$11,374,364	$10,316,997	$21,691,362
334	Computer & Electronic Prod Man.	$0	$9,033,957	$5,852,080	$14,886,037
335	Electric Equipment, Appliance Man.	$0	$5,661,876	$2,378,439	$8,040,316
336	Transportation Equip. Manufacturing	$0	$17,455,530	$4,922,170	$22,377,699
337	Furniture & Related Product Man.	$0	$7,241,389	$8,428,727	$15,670,116
339	Miscellaneous Manufacturing	$11,733,200	$6,873,929	$11,073,665	$29,680,793
42	**Wholesale Trade**				
423	Durable Goods	$0	$7,874,856	$15,487,346	$23,362,202
424	Nondurable Goods	$0	$5,655,530	$8,977,094	$14,632,624
44-45	**Retail Trade**				
441	Motor vehicle & parts dealers	$0	$7,527,359	$10,893,190	$18,420,549
442	Furniture & home furnishings stores	$0	$1,189,255	$2,999,352	$4,188,607
443	Electronics & appliance stores	$0	$409,951	$1,055,808	$1,465,759
444	Building material & garden equipment & dealers	$0	$2,242,308	$4,959,628	$7,201,936
445	Food & beverage stores	$0	$3,364,428	$6,317,082	$9,681,510
446	Health & personal care stores	$0	$6,627,927	$7,761,956	$14,389,883
447	Gasoline stations	$0	$1,851,542	$4,768,338	$6,619,880
448	Clothing & clothing accessories stores	$0	$346,898	$893,376	$1,240,274

Table VII-4
Total Costs of Compliance During Transition Period
(Continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Cost of Training Employees	Management Familiarization and Other Costs	Total Costs During Transition Period
451	Sporting goods, hobby, book, & music stores	$0	$476,725	$1,227,734	$1,704,459
452	General merchandise stores	$0	$1,954,062	$3,818,468	$5,772,530
453	Miscellaneous store retailers	$0	$939,338	$2,419,090	$3,358,428
454	Nonstore retailers	$0	$1,013,374	$1,957,174	$2,970,548
48-49	**Transportation & Warehousing**				
481	Air transportation	$0	$688,140	$366,506	$1,054,646
483	Water transportation	$0	$256,646	$172,584	$429,230
484	Truck transportation	$0	$5,219,830	$7,187,616	$12,407,446
485	Transit & ground passenger transportation	$0	$491,768	$769,954	$1,261,722
486	Pipeline transportation	$0	$175,564	$250,980	$426,544
487	Scenic & sightseeing transportation	$0	$54,398	$95,786	$150,184
488	Support activities for transportation	$0	$1,653,084	$2,468,722	$4,121,806
492	Couriers & messengers	$0	$1,290,104	$855,682	$2,145,786
493	Warehousing & storage	$0	$812,481	$717,126	$1,529,607
51	**Information**				
511	Publishing industries	$0	$641,493	$1,192,108	$1,833,601
512	Motion picture & sound recording industries	$0	$142,127	$366,036	$508,163
513	Broadcasting & telecommunications	$0	$1,340,066	$3,451,116	$4,791,182
514	Information services & data processing services	$0	$236,421	$608,838	$845,259
52	**Finance & Insurance**				
521	Monetary authorities - central bank	$0	$0	$0	$0
522	Credit intermediation & related activities	$0	$220,676	$568,324	$789,000

Table VII-4
Total Costs of Compliance During Transition Period
(Continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Cost of Training Employees	Management Familiarization and Other Costs	Total Costs During Transition Period
523	Securities intermediation & related activities	$0	$81,644	$210,278	$291,922
524	Insurance carriers & related activities	$0	$1,553,569	$4,001,016	$5,554,585
525	Funds, trusts, & other financial vehicles	$0	$27,225	$70,124	$97,349
53	**Real Estate & Rental and Leasing**				
531	Real estate	$0	$4,615,543	$10,154,632	$14,770,175
532	Rental & leasing services	$0	$2,011,076	$4,464,060	$6,475,136
533	Lessors of intangibles, except copyrighted works	$0	$24,196	$60,818	$85,014
54	**Professional, Scientific, & Technical**				
5411	Legal services	$0	$51,540	$132,728	$184,268
5412	Accounting, tax, bookkeeping, & payroll services	$0	$522,866	$1,346,550	$1,869,416
5413	Architectural, engineering, & related services	$0	$980,735	$2,419,278	$3,400,013
5414	Specialized design services	$0	$249,943	$583,552	$833,495
5415	Computer systems design & related services	$0	$185,869	$478,648	$664,517
5416	Management, scientific, & tech consulting services	$0	$829,815	$1,862,516	$2,692,331
5417	Scientific R&D Serv.	$0	$396,555	$610,154	$1,006,709
5418	Advertising & related services	$0	$484,796	$1,044,152	$1,528,948
5419	Other professional, scientific, & technical services	$0	$4,286.510	$6,796,482	$11,082,992
55	**Management of Companies**				
551111	Offices of bank holding companies	$0	$50,226	$95,974	$146,200
551112	Offices of other holding companies	$0	$264,405	$496,884	$761,289
551114	Corporate, subsidiary, & regional managing offices	$0	$2,619,232	$3,248,452	$5,867.684

Table VII-4
Total Costs of Compliance During Transition Period
(Continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Cost of Training Employees	Management Familiarization and Other Costs	Total Costs During Transition Period
56	**Adm and Support & Waste Management**				
561	Administrative and Support Serv.	$0	$32,331,965	$25,922,756	$58,254,721
562	Waste management & Remediation Serv.	$0	$1,696,637	$1,663,612	$3,360,249
61	**Educational Services**				
6111	Elementary & secondary schools	$0	$923,342	$1,503,906	$2,427,248
6112	Junior colleges	$0	$51,746	$67,022	$118,768
6113	Colleges, universities, & profesional schools	$0	$1,785,754	$259,722	$2,045,476
6114	Business schools, & computer & mgmt training	$0	$10,398	$26,790	$37,188
6115	Technical & trade schools	$0	$72,860	$182,172	$255,032
6116	Other schools & instruction	$0	$78,773	$202,852	$281,625
6117	Educational support services	$0	$36,461	$93,906	$130,367
62	**Healthcare and Social Assistance**				
621	Ambulatory health care services	$0	$51,986,365	$45,848,218	$97,834,583
622	Hospitals	$0	$53,071,728	$711,486	$53,783,214
623	Nursing & residential care facilities	$0	$26,224,786	$6,382,600	$32,607,386
624	Social assistance	$0	$5,190,700	$9,590,632	$14,781,332
71	**Arts, Entertainment & Recreation**				
711	Performing arts, spectator sports, etc.	$0	$474,519	$758,956	$1,233,475
712	Museums, historical sites, & similar institutions	$0	$136,290	$237,820	$374,110
713	Amusement, gambling, & recreation industries	$0	$2,303,600	$3,334,838	$5,638,438

Table VII-4
Total Costs of Compliance During Transition Period
(Continued)

NAICS Code	Industry	Cost of Reclassification and Revision of SDSs and Labels	Cost of Training Employees	Management Familiarization and Other Costs	Total Costs During Transition Period
72	**Accommodation & Food Services**				
721	Accommodation	$0	$5,899,440	$5,428,876	$11,328,316
722	Food services & drinking places	$0	$1,554,247	$4,002,708	$5,556,955
81	**Other Services (except Public Adm.)**				
811	Repair & maintenance	$0	$12,882,110	$21,919,766	$34,801,876
812	Personal & laundry services	$0	$5,893,890	$12,969,932	$18,863,822
813	Religious/grantmaking/civic/professional	$0	$3,342,423	$7,711,008	$11,053,431
99	**State and Local Government** (about half covered by OSHA standards)				
9992	State Government	$0	$3,455,206	$1,198,500	$4,653,706
9993	Local Government	$0	$17,432,651	$1,001,570	$18,434,221
	Total	**$131,949,731**	**$519,238,565**	**$489,511,630**	**$1,140,699,926**

Note: Costs are expressed in 2007 dollars
Source: Office of Regulatory Analysis, OSHA, based on PP&E (2008)

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G. Economic Feasibility and Impacts

This section presents OSHA's analysis of the potential economic impacts of the proposal 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 Initial Regulatory Flexibility Screening Analysis, conducted in accordance with the criteria laid out in the Regulatory Flexibility Act.

In order to assess the nature and magnitude of the economic impacts associated with compliance with the proposal, 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 F of this economic analysis were compared with industry revenues and profits to provide a measure of potential economic impacts.

Table VII–5 presents data on revenues and profits for each affected industry sector, 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 VII–5, the costs of compliance for the proposal are not large in relation to the corresponding revenues and profits in each of the industry sectors. The estimated costs of compliance represent about 0.0004 percent of revenues and about 0.00712 percent of profits on average across all entities; compliance costs do not represent more than 0.02 percent of revenues or more than 0.3 percent of profits in any individual industry sector.

The Agency preliminarily concludes that the proposal 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 (D.C. Cir. 1980)). The potential impacts of employer costs associated with achieving compliance with the proposal fall well within the bounds of economic feasibility in each industry sector. OSHA does not expect compliance with the requirements of the proposal to threaten the viability of employers or the competitive structure of any of the affected industry sectors.

The economic impact of the proposal is most likely to consist of a very small increase in prices for affected hazardous chemicals, of about 0.0004 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 change to revised SDS and labeling criteria 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 proposal can be substantially recouped with a minimal increase in prices, there would be little or no effect on profits.

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Table VII-5
Potential Economic Impacts

NAICS Code	Industry	Total Annualized Costs	Revenues (Thousands of Dollars)	Profits (Thousands of Dollars)	Costs as a Percent of Revenues	Costs as a Percent of Profits
11	**Agriculture, Forestry, Fishing & Hunting**					
113	Forestry & Logging	$96,237	$11,235,337	$358,643	0.0009%	0.0268%
114	Fishing, Hunting and Trapping	$9,157	$1,974,301	$66,735	0.0005%	0.0137%
115	Support Activities for Ag & Forestry	$44,529	$12,663,500	$427,536	0.0004%	0.0104%
211	**Oil and Gas Extraction**					
211111	Crude petroleum & natural gas extraction	$1,419,643	$111,285,360	$11,799,999	0.0013%	0.0120%
211112	Natural gas liquid extraction	$107,438	$72,490,930	$6,532,998	0.0001%	0.0016%
212	Mining (except Oil & Gas)	$157,819	$47,733,102	$4,295,979	0.0003%	0.0037%
213	Support Activities for Mining	$134,222	$28,960,730	$1,448,037	0.0005%	0.0093%
22	**Utilities**					
2211	Electric Power Gen, Trans & Distrib	$719,520	$320,502,670	$9,615,080	0.0002%	0.0075%
2212	Natural Gas Distribution	$157,859	$67,275,310	$2,018,259	0.0002%	0.0078%
2213	Water, Sewage, & Other Systems	$239,408	$8,298,663	$414,933	0.0029%	0.0577%
23	**Construction**					
236	Construction of Buildings	$3,021,507	$534,991,934	$26,749,597	0.0006%	0.0113%
237	Heavy Construction	$783,927	$174,384,008	$6,975,360	0.0004%	0.0112%
238	Special Trade Contractors	$6,241,175	$468,167,745	$19,361,840	0.0013%	0.0322%
31	**Manufacturing**					
311	Food Manufacturing	$2,285,830	$457,521,297	$17,362,093	0.0005%	0.0132%
312	Beverage &Tobacco Prod. Manuf.	$224,301	$107,946,351	$10,623,677	0.0002%	0.0021%
313	Textile Mills	$419,890	$43,236,210	$6,080,437	0.0010%	0.0069%
314	Textile Product Mills	$445,179	$35,012,642	$4,478,866	0.0013%	0.0099%
315	Apparel Manufacturing	$814,664	$48,399,376	$3,201,298	0.0017%	0.0254%
316	Leather & Allied Product Manufac.	$101,328	$7,106,166	$408,472	0.0014%	0.0248%
321	Wood Product Manufacturing	$1,122,533	$88,649,041	$1,973,491	0.0013%	0.0569%

Table VII-5
Potential Economic Impacts
(Continued)

NAICS Code	Industry	Total Annualized Costs	Revenues (Thousands of Dollars)	Profits (Thousands of Dollars)	Costs as a Percent of Revenues	Costs as a Percent of Profits
322	Paper Manufacturing	$662,213	$154,746,086	$5,668,851	0.0004%	0.0117%
323	Printing and Related Support	$1,900,499	$93,105,255	$3,903,103	0.0020%	0.0487%
324	**Petroleum & Coal Prod. Manufac.**					
324110	Petroleum refineries	$336,257	$425,334,802	$29,170,039	0.0001%	0.0012%
324121	Asphalt paving mixture & block mfg	$1,169,305	$7,327,950	$391,283	0.0160%	0.2988%
324122	Asphalt shingle & coating materials mfg	$211,098	$6,483,151	$406,967	0.0033%	0.0519%
324191	Petroleum lubricating oil & grease mfg	$224,737	$5,659,274	$325,292	0.0040%	0.0691%
324199	All other petroleum & coal products mfg	$63,043	$1,402,010	$69,589	0.0045%	0.0906%
325	**Chemical Manufacturing**					
325110	Petrochemical mfg	$55,368	$20,967,769	$2,083,973	0.0003%	0.0027%
325120	Industrial gas mfg	$53,305	$5,780,466	$563,862	0.0009%	0.0095%
325131	Inorganic dye & pigment mfg	$18,569	$3,642,670	$347,775	0.0005%	0.0053%
325132	Synthetic organic dye & pigment mfg	$48,689	$2,419,490	$223,487	0.0020%	0.0218%
325181	Alkalies & chlorine mfg	$9,073	$2,070,537	$196,164	0.0004%	0.0046%
325182	Carbon black mfg	$4,449	$1,015,512	$80,980	0.0004%	0.0055%
325188	All other basic inorganic chemical mfg	$234,368	$16,313,991	$1,555,895	0.0014%	0.0151%
325191	Gum & wood chemical mfg	$34,741	$1,003,423	$94,642	0.0035%	0.0367%
325192	Cyclic crude & intermediate mfg	$10,922	$4,833,694	$479,191	0.0002%	0.0023%
325193	Ethyl alcohol mfg	$17,788	$2,096,502	$166,960	0.0008%	0.0107%
325199	All other basic organic chemical mfg	$334,537	$46,874,101	$4,574,667	0.0007%	0.0073%
325211	Plastics material & resin mfg	$779,231	$48,215,976	$4,656,112	0.0016%	0.0167%
325212	Synthetic rubber mfg	$36,361	$5,637,687	$536,196	0.0006%	0.0068%
325221	Cellulosic organic fiber mfg	$3,704	$637,425	$50,323	0.0006%	0.0074%

Table VII-5
Potential Economic Impacts
(Continued)

NAICS Code	Industry	Total Annualized Costs	Revenues (Thousands of Dollars)	Profits (Thousands of Dollars)	Costs as a Percent of Revenues	Costs as a Percent of Profits
325222	Noncellulosic organic fiber mfg	$29,413	$8,839,294	$714,349	0.0003%	0.0041%
325311	Nitrogenous fertilizer mfg	$13,230	$3,335,111	$317,948	0.0004%	0.0042%
325312	Phosphatic fertilizer mfg	$8,688	$3,997,496	$395,032	0.0002%	0.0022%
325314	Fertilizer (mixing only) mfg	$90,299	$3,070,891	$257,313	0.0029%	0.0351%
325320	Pesticide & other agricultural chemical mfg	$88,203	$10,402,745	$995,673	0.0008%	0.0089%
325411	Medicinal & botanical mfg	$87,388	$12,650,827	$1,976,697	0.0007%	0.0044%
325412	Pharmaceutical preparation mfg	$275,819	$104,772,298	$10,248,434	0.0003%	0.0027%
325413	In-vitro diagnostic substance mfg	$253,741	$13,942,412	$1,367,932	0.0018%	0.0185%
325414	Biological product (except diagnostic) mfg	$67,539	$11,958,433	$1,161,619	0.0006%	0.0058%
325510	Paint & coating mfg	$1,052,551	$20,395,969	$1,891,272	0.0052%	0.0557%
325520	Adhesive mfg	$362,051	$7,361,310	$660,739	0.0049%	0.0548%
325611	Soap & other detergent mfg	$270,329	$17,928,741	$1,644,627	0.0015%	0.0164%
325612	Polish & other sanitation good mfg	$220,327	$10,054,392	$935,831	0.0022%	0.0235%
325613	Surface active agent mfg	$82,822	$5,731,687	$542,155	0.0014%	0.0153%
325620	Toilet preparation mfg	$316,775	$31,679,852	$3,039,016	0.0010%	0.0104%
325910	Printing ink mfg	$567,295	$4,174,624	$373,220	0.0136%	0.1520%
325920	Explosives mfg	$34,238	$1,111,244	$103,754	0.0031%	0.0330%
325991	Custom compounding of purchased resin	$115,922	$7,431,222	$660,560	0.0016%	0.0175%
325992	Photographic film, paper, plate, & chemical mfg	$88,594	$14,261,839	$1,396,003	0.0006%	0.0063%
325998	Miscellaneous chemical product & preparation mfg	$682,456	$13,601,631	$1,213,892	0.0050%	0.0562%
326	Plastics and Rubber Products Man.	$2,064,037	$169,377,747	$8,036,289	0.0012%	0.0257%
327	Nonmetallic Mineral Prod. Manufac.	$1,635,846	$95,442,761	$3,597,010	0.0017%	0.0455%
331	Primary Metal Manufacturing	$972,539	$139,461,013	$5,449,204	0.0007%	0.0178%

Table VII-5
Potential Economic Impacts
(Continued)

NAICS Code	Industry	Total Annualized Costs	Revenues (Thousands of Dollars)	Profits (Thousands of Dollars)	Costs as a Percent of Revenues	Costs as a Percent of Profits
332	Fabricated Metal Prod. Manufac.	$3,581,790	$248,973,057	$14,000,518	0.0014%	0.0256%
333	Machinery Manufacturing	$1,850,969	$251,308,533	$9,581,635	0.0007%	0.0193%
334	Computer & Electronic Prod Man.	$1,270,256	$379,931,227	$17,984,765	0.0003%	0.0071%
335	Electric Equipment, Appliance Man.	$686,097	$181,805,371	$8,353,902	0.0004%	0.0082%
336	Transportation Equip. Manufacturing	$1,909,535	$1,021,093,021	$22,567,653	0.0002%	0.0085%
337	Furniture & Related Product Man.	$1,337,163	$73,497,087	$2,939,883	0.0018%	0.0455%
339	Miscellaneous Manufacturing	$2,500,342	$118,090,424	$4,723,617	0.0021%	0.0529%
42	**Wholesale Trade**					
423	Durable Goods	$1,993,545	$2,332,184,855	$67,395,831	0.0001%	0.0030%
424	Nondurable Goods	$1,248,632	$2,157,881,220	$74,888,255	0.0001%	0.0017%
44-45	**Retail Trade**					
441	Motor vehicle & parts dealers	$1,571,863	$813,208,907	$16,264,178	0.0002%	0.0097%
442	Furniture & home furnishings stores	$357,422	$97,073,126	$3,230,582	0.0004%	0.0111%
443	Electronics & appliance stores	$125,076	$92,280,756	$3,315,716	0.0001%	0.0038%
444	Building material & garden equipment & dealers	$614,556	$288,435,295	$12,675,063	0.0002%	0.0048%
445	Food & beverage stores	$826,143	$464,412,506	$9,288,250	0.0002%	0.0089%
446	Health & personal care stores	$1,227,918	$186,448,806	$6,821,530	0.0007%	0.0180%
447	Gasoline stations	$564,888	$238,083,074	$8,151,176	0.0002%	0.0069%
448	Clothing & clothing accessories stores	$105,835	$170,396,483	$8,096,545	0.0001%	0.0013%
451	Sporting goods, hobby, book, & music stores	$145,445	$76,687,429	$2,300,623	0.0002%	0.0063%
452	General merchandise stores	$492,582	$444,604,851	$17,784,194	0.0001%	0.0028%
453	Miscellaneous store retailers	$286,582	$97,907,211	$3,291,039	0.0003%	0.0087%
454	Nonstore retailers	$253,483	$164,914,253	$6,166,255	0.0002%	0.0041%

Table VII-5
Potential Economic Impacts
(Continued)

NAICS Code	Industry	Total Annualized Costs	Revenues (Thousands of Dollars)	Profits (Thousands of Dollars)	Costs as a Percent of Revenues	Costs as a Percent of Profits
48-49	**Transportation & Warehousing**					
481	Air transportation	$89,995	$107,699,651	$3,230,990	0.0001%	0.0028%
483	Water transportation	$36,627	$22,088,696	$1,104,435	0.0002%	0.0033%
484	Truck transportation	$1,058,753	$166,722,008	$4,260,349	0.0006%	0.0249%
485	Transit & ground passenger transportation	$107,665	$19,127,060	$496,892	0.0006%	0.0217%
486	Pipeline transportation	$36,398	$45,053,289	$7,520,512	0.0001%	0.0005%
487	Scenic & sightseeing transportation	$12,816	$1,762,260	$40,596	0.0007%	0.0316%
488	Support activities for transportation	$351,722	$60,079,175	$1,559,971	0.0006%	0.0225%
492	Couriers & messengers	$183,104	$58,881,643	$1,718,986	0.0003%	0.0107%
493	Warehousing & storage	$130,525	$17,808,341	$712,334	0.0007%	0.0183%
51	**Information**					
511	Publishing industries	$270,135	$52,072,418	$3,359,109	0.0005%	0.0080%
512	Motion picture & sound recording industries	$43,363	$73,280,977	$4,396,859	0.0001%	0.0010%
513	Broadcasting & telecommunications	$408,841	$477,413,344	$33,159,425	0.0001%	0.0012%
514	Information services & data processing services	$72,128	$90,910,435	$5,454,626	0.0001%	0.0013%
52	**Finance & Insurance**					
521	Monetary authorities - central bank	$767	$0	$0		
522	Credit intermediation & related activities	$67,327	$1,030,210,082	$141,175,129	0.0000%	0.0000%
523	Securities intermediation & related activities	$24,910	$367,487,329	$49,778,608	0.0000%	0.0001%
524	Insurance carriers & related activities	$473,984	$1,312,063,818	$77,867,525	0.0000%	0.0006%
525	Funds, trusts, & other financial vehicles	$8,307	$23,281,761	$10,012,080	0.0000%	0.0001%

Table VII-5
Potential Economic Impacts
(Continued)

Industry	Total Annualized Costs	Revenues (Thousands of Dollars)	Profits (Thousands of Dollars)	Costs as a Percent of Revenues	Costs as a Percent of Profits
Real Estate & Rental and Leasing					
Real estate	$1,260,369	$236,657,346	$28,134,720	0.0005%	0.0045%
Rental & leasing services	$552,537	$98,997,720	$4,219,658	0.0006%	0.0131%
Lessors of intangibles, except copyrighted works	$7,254	$14,894,889	$2,645,765	0.0000%	0.0003%
Professional, Scientific, & Technical					
Legal services	$15,724	$182,828,620	$16,701,874	0.0000%	0.0001%
Accounting, tax, bookkeeping, & payroll services	$159,521	$86,243,925	$8,796,205	0.0002%	0.0018%
Architectural, engineering, & related services	$290,130	$166,219,410	$7,393,783	0.0002%	0.0039%
Specialized design services	$71,124	$19,598,570	$1,175,914	0.0004%	0.0060%
Computer systems design & related services	$56,705	$181,779,719	$9,611,552	0.0000%	0.0006%
Management, scientific, & tech consulting services	$229,742	$130,823,753	$9,762,623	0.0002%	0.0024%
Scientific R&D Serv.	$85,905	$62,482,362	$5,314,515	0.0001%	0.0016%
Advertising & related services	$130,468	$60,400,991	$3,318,277	0.0002%	0.0039%
Other professional, scientific, & technical services	$945,735	$53,688,288	$3,039,380	0.0018%	0.0311%
Management of Companies					
Offices of bank holding companies	$12,476	$11,380,300	$1,945,123	0.0001%	0.0006%
Offices of other holding companies	$64,962	$87,606,642	$56,387,562	0.0001%	0.0001%
Corporate, subsidiary, & regional managing offices	$500,702	$213,897,581	$140,770,910	0.0002%	0.0004%
Adm and Support & Waste Management					
Administrative and Support Serv.	$4,970,996	$409,237,061	$18,551,991	0.0012%	0.0268%
Waste management & Remediation Serv.	$286,737	$48,203,744	$2,216,582	0.0006%	0.0129%

Table VII-5
Potential Economic Impacts
(Continued)

NAICS Code	Industry	Total Annualized Costs	Revenues (Thousands of Dollars)	Profits (Thousands of Dollars)	Costs as a Percent of Revenues	Costs as a Percent of Profits
61	**Educational Services**					
6111	Elementary & secondary schools	$207,122	$41,859,655	$2,939,909	0.0005%	0.0070%
6112	Junior colleges	$10,135	$3,759,090	$279,302	0.0003%	0.0036%
6113	Colleges, universities, & profesional schools	$174,545	$104,059,977	$8,207,275	0.0002%	0.0021%
6114	Business schools, & computer & mgmt training	$3,173	$6,649,972	$454,828	0.0000%	0.0007%
6115	Technical & trade schools	$21,762	$7,162,633	$502,237	0.0003%	0.0043%
6116	Other schools & instruction	$24,032	$10,723,900	$709,033	0.0002%	0.0034%
6117	Educational support services	$11,125	$6,063,612	$433,589	0.0002%	0.0026%
62	**Healthcare and Social Assistance**					
621	Ambulatory health care services	$8,348,427	$505,690,644	$21,414,681	0.0017%	0.0390%
622	Hospitals	$4,589,433	$499,145,896	$29,567,549	0.0009%	0.0155%
623	Nursing & residential care facilities	$2,782,456	$126,267,746	$6,664,367	0.0022%	0.0418%
624	Social assistance	$1,261,322	$90,179,715	$4,049,544	0.0014%	0.0311%
71	**Arts, Entertainment & Recreation**					
711	Performing arts, spectator sports, etc.	$105,255	$55,904,896	$2,477,481	0.0002%	0.0042%
712	Museums, historical sites, & similar institutions	$31,924	$8,655,007	$398,588	0.0004%	0.0080%
713	Amusement, gambling, & recreation industries	$481,140	$82,994,366	$4,024,972	0.0006%	0.0120%
72	**Accommodation & Food Services**					
721	Accommodation	$966,669	$122,505,607	$6,447,175	0.0008%	0.0150%
722	Food services & drinking places	$474,186	$324,210,635	$13,800,298	0.0001%	0.0034%

Table VII-5
Potential Economic Impacts
(Continued)

NAICS Code	Industry	Total Annualized Costs	Revenues (Thousands of Dollars)	Profits (Thousands of Dollars)	Costs as a Percent of Revenues	Costs as a Percent of Profits
81	**Other Services (except Public Adm.)**					
811	Repair & maintenance	$2,969,716	$130,610,519	$4,243,038	0.0023%	0.0700%
812	Personal & laundry services	$1,609,689	$75,128,325	$2,533,843	0.0021%	0.0635%
813	Religious/grantmaking/civic/professional	$943,212	$220,360,946	$5,068,659	0.0004%	0.0186%
99	**State and Local Government** (about half covered by OSHA standards)					
9992	State Government	$397,110	n.a.	n.a.		
9993	Local Government	$1,573,030	n.a.	n.a.		
	Total	**$97,088,564**	**$22,526,419,824**	**$1,336,589,692**	**0.0004%**	**0.0073%**

Note: Costs are expressed in 2007 dollars
Source: Office of Regulatory Analysis, OSHA, based on PP&E (2008)

In profit-earning entities, compliance costs can generally be expected to be absorbed through a combination of increases in prices or reduction in

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profits. The extent to which the impacts of cost increases affect prices or profits depends on the price elasticity of demand for the products or services produced and sold by the entity.

The price elasticity of demand refers to the relationship between changes in the price charged for a product and the resulting changes in the demand for that product. A greater degree of 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 proposal, 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 incremental increases in prices potentially resulting from compliance with the proposed standards 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 economic impact of the proposed rulemaking 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 proposal, OSHA expects that societal welfare will increase as a result of these standards, as the benefits exceed the necessary compliance costs. The proposal is estimated to yield net benefits of over $500 million annually that would be achieved in a cost-effective manner.

Second, until now, many of the costs associated with the injuries, illnesses, and fatalities resulting from the risks addressed by the proposal 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 preliminarily concludes that the effects of the proposal on employment, wages, and economic growth for the United States would be negligible. The effects on international trade are expected to be small but not negligible, because of the increased import and export opportunities with U.S. trading partners arising from harmonization of the U.S. system with GHS. Hence, the primary effect on international trade is likely to be beneficial.

OSHA requests comments from the public regarding these preliminary conclusions and requests information on whether and how much this proposal would affect international trade.

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 proposed 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.

H. Initial Regulatory Flexibility Screening Analysis

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

1. A description of the impact of the proposed rule on small entities;

2. A description of the reasons why action by the agency is being considered;

3. A succinct statement of the objectives of, and legal basis for, the proposed rule;

4. A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;

5. A description of the projected reporting, recordkeeping and other compliance requirements of the proposed 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;

6. An identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule; and

7. A description and discussion of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities, such as

(a) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;

(b) The clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;

(c) The use of performance rather than design standards; and

(d) An exemption from coverage of the rule, or any part thereof, for such small entities.

The Regulatory Flexibility Act further states that the required elements of the IRFA 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.

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 PEA and its supporting materials, this IRFA will summarize the key aspects of OSHA's analysis as they affect small businesses.

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

The proposed regulation would require 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 V of the preamble, the HCS

does not currently require testing of chemicals, and will not require testing with adoption of the GHS.)

For the purpose of its cost analysis, OSHA estimated three 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); and

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

OSHA believes that each of these is a one-time cost that would be incurred during the three-year transition period after the final rule is published. OSHA anticipates that, once the final rule is implemented, the costs under GHS will be equivalent to the costs under the existing HCS system. In other words, once chemical producers and distributors set up for and shift to the GHS system, OSHA expects there will be no additional costs arising from the proposed rule for classification, SDSs, and labeling.

OSHA also anticipates that, after the three-year transition period, the familiarization costs for health and safety managers, logistics personnel, and emergency response planners and the training costs for affected employees will be lower under the uniform GHS system than under the existing HCS system. (However, in its estimates of economic impacts, OSHA has not included any cost savings for the expected lower training costs.)

OSHA welcomes comments on these points, which are critical to OSHA's economic analysis of costs, benefits, and economic impacts.

OSHA's criteria for determining whether there are significant economic impacts on a substantial number of small firms are that, for any given industry, the annualized costs as a percentage of revenues do not exceed 1 percent and that the annualized costs as a percentage of profits do not exceed 5 percent. 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 with fewer than 20 employees, shows that in no industry size class do the annualized costs exceed 0.013 percent of revenues or 0.4 percent of profits. For affected small firms as defined by SBA, the average annualized cost per firm of the proposed rule would be $16 per year. In terms of chemical producing industries only, the average annualized cost per small firm as defined by SBA would be $452 per year. For affected firms with fewer than 20 employees, the average annualized cost per firm of the proposed rule would be $12 per year, and the average annualized cost per firm that produces chemicals would be $167 per year.

Given these results, OSHA concludes that the proposed rule will not have a significant economic impact on a substantial number of small firms. Thus, an IRFA 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 IRFA as part of this Initial Regulatory Flexibility Screening Analysis (IRFSA) and has analyzed the potential impact of the proposed revisions on small entities. As described in Section D of this economic analysis, the proposed revisions to HCS, on the whole, are expected to result in significant net benefits to employers, as the associated cost savings outweigh the corresponding compliance costs. The underlying analysis included the effects on small entities, and this conclusion generally applies to the small entities affected by the proposed 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 savings.

The total annualized cost of compliance with the proposal for small entities is estimated to be approximately $63 million, as shown by industry in Table VII–6.

To assess the potential economic impact of the proposal 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 VII–6. OSHA expects that among small entities potentially affected by the proposal, the average increase in prices necessary to completely offset the compliance costs would be 0.0009 percent. The average price increase necessary to completely offset compliance costs would not exceed 0.02 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 0.02 percent. In most affected industries the compliance costs could be completely absorbed through an average reduction in profits of less than 0.05 percent; the reduction would be no more than 0.4 percent in any of the affected industries.

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

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Table VII-6
Potential Economic Impacts on Small Entities

NAICS Code	Industry	Number of Small Entities	Number of Affected Small Entities	Total Annualized Costs for Small Entities	Revenues of Small Entities (Thousands of Dollars)	Profits of Small Entities (Thousands of Dollars)	Costs as a Percent of Revenues for Small Entities	Costs as a Percent of Profits for Small Entities
11	**Agriculture, Forestry, Fishing & Hunting**							
113	Forestry & Logging	12,240	12,240	$92,470	$9,207,817	$277,542	0.0010%	0.0333%
114	Fishing, Hunting and Trapping	2,324	1,042	$8,725	$1,089,599	$32,688	0.0008%	0.0267%
115	Support Activities for Ag & Forestry	10,984	4,840	$36,863	$8,388,285	$256,527	0.0004%	0.0144%
211	**Oil and Gas Extraction**							
211111	Crude petroleum & natural gas extraction	6,154	6,154	$1,271,520	$22,897,060	$2,952,894	0.0056%	0.0431%
211112	Natural gas liquid extraction	77	77	$25,184	$1,075,086	$105,572	0.0023%	0.0239%
212	Mining (except Oil & Gas)	4,484	4,484	$83,383	$14,679,509	$1,321,156	0.0006%	0.0063%
213	Support Activities for Mining	7,354	7,354	$89,376	$7,715,878	$385,794	0.0012%	0.0232%
22	**Utilities**							
2211	Electric Power Gen, Trans & Distrib	736	736	$28,601	$4,758,181	$142,745	0.0006%	0.0200%
2212	Natural Gas Distribution	546	546	$29,258	$13,126,957	$393,809	0.0002%	0.0074%
2213	Water, Sewage, & Other Systems	5,207	5,207	$198,915	$3,068,594	$153,430	0.0065%	0.1296%
23	**Construction**							
236	Construction of Buildings	223,243	223,243	$2,815,174	$364,717,977	$18,235,899	0.0008%	0.0154%
237	Heavy Construction	38,077	38,077	$626,136	$110,852,266	$4,434,091	0.0006%	0.0141%
238	Special Trade Contractors	436,598	436,598	$5,813,278	$368,872,523	$14,754,901	0.0016%	0.0394%
31	**Manufacturing**							
311	Food Manufacturing	20,833	20,833	$1,182,157	$103,598,547	$3,205,183	0.0011%	0.0369%
312	Beverage &Tobacco Prod. Manuf.	2,624	2,624	$124,409	$12,687,241	$1,097,766	0.0010%	0.0113%
313	Textile Mills	3,247	3,247	$219,961	$14,287,327	$1,448,616	0.0015%	0.0152%
314	Textile Product Mills	6,834	6,834	$342,832	$13,004,295	$957,531	0.0026%	0.0358%
315	Apparel Manufacturing	12,727	12,727	$704,117	$27,858,961	$1,558,065	0.0025%	0.0452%
316	Leather & Allied Product Manufac.	1,444	1,444	$78,406	$3.423,743	$187,526	0.0023%	0.0418%
321	Wood Product Manufacturing	14,958	14,958	$872,312	$46,891,917	$1,555,920	0.0019%	0 0561%
322	Paper Manufacturing	3,313	3,313	$269,102	$29,561,890	$661,483	0.0009%	0.0407%
323	Printing and Related Support	34,896	34,896	$1,649,985	$54,337,410	$2,352,389	0.0030%	0.0701%
324	**Petroleum & Coal Prod. Manufac.**							
324110	Petroleum refineries	182	182	$238,421	$118,692,945	$8,006,808	0.0002%	0.0030%
324121	Asphalt paving mixture & block mfg	446	446	$482,870	$3,477,972	$121,785	0.0139%	0 3965%

Table VII-6
Potential Economic Impacts on Small Entities
(Continued)

NAICS Code	Industry	Number of Small Entities	Number of Affected Small Entities	Total Annualized Costs for Small Entities	Revenues of Small Entities (Thousands of Dollars)	Profits of Small Entities (Thousands of Dollars)	Costs as a Percent of Revenues for Small Entities	Costs as a Percent of Profits for Small Entities
324122	Asphalt shingle & coating materials mfg	118	118	$135,988	$2,780,865	$147,807	0.0049%	0.0920%
324191	Petroleum lubricating oil & grease mfg	246	246	$155,005	$1,912,869	$63,044	0.0081%	0.2459%
324199	All other petroleum & coal products mfg	55	55	$41,817	$737,624	$23,082	0.0057%	0.1812%
325	**Chemical Manufacturing**							
325110	Petrochemical mfg	30	30	$37,840	$9,329,936	$920,190	0.0004%	0.0041%
325120	Industrial gas mfg	77	77	$29,078	$2,778,593	$263,675	0.0010%	0.0110%
325131	Inorganic dye & pigment mfg	52	52	$13,365	$1,976,099	$181,118	0.0007%	0.0074%
325132	Synthetic organic dye & pigment mfg	84	84	$38,016	$1,219,851	$103,523	0.0031%	0.0367%
325181	Alkalies & chlorine mfg	21	21	$6,209	$1,063,109	$95,422	0.0006%	0.0065%
325182	Carbon black mfg	6	6	$2,080	$113,030	$7,686	0.0018%	0.0271%
325188	All other basic inorganic chemical mfg	320	320	$159,060	$8,736,416	$798,137	0.0018%	0.0199%
325191	Gum & wood chemical mfg	36	36	$23,101	$201,257	$14,426	0.0115%	0.1601%
325192	Cyclic crude & intermediate mfg	24	24	$5,373	$1,517,099	$147,531	0.0004%	0.0036%
325193	Ethyl alcohol mfg	56	56	$15,718	$1,644,074	$121,718	0.0010%	0.0129%
325199	All other basic organic chemical mfg	379	379	$220,464	$22,851,825	$2,172,440	0.0010%	0.0101%
325211	Plastics material & resin mfg	387	387	$396,754	$19,060,144	$1,740,529	0.0021%	0.0228%
325212	Synthetic rubber mfg	121	121	$24,854	$3,094,417	$281,869	0.0008%	0.0088%
325221	Cellulosic organic fiber mfg	9	9	$3,348	$560,934	$42,674	0.0006%	0.0078%
325222	Noncellulosic organic fiber mfg	53	53	$22,203	$6,484,391	$478,859	0.0003%	0.0046%
325311	Nitrogenous fertilizer mfg	119	119	$10,722	$1,695,598	$153,997	0.0006%	0.0070%
325312	Phosphatic fertilizer mfg	24	24	$2,138	$205,946	$15,877	0.0010%	0.0135%
325314	Fertilizer (mixing only) mfg	344	344	$65,354	$1,884,424	$138,667	0.0035%	0.0471%
325320	Pesticide & other agricultural chemical mfg	166	166	$57,717	$1,675,332	$122,932	0.0034%	0.0470%
325411	Medicinal & botanical mfg	302	302	$74,180	$4,871,371	$440,499	0.0015%	0.0168%
325412	Pharmaceutical preparation mfg	662	662	$198,401	$37,183,323	$3,489,537	0.0005%	0.0057%
325413	In-vitro diagnostic substance mfg	145	145	$99,582	$1,116,080	$85,298	0.0089%	0.1167%
325414	Biological product (except diagnostic) mfg	215	215	$37,890	$1,284,300	$94,206	0.0030%	0.0402%
325510	Paint & coating mfg	1,052	1,052	$595,511	$5,300,432	$381,719	0.0112%	0.1560%
325520	Adhesive mfg	423	423	$241,020	$2,852,112	$209,820	0.0085%	0.1149%

Table VII-6
Potential Economic Impacts on Small Entities
(Continued)

NAICS Code	Industry	Number of Small Entities	Number of Affected Small Entities	Total Annualized Costs for Small Entities	Revenues of Small Entities (Thousands of Dollars)	Profits of Small Entities (Thousands of Dollars)	Costs as a Percent of Revenues for Small Entities	Costs as a Percent of Profits for Small Entities
325611	Soap & other detergent mfg	653	653	$212,306	$8,060,850	$657,838	0.0026%	0.0323%
325612	Polish & other sanitation good mfg	562	562	$147,159	$2,558,341	$186,226	0.0058%	0.0790%
325613	Surface active agent mfg	124	124	$48,072	$1,137,822	$82,768	0.0042%	0.0581%
325620	Toilet preparation mfg	677	677	$209,384	$4,991,963	$370,227	0.0042%	0.0566%
325910	Printing ink mfg	209	209	$286,003	$1,683,276	$124,085	0.0170%	0.2305%
325920	Explosives mfg	52	52	$21,341	$551,976	$47,828	0.0039%	0.0446%
325991	Custom compounding of purchased resin	510	510	$77,141	$3,153,348	$232,773	0.0024%	0.0331%
325992	Photographic film, paper, plate, & chemical mfg	319	319	$57,415	$1,116,374	$81,456	0.0051%	0.0705%
325998	Miscellaneous chemical product & preparation mfg	895	895	$454,837	$5,380,064	$391,736	0.0085%	0.1161%
326	Plastics and Rubber Products Man.	11,566	11,566	$1,374,421	$58,620,581	$2,498,431	0.0023%	0.0550%
327	Nonmetallic Mineral Prod. Manufac.	11,070	11,070	$1,217,009	$36,791,748	$1,250,969	0.0033%	0.0973%
331	Primary Metal Manufacturing	4,898	4,898	$681,803	$63,041,139	$2,392,409	0.0011%	0.0285%
332	Fabricated Metal Prod. Manufac.	56,564	56,564	$3,002,615	$135,135,617	$4,893,522	0.0022%	0.0614%
333	Machinery Manufacturing	24,476	24,476	$1,331,083	$84,091,181	$2,892,941	0.0016%	0.0460%
334	Computer & Electronic Prod Man.	13,165	13,165	$741,094	$68,659,714	$2,421,189	0.0011%	0.0306%
335	Electric Equipment, Appliance Man.	5,307	5,307	$427,644	$48,948,920	$2,079,263	0.0009%	0.0206%
336	Transportation Equip. Manufacturing	9,728	9,728	$1,025,150	$221,368,223	$5,500,261	0.0005%	0.0186%
337	Furniture & Related Product Man.	21,000	21,000	$1,064,520	$36,196,176	$1,447,847	0.0029%	0.0735%
339	Miscellaneous Manufacturing	27,871	27,871	$2,235,480	$52,087,901	$2,083,516	0.0043%	0.1073%
42	**Wholesale Trade**							
423	Durable Goods	214,860	214,860	$1,301,971	$722,292,128	$21,668,764	0.0002%	0.0060%
424	Nondurable Goods	119,975	119,975	$797,630	$601,304,420	$18,039,133	0.0001%	0.0044%
44-45	**Retail Trade**							
441	Motor vehicle & parts dealers	81,582	81,582	$848,628	$202,827,984	$4,056,560	0.0004%	0.0209%
442	Furniture & home furnishings stores	49,265	48,753	$216,730	$54,214,566	$1,626,437	0.0004%	0.0133%
443	Electronics & appliance stores	33,668	13,139	$55,483	$31,834,509	$955,035	0.0002%	0.0058%
444	Building material & garden equipment & dealers	66,835	66,835	$350,565	$109,523,264	$5,476,163	0.0003%	0.0064%
445	Food & beverage stores	117,704	67,850	$374,296	$115,182,044	$2,303,641	0.0003%	0.0162%
446	Health & personal care stores	42,065	42,065	$585,661	$59,014,974	$1,770,449	0.0010%	0.0331%

Table VII-6
Potential Economic Impacts on Small Entities
(Continued)

NAICS Code	Industry	Number of Small Entities	Number of Affected Small Entities	Total Annualized Costs for Small Entities	Revenues of Small Entities (Thousands of Dollars)	Profits of Small Entities (Thousands of Dollars)	Costs as a Percent of Revenues for Small Entities	Costs as a Percent of Profits for Small Entities
447	Gasoline stations	63,569	37,410	$338,972	$128,714,360	$3,861,431	0.0003%	0.0088%
448	Clothing & clothing accessories stores	68,371	6,219	$26,824	$43,905,559	$1,771,999	0.0001%	0.0015%
451	Sporting goods, hobby, book, & music stores	43,547	11,500	$61,169	$28,812,018	$864,361	0.0002%	0.0071%
452	General merchandise stores	9,474	3,033	$99,197	$6,860,862	$274,434	0.0014%	0.0361%
453	Miscellaneous store retailers	103,856	46,155	$196,124	$59,889,693	$1,796,691	0.0003%	0.0109%
454	Nonstore retailers	34,755	27,432	$132,469	$36,889,154	$1,211,961	0.0004%	0.0109%
48-49	**Transportation & Warehousing**							
481	Air transportation	2,688	1,633	$53,732	$56,475,397	$1,694,262	0.0001%	0.0032%
483	Water transportation	1,384	1,384	$29,001	$14,075,088	$703,754	0.0002%	0.0041%
484	Truck transportation	97,053	97,053	$768,455	$77,594,180	$1,586,514	0.0010%	0.0484%
485	Transit & ground passenger transportation	14,575	7,106	$75,660	$10,576,403	$240,372	0.0007%	0.0315%
486	Pipeline transportation	206	206	$18,996	$23,211,077	$3,807,336	0.0001%	0.0005%
487	Scenic & sightseeing transportation	2,400	1,665	$11,473	$1,415,420	$30,190	0.0008%	0.0380%
488	Support activities for transportation	25,818	25,818	$242,059	$25,680,060	$527,997	0.0009%	0.0458%
492	Couriers & messengers	8,346	8,346	$59,414	$6,592,619	$150,316	0.0009%	0.0395%
493	Warehousing & storage	4,795	4,795	$99,151	$11,718,324	$468,733	0.0008%	0.0212%
51	**Information**							
511	Publishing industries	24,243	17,550	$156,465	$52,072,418	$3,359,109	0.0003%	0.0047%
512	Motion picture & sound recording industries	18,831	3,116	$14,250	$17,820,427	$1,069,226	0.0001%	0.0013%
513	Broadcasting & telecommunications	16,064	4,614	$35,274	$25,408,061	$1,524,484	0.0001%	0.0023%
514	Information services & data processing services	16,334	2,589	$17,205	$16,546,313	$992,779	0.0001%	0.0017%
52	**Finance & Insurance**							
521	Monetary authorities - central bank	0	0	$0	$0	$0		
522	Credit intermediation & related activities	53,814	2,377	$10,767	$89,157,861	$9,807,365	0.0000%	0.0001%
523	Securities intermediation & related activities	45,746	776	$3.959	$44,517,277	$4,896,900	0.0000%	0.0001%
524	Insurance carriers & related activities	127,249	10,946	$107.398	$79,476,951	$3,973,848	0.0001%	0.0027%
525	Funds, trusts, & other financial vehicles	2,283	195	$1,456	$5,864,061	$1,471,133	0.0000%	0 0001%

Table VII-6
Potential Economic Impacts on Small Entities
(Continued)

NAICS Code	Industry	Number of Small Entities	Number of Affected Small Entities	Total Annualized Costs for Small Entities	Revenues of Small Entities (Thousands of Dollars)	Profits of Small Entities (Thousands of Dollars)	Costs as a Percent of Revenues for Small Entities	Costs as a Percent of Profits for Small Entities
53	**Real Estate & Rental and Leasing**							
531	Real estate	223,997	191,072	$960,273	$154,626,867	$17,470,758	0.0006%	0.0055%
532	Rental & leasing services	30,723	30,723	$213,805	$27,673,660	$1,366,695	0.0008%	0.0156%
533	Lessors of intangibles, except copyrighted works	1,749	408	$2,900	$2,926,520	$263,387	0.0001%	0.0011%
54	**Professional, Scientific, & Technical**							
5411	Legal services	169,334	3,575	$10,959	$108,511,389	$5,554,289	0.0000%	0.0002%
5412	Accounting, tax, bookkeeping, & payroll services	98,573	10,121	$70,201	$41,067,013	$2,471,437	0.0002%	0.0028%
5413	Architectural, engineering, & related services	94,197	23,309	$173,756	$78,112,103	$3,869,491	0.0002%	0.0045%
5414	Specialized design services	30,292	9,890	$67,503	$16,802,471	$1,008,148	0.0004%	0.0067%
5415	Computer systems design & related services	90,926	3,810	$23,265	$66,058,023	$2,668,250	0.0000%	0.0009%
5416	Management, scientific, & tech consulting services	108,952	19,564	$153,540	$62,845,228	$5,004,126	0.0002%	0.0031%
5417	Scientific R&D Serv.	10,516	3,926	$40,392	$15,564,979	$1,091,951	0.0003%	0.0037%
5418	Advertising & related services	33,927	12,202	$88,269	$30,695,557	$1,833,006	0.0003%	0.0048%
5419	Other professional, scientific, & technical services	64,123	64,123	$813,898	$37,299,792	$2,219,955	0.0022%	0.0367%
55	**Management of Companies**							
551111	Offices of bank holding companies	1,017	747	$6,760	$3,847,239	$591,867	0.0002%	0.0011%
551112	Offices of other holding companies	7,415	3,571	$35,240	$21,328,497	$12.631,626	0.0002%	0.0003%
551114	Corporate, subsidiary, & regional managing offices	14,223	13,261	$175,995	$48,945,160	$31,902,312	0.0004%	0.0006%
56	**Adm and Support & Waste Management**							
561	Administrative and Support Serv.	270,510	270,510	$3,055,830	$178,323,783	$7,132,951	0.0017%	0.0428%
562	Waste management & Remediation Serv.	13,846	13,846	$183,146	$14,875,499	$595,020	0.0012%	0.0308%
61	**Educational Services**							
6111	Elementary & secondary schools	17,632	14,686	$174,759	$30,848,661	$2,130,303	0.0006%	0.0082%
6112	Junior colleges	499	387	$4,263	$1,369,120	$94,439	0.0003%	0.0045%
6113	Colleges, universities, & profesional schools	1,488	1,042	$14,192	$3,971,847	$272,776	0.0004%	0.0052%
6114	Business schools, & computer & mgmt training	6,643	507	$2,230	$4,450,594	$288.924	0.0001%	0.0008%
6115	Technical & trade schools	5,974	2,101	$16,762	$4,766,202	$312,758	0.0004%	0.0054%
6116	Other schools & instruction	26,938	3,356	$21,986	$9,625,037	$621,124	0.0002%	0.0035%
6117	Educational support services	4,448	596	$5,479	$2,859,237	$184,820	0.0002%	0.0030%

Table VII-6
Potential Economic Impacts on Small Entities
(Continued)

NAICS Code	Industry	Number of Small Entities	Number of Affected Small Entities	Total Annualized Costs for Small Entities	Revenues of Small Entities (Thousands of Dollars)	Profits of Small Entities (Thousands of Dollars)	Costs as a Percent of Revenues for Small Entities	Costs as a Percent of Profits for Small Entities
62	**Healthcare and Social Assistance**							
621	Ambulatory health care services	419,668	419,668	$6,533,243	$328,680,492	$11,250,866	0.0020%	0.0581%
622	Hospitals	1,287	1,287	$76,052	$6,819,758	$289,304	0.0011%	0.0263%
623	Nursing & residential care facilities	30,600	30,600	$922,713	$33,237,359	$1,393,544	0.0028%	0.0662%
624	Social assistance	101,396	77,537	$1,047,526	$70,445,700	$2,893,937	0.0015%	0.0362%
71	**Arts, Entertainment & Recreation**							
711	Performing arts, spectator sports, etc.	36,900	12,342	$81,465	$28,441,869	$961,722	0.0003%	0.0085%
712	Museums, historical sites, & similar institutions	5,949	3,246	$24,781	$4,767,676	$184,607	0.0005%	0.0134%
713	Amusement, gambling, & recreation industries	58,582	47,069	$377,453	$42,619,782	$1,636,941	0.0009%	0.0231%
72	**Accommodation & Food Services**							
721	Accommodation	50,134	50,134	$621,322	$39,300,838	$1,503,225	0.0016%	0.0413%
722	Food services & drinking places	375,367	61,661	$304,272	$206,401,623	$7,909,848	0.0001%	0.0038%
81	**Other Services (except Public Adm.)**							
811	Repair & maintenance	214,106	214,106	$2,742,637	$103,334,529	$3,151,999	0.0027%	0.0870%
812	Personal & laundry services	168,594	127,794	$1,294,447	$51,782,390	$1,600,005	0.0025%	0.0809%
813	Religious/grantmaking/civic/professional	288,723	120,430	$845,582	$166,541,184	$3,454,066	0.0005%	0.0245%
99	**State and Local Government** (about half covered by OSHA standards)							
9992	State Government	n.a.	n.a.					
9993	Local Government	n.a.	n.a.					
	Total	**5,635,302**	**3,877,457**	**62,888,049**	**7,145,213,794**	**346,763,535**	**0.0009%**	**0.0181%**

Note: Costs are expressed in 2007 dollars
Source: Office of Regulatory Analysis, OSHA, based on PP&E (2008)

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The total non-annualized compliance costs for small entities during the three-year transition period are estimated to be $740 million, or about $247 million

per year for three years. Thus, the potential temporary impact would be about 0.003 percent of revenues or about 0.1 percent of profits, on average, per year for three years.

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 proposed standard on very small entities, defined as those with fewer than 20 employees. As shown in Table VII–7, the total annualized costs for entities in this size class would be an estimated $40 million. The annualized costs represent about 0.001 percent of revenues and less than 0.03 percent of profits. The total non-annualized compliance costs for very small entities during the three-year transition period are estimated to be $463 million, or about $154 million per year for three years. Thus, the potential temporary impact would be less than 0.005 percent of revenues or 0.15 percent of profits, on average, per year for three 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 proposed rule to exceed 5 percent of profits. OSHA found that the firm would have to produce 3,385 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 3,385 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____4268.aspx, 2007 data.*)

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 140 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 3,385 chemical products and very small firms that produce more than 140 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 by hand, as OSHA assumes most small firms do, 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. Once appropriate data for the ingredients of these mixtures had been developed, using the bridging principles outlined in Appendix A of the 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.

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Table VII-7
Potential Economic Impacts on Very Small Entities

NAICS Code	Industry	Number of Very Small Entities	Number of Affected Very Small Entities	Total Annualized Costs for Very Small Entities	Revenues of Very Small Entities (Thousands of Dollars)	Profits of Very Small Entities (Thousands of Dollars)	Costs as a Percent of Revenues for Very Small Entities	Costs as a Percent of Profits for Very Small Entities
11	**Agriculture, Forestry, Fishing & Hunting**							
113	Forestry & Logging	11,620	11,620	82,661	6,581,348	197,440	0.0013%	0.0419%
114	Fishing, Hunting and Trapping	2,290	1,008	7,283	877,772	26,333	0.0008%	0.0277%
115	Support Activities for Ag & Forestry	10,238	4,094	25,768	4,877,980	146,339	0.0005%	0.0176%
211	**Oil and Gas Extraction**							
211111	Crude petroleum & natural gas extraction	5,721	5,721	987,327	7,517,063	1,503,413	0.0131%	0.0657%
211112	Natural gas liquid extraction	60	60	10,295	56,333	11,267	0.0183%	0.0914%
212	Mining (except Oil & Gas)	3,390	3,390	41,406	2,875,275	258,775	0.0014%	0.0160%
213	Support Activities for Mining	6,426	6,426	67,773	3,338,633	166,932	0.0020%	0.0406%
22	**Utilities**							
2211	Electric Power Gen, Trans & Distrib	733	733	28,374	4,696,110	140,883	0.0006%	0.0201%
2212	Natural Gas Distribution	461	461	17,537	2,524,266	75,728	0.0007%	0.0232%
2213	Water, Sewage, & Other Systems	5,021	5,021	184,856	2,032,991	101,650	0.0091%	0.1819%
23	**Construction**							
236	Construction of Buildings	210,575	210,575	2,425,160	194,216,746	9,710,837	0.0012%	0.0250%
237	Heavy Construction	30,976	30,976	371,033	29,095,896	1,163,836	0.0013%	0.0319%
238	Special Trade Contractors	401,117	401,117	4,683,194	182,919,071	7,316,763	0.0026%	0.0640%
31	**Manufacturing**							
311	Food Manufacturing	15,651	15,651	602,160	14,663,498	293,270	0.0041%	0.2053%
312	Beverage &Tobacco Prod. Manuf.	2,012	2,012	74,557	1,853,790	129,765	0.0040%	0.0575%
313	Textile Mills	2,284	2,284	89,351	2,340,008	117,000	0.0038%	0.0764%
314	Textile Product Mills	5,584	5,584	215,396	3,993,393	119,802	0.0054%	0.1798%
315	Apparel Manufacturing	9,593	9,593	378,203	5,293,683	158,810	0.0071%	0.2381%
316	Leather & Allied Product Manufac.	1,123	1,123	43,253	596,603	17,898	0.0072%	0.2417%
321	Wood Product Manufacturing	10,887	10,887	435,528	8,898,673	444,934	0.0049%	0.0979%
322	Paper Manufacturing	1,637	1,637	66,304	2,458,540	24,585	0.0027%	0.2697%
323	Printing and Related Support	29,188	29,188	1,121,299	14,382,705	575,308	0.0078%	0.1949%
324	**Petroleum & Coal Prod. Manufac.**							
324110	Petroleum refineries	106	106	32,766	521,250	26,063	0.0063%	0.1257%
324121	Asphalt paving mixture & block mfg	279	279	88,511	872,276	43,614	0.0101%	0.2029%

Table VII-7
Potential Economic Impacts on Very Small Entities
(Continued)

NAICS Code	Industry	Number of Very Small Entities	Number of Affected Very Small Entities	Total Annualized Costs for Very Small Entities	Revenues of Very Small Entities (Thousands of Dollars)	Profits of Very Small Entities (Thousands of Dollars)	Costs as a Percent of Revenues for Very Small Entities	Costs as a Percent of Profits for Very Small Entities
324122	Asphalt shingle & coating materials mfg	68	68	20,950	194,649	9,732	0.0108%	0.2153%
324191	Petroleum lubricating oil & grease mfg	167	167	51,206	282,884	14,144	0.0181%	0.3620%
324199	All other petroleum & coal products mfg	33	33	10,171	47,673	2,384	0.0213%	0.4267%
325	**Chemical Manufacturing**							
325110	Petrochemical mfg	13	13	3,992	44,755	2,238	0.0089%	0.1784%
325120	Industrial gas mfg	49	49	4,482	74,937	3,747	0.0060%	0.1196%
325131	Inorganic dye & pigment mfg	27	27	2,487	50,071	2,504	0.0050%	0.0993%
325132	Synthetic organic dye & pigment mfg	44	44	11,149	71,994	3,600	0.0155%	0.3097%
325181	Alkalies & chlorine mfg	11	11	1,952	142,840	7,142	0.0014%	0.0273%
325182	Carbon black mfg	4	4	714	113,030	5,651	0.0006%	0.0126%
325188	All other basic inorganic chemical mfg	150	150	26,417	296,723	14,836	0.0089%	0.1781%
325191	Gum & wood chemical mfg	28	28	5,011	44,561	2,228	0.0112%	0.2249%
325192	Cyclic crude & intermediate mfg	5	5	461	7,856	393	0.0059%	0.1174%
325193	Ethyl alcohol mfg	34	34	6,026	473,860	23,693	0.0013%	0.0254%
325199	All other basic organic chemical mfg	176	176	39,811	409,387	20,469	0.0097%	0.1945%
325211	Plastics material & resin mfg	208	208	36,212	467,525	23,376	0.0077%	0.1549%
325212	Synthetic rubber mfg	81	81	7,444	92,477	4,624	0.0080%	0.1610%
325221	Cellulosic organic fiber mfg	3	3	606	100,646	5,032	0.0006%	0.0120%
325222	Noncellulosic organic fiber mfg	24	24	7,817	2,305,903	115,295	0.0003%	0.0068%
325311	Nitrogenous fertilizer mfg	87	87	5,691	180,584	9,029	0.0032%	0.0630%
325312	Phosphatic fertilizer mfg	13	13	829	11,804	590	0.0070%	0.1405%
325314	Fertilizer (mixing only) mfg	238	238	22,041	299,080	14,954	0.0074%	0.1474%
325320	Pesticide & other agricultural chemical mfg	114	114	25,787	298,919	14,946	0.0086%	0.1725%
325411	Medicinal & botanical mfg	208	208	35,829	345,168	17,258	0.0104%	0.2076%
325412	Pharmaceutical preparation mfg	390	390	67,528	938,713	46,936	0.0072%	0.1439%
325413	In-vitro diagnostic substance mfg	88	88	26,927	86,920	4,346	0.0310%	0.6196%
325414	Biological product (except diagnostic) mfg	127	127	15,279	210,143	10,507	0.0073%	0.1454%
325510	Paint & coating mfg	757	757	130,992	1,101,860	55,093	0.0119%	0.2378%
325520	Adhesive mfg	289	289	49,956	454,470	22,724	0.0110%	0.2198%

Table VII-7
Potential Economic Impacts on Very Small Entities
(Continued)

NAICS Code	Industry	Number of Very Small Entities	Number of Affected Very Small Entities	Total Annualized Costs for Very Small Entities	Revenues of Very Small Entities (Thousands of Dollars)	Profits of Very Small Entities (Thousands of Dollars)	Costs as a Percent of Revenues for Very Small Entities	Costs as a Percent of Profits for Very Small Entities
325611	Soap & other detergent mfg	500	500	86,432	2,069,295	103,465	0.0042%	0.0835%
325612	Polish & other sanitation good mfg	420	420	38,575	469,259	23,463	0.0082%	0.1644%
325613	Surface active agent mfg	83	83	14,474	204,093	10,205	0.0071%	0.1418%
325620	Toilet preparation mfg	468	468	43,181	690,280	34,514	0.0063%	0.1251%
325910	Printing ink mfg	138	138	25,949	271,569	13,578	0.0096%	0.1911%
325920	Explosives mfg	24	24	2,196	16,123	806	0.0136%	0.2724%
325991	Custom compounding of purchased resin	337	337	31,356	420,318	21,016	0.0075%	0.1492%
325992	Photographic film, paper, plate, & chemical mfg	252	252	29,773	199,143	9,957	0.0150%	0.2990%
325998	Miscellaneous chemical product & preparation mfg	616	616	107,189	1,015,830	50,792	0.0106%	0.2110%
326	Plastics and Rubber Products Man.	6,746	6,746	453,564	6,931,026	346,551	0.0065%	0.1309%
327	Nonmetallic Mineral Prod. Manufac.	7,927	7,927	531,005	6,712,807	201,384	0.0079%	0.2637%
331	Primary Metal Manufacturing	3,024	3,024	201,692	3,992,418	119,773	0.0051%	0.1684%
332	Fabricated Metal Prod. Manufac.	42,782	42,782	1,682,920	27,514,141	1,100,566	0.0061%	0.1529%
333	Machinery Manufacturing	17,301	17,301	675,039	14,642,783	439,283	0.0046%	0.1537%
334	Computer & Electronic Prod Man.	8,725	8,725	329,998	9,728,863	291,866	0.0034%	0.1131%
335	Electric Equipment, Appliance Man.	3,383	3,383	131,643	3,698,292	110,949	0.0036%	0.1187%
336	Transportation Equip. Manufacturing	6,345	6,345	250,634	6,937,987	277,519	0.0036%	0.0903%
337	Furniture & Related Product Man.	17,205	17,205	668,114	8,289.830	331,593	0.0081%	0.2015%
339	Miscellaneous Manufacturing	23,393	23,393	1,515,805	11,628,672	465,147	0.0130%	0.3259%
42	**Wholesale Trade**							
423	Durable Goods	190,608	190,608	849,753	393,046,036	11,791,381	0.0002%	0.0072%
424	Nondurable Goods	104,949	104,949	537,560	286,772,122	8,603,164	0.0002%	0.0062%
44-45	**Retail Trade**							
441	Motor vehicle & parts dealers	77,264	77,264	755,766	113,707,749	2,274,155	0.0007%	0.0332%
442	Furniture & home furnishings stores	45,843	45,331	142,527	34,628,932	1,038,868	0.0004%	0.0137%
443	Electronics & appliance stores	31,831	11,302	37,895	20,271,717	608,152	0.0002%	0.0062%
444	Building material & garden equipment & dealers	59,236	59,236	213,629	56,743,312	2,837,166	0.0004%	0.0075%
445	Food & beverage stores	108,015	58,160	228,418	68,941,888	1,378,838	0.0003%	0.0166%
446	Health & personal care stores	38,874	38,874	483,686	41,223,847	1,236,715	0.0012%	0.0391%

Table VII-7
Potential Economic Impacts on Very Small Entities
(Continued)

NAICS Code	Industry	Number of Very Small Entities	Number of Affected Very Small Entities	Total Annualized Costs for Very Small Entities	Revenues of Very Small Entities (Thousands of Dollars)	Profits of Very Small Entities (Thousands of Dollars)	Costs as a Percent of Revenues for Very Small Entities	Costs as a Percent of Profits for Very Small Entities
447	Gasoline stations	57,901	31,742	184,143	76,120,504	2,283,615	0.0002%	0.0081%
448	Clothing & clothing accessories stores	65,360	4,458	18,830	31,408,124	1,256,325	0.0001%	0.0015%
451	Sporting goods, hobby, book, & music stores	40,955	8,908	39,332	18,955,488	568,665	0.0002%	0.0069%
452	General merchandise stores	8,844	2,403	90,919	4,077,685	163,107	0.0022%	0.0557%
453	Miscellaneous store retailers	98,841	41,141	132,795	42,062,319	1,261,870	0.0003%	0.0105%
454	Nonstore retailers	33,205	25,881	107,194	26,360,527	790,816	0.0004%	0.0136%
48-49	**Transportation & Warehousing**							
481	Air transportation	2,161	1,105	6,670	2,327,304	69,819	0.0003%	0.0096%
483	Water transportation	1,039	1,039	10,925	1,158,016	57,901	0.0009%	0.0189%
484	Truck transportation	89,042	89,042	606,179	39,358,113	787,162	0.0015%	0.0770%
485	Transit & ground passenger transportation	11,941	4,471	34,254	3,437,699	68,754	0.0010%	0.0498%
486	Pipeline transportation	132	132	1,125	1,176,902	117,690	0.0001%	0.0010%
487	Scenic & sightseeing transportation	2,201	1,466	8,063	682,483	13,650	0.0012%	0.0591%
488	Support activities for transportation	23,391	23,391	186,091	14,531,949	290,639	0.0013%	0.0640%
492	Couriers & messengers	7,454	7,454	38,107	2,724,131	54,483	0.0014%	0.0699%
493	Warehousing & storage	3,667	3,667	43,653	2,544,751	101,790	0.0017%	0.0429%
51	**Information**							
511	Publishing industries	20,130	13,437	73,006	11,384,800	683,088	0.0006%	0.0107%
512	Motion picture & sound recording industries	17,735	2,020	7,873	11,321,170	679,270	0.0001%	0.0012%
513	Broadcasting & telecommunications	13,917	2,466	15,334	10,989,900	659,394	0.0001%	0.0023%
514	Information services & data processing services	14,528	1,166	7,439	7,406,399	444,384	0.0001%	0.0017%
52	**Finance & Insurance**							
521	Monetary authorities - central bank	0	0	0	0	0		
522	Credit intermediation & related activities	47,056	971	4,399	36,003,115	3,960.343	0.0000%	0.0001%
523	Securities intermediation & related activities	44,538	581	2,962	30,923,715	3,401,609	0.0000%	0.0001%
524	Insurance carriers & related activities	123,333	8,026	78,741	49,172,468	2,458,623	0.0002%	0.0032%
525	Funds, trusts, & other financial vehicles	2,270	182	1,337	5,352,318	1,338,080	0.0000%	0.0001%

Table VII-7
Potential Economic Impacts on Very Small Entities
(Continued)

NAICS Code	Industry	Number of Very Small Entities	Number of Affected Very Small Entities	Total Annualized Costs for Very Small Entities	Revenues of Very Small Entities (Thousands of Dollars)	Profits of Very Small Entities (Thousands of Dollars)	Costs as a Percent of Revenues for Very Small Entities	Costs as a Percent of Profits for Very Small Entities
53	**Real Estate & Rental and Leasing**							
531	Real estate	215,880	182,955	775,332	112,822,181	12,410,440	0.0007%	0.0062%
532	Rental & leasing services	27,998	27,998	142,573	14,658,204	732,910	0.0010%	0.0195%
533	Lessors of intangibles, except copyrighted works	1,644	304	1,827	1,726,572	155,391	0.0001%	0.0012%
54	**Professional, Scientific, & Technical**							
5411	Legal services	162,242	2,368	7,260	69,818,935	3,490,947	0.0000%	0 0002%
5412	Accounting, tax, bookkeeping, & payroll services	93,935	6,508	40,769	24,545,007	1,227,250	0.0002%	0.0033%
5413	Architectural, engineering, & related services	85,978	15,091	87,828	38,647,371	1.932,369	0.0002%	0.0045%
5414	Specialized design services	29,466	9,064	56,035	13,020,339	781,220	0.0004%	0.0072%
5415	Computer systems design & related services	85,431	1,962	11,927	34,113,170	1,364,527	0.0000%	0.0009%
5416	Management, scientific, & tech consulting services	104,691	15,304	93,496	40,947,555	3,275,804	0.0002%	0.0029%
5417	Scientific R&D Serv.	9,033	2,444	18,675	6,087,663	426,136	0.0003%	0.0044%
5418	Advertising & related services	31,415	9,690	53,252	17,974,342	1,078,461	0.0003%	0.0049%
5419	Other professional, scientific, & technical services	59,690	59,690	695,583	24,949,687	1,496,981	0.0028%	0.0465%
55	**Management of Companies**							
551111	Offices of bank holding companies	392	122	690	764,994	107,099	0.0001%	0.0006%
551112	Offices of other holding companies	5,161	1,317	7,417	9,161,437	4,763,947	0.0001%	0.0002%
551114	Corporate, subsidiary, & regional managing offices	1,589	627	3,530	885,837	460,635	0.0004%	0.0008%
56	**Adm and Support & Waste Management**							
561	Administrative and Support Serv.	240,520	240,520	2,133,582	77,442,286	3,097,691	0.0028%	0.0689%
562	Waste management & Remediation Serv.	12,197	12,197	141,986	6,948,468	277,939	0.0020%	0.0511%
61	**Educational Services**							
6111	Elementary & secondary schools	8,205	5,259	37,016	2,910,337	174,620	0.0013%	0.0212%
6112	Junior colleges	258	81	445	139,933	8,396	0.0003%	0.0053%
6113	Colleges, universities, & profesional schools	979	533	4,086	525,361	31,522	0.0008%	0.0130%
6114	Business schools, & computer & mgmt training	6,128	248	1,036	2,261,725	135,704	0.0000%	0.0008%
6115	Technical & trade schools	5,195	1,322	6,948	2,087,622	125,257	0.0003%	0.0055%
6116	Other schools & instruction	24,568	1,791	10,991	5,390,673	323,440	0.0002%	0.0034%
6117	Educational support services	4,142	306	2,639	1,532,693	91,962	0.0002%	0.0029%

Table VII-7
Potential Economic Impacts on Very Small Entities
(Continued)

NAICS Code	Industry	Number of Very Small Entities	Number of Affected Very Small Entities	Total Annualized Costs for Very Small Entities	Revenues of Very Small Entities (Thousands of Dollars)	Profits of Very Small Entities (Thousands of Dollars)	Costs as a Percent of Revenues for Very Small Entities	Costs as a Percent of Profits for Very Small Entities
62	**Healthcare and Social Assistance**							
621	Ambulatory health care services	390,336	390,336	5,152,403	207,873,085	6,236,193	0.0025%	0.0826%
622	Hospitals	637	637	8,302	1,329,498	39,885	0.0006%	0 0208%
623	Nursing & residential care facilities	17,176	17,176	234,944	5,297,430	158,923	0.0044%	0.1478%
624	Social assistance	81,638	57,779	489,353	18,539,304	556,179	0.0026%	0.0880%
71	**Arts, Entertainment & Recreation**							
711	Performing arts, spectator sports, etc.	34,930	10,372	54,376	19,362,299	580,869	0.0003%	0.0094%
712	Museums, historical sites, & similar institutions	5,116	2,413	11,804	1,636,104	49,083	0.0007%	0.0240%
713	Amusement, gambling, & recreation industries	47,892	36,379	200,289	15,899,495	476,985	0.0013%	0.0420%
72	**Accommodation & Food Services**							
721	Accommodation	41,267	41,267	417,794	15,102,809	453,084	0.0028%	0.0922%
722	Food services & drinking places	301,189	21,393	92,127	77,599,440	2,327,983	0.0001%	0.0040%
81	**Other Services (except Public Adm.)**							
811	Repair & maintenance	205,196	205,196	2,442,589	74,764,586	2,242,938	0.0033%	0.1089%
812	Personal & laundry services	159,826	119,026	1,042,292	33,958,438	1,018,753	0.0031%	0.1023%
813	Religious/grantmaking/civic/professional	263,149	94,855	510,222	86,397,908	1,727,958	0.0006%	0.0295%
99	**State and Local Government** (about half covered by OSHA standards)							
9992	State Government	n.a.	n.a.					
9993	Local Government	n.a.	n.a.					
	Total	**5,061,427**	**3,358,052**	**39,457,326**	**3,124,004,335**	**132,300,139**	**0.0013%**	**0.0298%**

Note: Costs are expressed in 2007 dollars
Source: Office of Regulatory Analysis, OSHA, based on PP&E (2008)

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OSHA therefore concludes that there are not a substantial number of firms that would incur significant economic

impacts as a result of producing a very large number of chemical products.

OSHA remains concerned with the possible problems of small and very small firms that might produce very large numbers of distinct chemical products. OSHA welcomes comments on the issue of whether there are small and very small firms that produce a very large number of products, what industries they are in, and their anticipated costs to convert to the GHS system.

2. A description of the reasons why action by the agency is being considered.

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

The HCS requires chemical manufacturers and importers to evaluate the hazards of the chemicals they produce or import. The rule provides definitions of health and physical hazards to use as the criteria for determining hazards in the evaluation process. The information about the hazards and 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, and gives employees the right-to-know and the knowledge of the hazards and identities of the chemicals, as well as allowing them to participate actively in the successful control of exposures. Together, these actions of employers and employees reduce the potential for adverse effects to occur. The information transmitted under the HCS requirements provides the foundation upon which a chemical safety and health program is built in the workplace. Without this information, appropriate controls could not be identified and implemented.

OSHA's HCS is designed to disseminate information on chemicals to precipitate changes in handling methods and thus protect those 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 when 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 Labeling of Chemicals in December 2002.

The proposed modifications to the HCS incorporate the GHS's requirements. They would 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 would be standardized in a way that they are not under the existing hazard communication standard. 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 would benefit employers and enhance employee safety. Employers who use chemicals, and exposed employees, would benefit from receiving the revised labels and safety data sheets prepared in a consistent format. The information should 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 would be to integrate the new approach into the workplace hazard communication program, including assuring that both employers and employees understand the pictograms and other information provided on the chemicals.

OSHA believes that adoption of the GHS would improve labels and SDS comprehensibility through implementation of a standardized 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 results in a lack of consistency that makes it difficult for users of chemicals to properly identify their hazards and 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, would help all users, including employers, employees, and safety and health responders, more easily identify the critical information necessary to protect employees.

In addition, American employees and employers should 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 that there is a belief that there are significant benefits associated with implementation of a globally harmonized approach to hazard communication. Countries, international organizations, chemical producers, and users of chemicals would all benefit. There are at least four

reasons to expect that GHS will be adopted globally.

First and foremost, implementation of the GHS would enhance protection of humans 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 the preliminary economic analysis, the adoption of the proposed revisions 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, the majority of countries 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. In our country, we expect to improve and build on protections we already have.

Second, implementation of such an approach would facilitate international trade in chemicals. It would reduce the burdens caused by having to comply with differing requirements for the same product, and allow companies who do not have the resources to deal with those burdens to be involved 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 would reduce this duplicative testing. It should be noted, however, that OSHA 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 to accomplish 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 pollution and other effects of uncontrolled chemical exposures. In all countries, there is a need to acquire sufficient information to properly handle the chemical when it is 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. would 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, nearly every employer deals with at least two sets of Federal requirements. Thus every producer would be likely to experience some benefits from domestic harmonization.

OSHA has made a preliminary determination that the proposed revisions would 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 would 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 preliminarily estimates that (1) savings in benefits from improved employee health and safety exceed the costs of the proposed rule, and (2) cost savings to chemical users exceed the costs of the proposed rule.

An additional and more complete discussion of the reasons why this standard is being proposed by the Agency is provided in other parts of the preamble section of this Notice of Proposed Rulemaking (NPRM).

3. Statement of the objectives of, and legal basis for, the proposed rule.

The primary objective of the proposed revisions to the OSHA HCS is to achieve the potential 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 exposed to hazardous chemicals in the workplace.

Another objective of the proposed revisions is 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 the hazards of all chemicals are 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 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 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. Providing information to employers enables them to implement protective measures in the workplace. Less hazardous alternatives may be chosen, or appropriate engineering controls, work practices, and personal protective equipment can be selected. 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 proposed rule does not alter that approach. Rather, the proposed 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.

The legal basis for the rule is the responsibility given the Department of Labor through the Occupational Safety and Health (OSH) Act of 1970. The OSH Act authorizes and obligates the Secretary of Labor to promulgate mandatory occupational safety and health standards as necessary ''to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources.'' 29 U.S.C. 651(b). The OSH Act gives the Agency authority to issue and revise standards and regulations to further this goal. A thorough discussion of the legal basis can be found in the preamble to the proposed standard in Section VI—Pertinent Legal Authority.

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

OSHA has completed a preliminary analysis of the impacts associated with this proposal, including an analysis of the type and number of small entities to which the proposed rule would apply, as described above. 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 proposed standard would impact 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 proposal is estimated to potentially affect a total of 4,215,404 small entities, as shown in Table VII–6. The rule would have its greatest impacts on the 72,000 small firms that produce chemicals that require SDSs and labels.

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

The proposed 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 preamble to the proposed standard provides a comprehensive description of, and further detail regarding, the compliance requirements of the proposed 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, these costs would apply only to those businesses not already in compliance with the proposed revisions. OSHA requests comments and information from the public regarding these estimates:

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 $200 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:

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

6. Federal rules which may duplicate, overlap or conflict with the proposed rule.

OSHA has not identified any other Federal rules which may duplicate, overlap, or conflict with the proposal, and requests comments from the public regarding this issue.

7. Alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.

As discussed in Section IV, this rulemaking is unique for OSHA in that it seeks to improve employee protections by adopting an internationally harmonized approach to hazard communication issues. While the current HCS has provided protections for exposed workers by disseminating information about chemicals in their workplaces for many years now, the approach taken in the GHS strengthens and refines the system, and gives OSHA the opportunity to improve hazard communication by adopting it. The GHS has the same general concept of an integrated, comprehensive process of identifying and communicating hazards, but provides more extensive criteria to define the hazards in a consistent manner, as well as standardizes label elements and SDS formats to help to ensure that the information is conveyed consistently.

OSHA has preliminarily concluded that required adoption of GHS is the

best approach to modifying the HCS to achieve the goals of global harmonization, ease of use, and improved health and safety. As addressed in Section XV of the preamble, many commenters supported the concept of OSHA moving forward to adopt the GHS. Several objected to adoption, and OSHA has identified and responded to their concerns in Section XV of the preamble as well. In addition, there were several commenters who noted that small chemical manufacturers that are not engaged in international trade of chemicals would have a large burden associated with adopting the GHS, and questionable benefits due to their lack of involvement in international trade. The Small Business Administration (SBA) suggested that OSHA ''consider 'grandfathering' or exempting small businesses that do not export regulated chemicals.'' (Document ID # 0022) Others simply noted that they believed there would be high costs and limited benefits for such employers, or that it would be costly and difficult to adopt (Document ID #s 0015, 0026, 0178, and 0144). There was no discussion in any of these comments about how this might work in the revised standard.

None of these commenters suggested a detailed approach to exactly how such a grandfathering or exemptions might work. OSHA welcomes comments on how such approaches might work.

A somewhat different alternative that might achieve the goals of those employers who anticipate high costs for little benefit to themselves would be for OSHA to consider simply facilitating the voluntary adoption of GHS. With some very minor exceptions that could easily be changed by rule, the existing HCS performance-based approach to MSDS would permit chemical producers and importers to use the proposed GHS SDS format and approach. They could not however, adopt the GHS classifications without a change to the rule allowing the use of GHS classifications where they differed from those in HCS. The use of labels adopting GHS signal words, precautionary statements, formats, and pictograms could be possible under the HCS performance-based approach to labels. However, it should be carefully noted that, although the resulting label might appear GHS compliant, it need not actually be GHS-compliant, and in some case would not be based on the GHS classifications. Further, individual firms could produce labels using GHS formats, *etc.,* with meanings quite different from those in GHS.

The advantages of a system that simply facilitated voluntary adoption of GHS are that (1) those engaged in international trade, whether as exporters or importers, could obtain the full benefits of international harmonization; (2) those producers of chemicals who saw no market advantage to changing systems would not need to incur the costs associated with changing their hazard classification, MSDSs, and labels and (3) it is possible that employee training under a performance-based system for MSDSs and labels would not need to be required or changed.

OSHA sees a number of disadvantages to a rule that simply facilitates the voluntary adoption of GHS. First consider the issues of a common MSDS/SDS format versus MSDS/SDS formats that can vary in any way whatsoever while meeting a standard of what an MSDS must contain. Such an approach would eliminate a proportion of the possible benefits from knowing where to look in an SDS for the information one wants or needs, since many SDSs will still not be standardized.

From OSHA's perspective, a key issue of concern in such an approach is that the classification criteria in the GHS are different from the hazard definitions in the current HCS. In general, as discussed in Section XV of the preamble, they cover the same scope of hazard, so these differences do not result in significant differences in the chemicals covered. But the GHS criteria divide most of the hazard classes into hazard categories that convey the severity of the effect, while few of the hazard definitions in the current HCS take this approach. The standardized label elements are associated with these specific hazard categories, *i.e.,* the harmonized pictograms, signal words, and hazard statements are assigned by hazard category and reflect the degree of hazard it presents to those exposed. Likewise, the precautionary statements assigned are also reflective of the degree of hazard, with responses related to these presumed hazard levels.

Third, consider the possible disadvantages of not having a common, well-understood labeling system with signal words, pictograms, precautionary statements and common formatting. In the absence of such a system it would be extremely difficult to teach persons not literate in English how to understand labels, and even those literate in English may have difficulty with major differences in the symbols and language used for the same substance or hazard.

It should also be noted that allowing the voluntary use of GHS might not be considered GHS-compliant as the phrase is used in GHS publications.

It is difficult to quantify the benefits and costs of the alternative of simply facilitating adoption of GHS. Part of the problem is that it is difficult to forecast the extent to which persons would voluntarily adopt GHS. OSHA therefore considered two scenarios. In the first scenario, there is no extensive adoption of GHS and GHS becomes simply a minor sub-class of the performance-oriented options already available. This scenario has the effect of minimizing the costs associated with the facilitation of voluntary adoption of GHS, but at the expense of minimizing the benefits of this alternative. In the second scenario, GHS would be adopted widely enough to become the norm for hazard communication, but some would continue their existing HCS approaches unchanged. Under this scenario, most firms would insist that their health and safety managers and logistics personnel be thoroughly familiar with GHS, and that employees be trained on GHS. This scenario minimizes the loss in benefits associated with the first scenario, but involves much greater costs than scenario 1 and may involve significantly increased costs over the option of full compliance with GHS. OSHA believes that the actual results will fall between these two scenarios and is seeking comment on the relative likelihood of these or other scenarios.

OSHA suspects that second scenario might be the more likely possibility. For example, the standardized MSDS system adopted by GHS is widely used in the U.S., particularly by large firms and firms with many MSDSs, though many have not adopted this system. Domestic and international producers, and large and small producers are not mutually exclusive—a large business engaged in international trade can not simply implement the GHS regardless of its suppliers. Small businesses sell to large businesses. If small businesses do not adopt the GHS, then the large businesses would have to generate GHS classifications for chemicals they buy from them in order to follow the GHS. It would be difficult for them to do this, particularly for mixtures, since they are not the producer of the chemicals. This concept was addressed in comments regarding the effective dates for the rule, when many suggested it was not appropriate to differentiate dates based on the size of the business. For example, ORC Worldwide, Inc. stated (Document ID # 0123):

> OSHA should consider a company's place in the manufacturing supply chain, not size, in determining how the phase-in is implemented. It would be sensible to start with producers of raw materials and basic chemicals. The technical information,

classification and categorization they perform will be useful downstream for the intermediate chemical producers and specialty chemical manufacturers. Lastly, the end user will benefit from the influx of information developed by the upstream professionals.

Just as the size of the company may not be an appropriate criterion to determine when that company should be in compliance, it also does not appear to be a useful way to determine whether the GHS provisions should be adopted by them. It is difficult to determine how a voluntary system, or a system based on business size, would be successfully implemented and enforced given the structure of the supply system. Because of these factors, OSHA anticipates that many smaller firms who may think they do not need GHS may be forced through the market to adopt the system to satisfy the needs of customers who do engage in international trade.

Under the first scenario, with no extensive voluntary adoption of GHS, the annualized costs $11 million per year for reclassification of chemicals and the $44 million in annualized costs for one-time retraining of workers would be largely eliminated. OSHA estimates that the $45 million in annualized costs for health and safety managers and logistics personnel to familiarize themselves with the GHS system would still be incurred. This alternative might add a continuing cost not present under either system of the need for new health and safety managers and logistics personnel to be familiar with both systems. Assuming a 5 percent annual turnover among such professional, assuring continuing knowledge of both systems would add costs of $25 million per year. This alternative under Scenario 1 would thus reduce the costs from $97 million per year to between $42 million per year and $77 million per year depending on whether it is assumed that new health and safety managers and logistics personnel would need to be familiar with both systems. In return for this reduction in costs, under Scenario 1, because of the assumption of no significant adoption of GHS, the benefits of $851 million per year are also lost. Furthermore, this analysis ignores non-quantified benefits of full adoption of GHS, such as decreases in training costs associated a full GHS system.

In choosing the voluntary adoption of GHS alternative, OSHA would be ignoring the potentially substantial health and safety benefits arising from the economically feasible (and, for most businesses, the economically desirable) option of full compliance with GHS and instead adopting a system with no such health and safety benefits for the sole reason of possibly saving a small minority of all affected businesses some costs.

Under Scenario 2, with widespread voluntary adoption of GHS, more benefits would be achieved than under Scenario 1, but all the benefits available under the proposed rule would not be achieved, and OSHA believes there would be greater costs than under the option of requiring full compliance with GHS. However, if widespread adoption of GHS is to result in substantially higher benefits than under Scenario 1, then health and safety managers and logistic personnel would have to be fully familiar with both systems, and employees would also need to be trained on GHS as the primary system and not just as one of many performance-oriented options. Thus, Scenario 2 would save some portion of the $11 million in annualized costs per year spent by chemical producers for reclassification and modifying SDSs and labels. However, the full costs of management familiarization and one-time employee training would still need to be incurred. In addition continuing costs would have to be incurred for new health and safety managers and logistic personnel to familiarize themselves with two systems and for new employees to be trained on both systems. Assuming turnover of 5 percent for manager and 20 percent for employees, the associated annual costs would be $150 million per year. Under Scenario 2, the alternative of facilitating voluntary adoption would achieve some portion of the benefits of GHS but with significantly greater costs—an additional $150 million per year for continuing GHS training of new employees and GHS familiarization for new health and safety managers and logistics personnel, offset by a very modest reduction in costs to chemical producers.

In terms of benefits, both OSHA's proposed full GHS compliant approach and that of a dual system would retain possible benefits to chemical producers and to international trade. However, OSHA is concerned that the confusions arising might negate some of the benefits associated with reduced injuries, illnesses and fatalities. While there would still be some situations where use of GHS would prevent injuries, there would also be situations where confusion and misunderstanding would lead to injuries, illnesses, and fatalities that might not otherwise be incurred. For example, employees used to seeing pictograms might easily make the false assumption that chemicals without a pictogram are safe. This has the potential to eliminate a significant portion of the annual health and safety benefits. Other benefits would also need to be reduced, though it is not clear by how much.

In addition to the chosen alternative of full compliance with GHS, OSHA also considered options requiring full compliance with some but not all portions of GHS. One such option would be to adopt the provisions of the GHS that are presumed to provide the greatest benefits at the least cost. For example, OSHA could adopt the standardized label provisions without the associated hazard classification criteria. Employers would be free to continue to use the existing hazard determination scheme, but present the label information in the standardized form anticipated under the GHS. Since the standardized labels appear to be relatively inexpensive to implement, while reviewing classifications is more costly, this has the potential to reduce the overall cost of implementation of the revised rule.

This option—adopting the label provisions but not the classification criteria—presents many of the same concerns. First, the reason the label provisions are relatively cost-efficient to adopt is that the GHS assigns the various required elements by hazard class and category. It is basically a cookbook approach. Once the classification or re-classification has been accomplished, the GHS provides the specific information for the label.

Requiring this standardized approach to labeling without the infrastructure of the criteria would be more burdensome for the chemical manufacturer to accomplish, though OSHA could consider whether it would be appropriate to provide criteria for HCS classification under this alternative that would reduce burden. However, OSHA is also concerned that this alternative would result in labels that may look the same but which actually do not have consistent warnings based on the precise hazardous effect. Without the GHS criteria that breaks hazard classes into multiple categories for most effects, it would be difficult to relate the label elements to the hazard determinations under the current HCS. For example, the current standard treats all carcinogens the same way, rather than differentiating them into several categories. OSHA would either have to provide some type of decision logic to employers in order to have a consistent approach or allow the responsible party to determine the appropriate labeling elements that should be included on the label. The most protective approach would be to treat all carcinogens or other effects as

being in the most hazardous category of each class so there will be no choice of label elements that would cause differences among employers. Regardless, chemical producers will have to undergo an assessment of their current determinations and attempt to relate them to the established hazard categories. This will be difficult, particularly for small producers. Alternatively, OSHA could create a regulatory system assigning HCS categories to each GHS label, but this would be totally contrary to the performance-orientation of the current HCS system, as well as having undetermined costs. It is thus unlikely that this would provide significant savings relative to simply reviewing classifications for purposes of putting the chemicals into GHS classes and categories.

However, apart from this burden, the benefits of standardized labeling would be reduced by not having common criteria upon which they are based. Chemical producers following this approach would likely not be able to use their labels in other countries where the GHS has been adopted. Hence, there would be costs of adoption without commensurate benefits in either comprehensibility or facilitation of trade.

Another type of dual approach would have OSHA adopt some, but not all, of the label elements. In particular, the Agency might not adopt the exact language of the precautionary statements since this language has been codified but are not yet considered to be ''harmonized'' under the GHS—they are provided for guidance and reference, but competent authorities may choose to implement other statements. The exact language for precautionary statements could be adopted later when they are harmonized under the GHS. Alternatively, OSHA could either allow label preparers to use whatever precautionary statements they deem appropriate or develop its own set of statements to require.

The precautionary statements, however, are the part of the GHS label that provides the measures to follow to ameliorate the possible hazardous effects of exposure. Delaying adoption of the precautionary statements would likely reduce the effectiveness of the labels significantly, and reduce the appropriate information on the SDSs as well. Labels that lack a precautionary statement would not be fully harmonized. The second alternative, to simply require precautionary statements, but not to specify what they are, would provide some protection but would not correct the current situation of inconsistent precautions due to the performance-oriented approach that allows the label preparer to determine what they are or if they are included. One communication advantage of providing the information in the same language from label-to-label is that workers and other users can be assured that the same action is required. If you take a simple preventive measure such as ''wash your hands,'' but convey it in several different ways, the reader of the label could think you mean something different. This is one of the advantages of providing the text for these statements in the revised HCS.

It should be noted that it appears that all of the commenters favoring an alternative of less than full compliance with GHS saw the primary benefits of adopting the GHS would be in facilitating international trade. As has been addressed throughout the PEA, however, OSHA has based the benefits of this action on improved communication to workers and to health and safety managers and logistics personnel resulting in improved safe handling of hazardous chemicals, not on the trade benefits which, while recognized, have not been quantified. Therefore, OSHA believes that any grandfathering or exemption related to this rule would result in some of these parties not obtaining the same level of benefits of increased comprehensibility as workers in other types and sizes of workplaces.

OSHA welcomes comments on these issues, but in the absence of a clear case for one of the alternatives presented, OSHA will continue to consider the alternative proposed, full compliance with GHS by all U.S. firms, the best alternative.

OSHA considered one other set of alternatives to the proposed rule: changing the proposed three-year duration of the phase-in. A shorter phase-in period was criticized by all commenters both because of feasibility issues and for radically increasing compliance costs. OSHA did examine the costs and benefits of a longer phase-in, over a five-year period, and found that the longer phase-in would lower annualized costs from $97 million to $88 million per year, but would also lower the annualize benefits from $851 million per year to $693 million per year, with the ultimate effect of lowering net benefits. Even the lowering of costs may be somewhat illusory because these estimates do not take account of the additional confusion caused by having two different systems in place for an additional two years.

I. Environmental Impacts

The provisions of this proposal have been reviewed 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 DOL NEPA Procedures (29 CFR part 11). As a result of this review, OSHA has determined that the proposed standards would 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 proposal would, in addition to increasing employee health and safety, have positive effects on the environment.

J. 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 a proposal, the proposal would not involve any unfunded mandates being imposed on any State or local government entity.

Based on the analysis presented in this preliminary economic analysis, OSHA concludes that the proposal would impose a Federal mandate on the private sector in excess of $100 million in expenditures in any one year. Accordingly, this preliminary economic analysis of the proposed 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)).

K. Sensitivity Analysis

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 benefits for the proposed rule regardless of the individual revisions to costs, benefits, or discount rate. The results of the individual sensitivity tests are summarized in Table VII–8 and are described in more detail below.

In the sensitivity test 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 VII–8, the estimated total costs of compliance would increase by $8 million annually, or by about 8 percent, while net benefits would also decline by $8 million, from $754 million to $746 million annually.

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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					*$97 million*	*$754 million*
Time to Reclassify Chemicals; Revise SDSs and Labels	5.1 hours	100 % increase	$8 million	8%	$105 million	$746 million
Number of SDSs	880,260	50% increase	$5.5 million	6%	$103 million	$748 million
Number of Employers Requiring Training	41.6 million	50% increase	$22 million	23%	$119 million	$732 million
Training Time Per Employee	0.42 hours	100% increase	$44 million	45%	$141 million	$710 million
Benefit				**Percentage Benefit Impact**	**Adjusted Benefits**	
OSHA's Best Estimate of Annualized Total and Net Benefits					*$851 million*	*$754 million*
Reduced Injuries, Illnesses, and Fatalities Relative to HCS Estimate	1%	0.5%	$133 million	16%	$728 million	$621 million
	1%	5%	$1,064 million	125%	$1,915 million	$1,818 million
Savings due to Improved Efficiency in Creating and Revising SDSs	3.2 hours	50% decrease	$8 million	1%	$843 million	$746 million
Savings due to Improved Efficiency of S&H Managers and Logistics Personnel	3%, 15%	67% decrease	$313 million	37%	$538 million	$441 million
Discount Rate	7%	3%	$89 million	12%		$843 million

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In a second sensitivity test, when OSHA increased the estimated total number of affected SDSs addressed by this rulemaking by 50 percent, the

corresponding estimated total cost of reclassification and revision of SDSs and labels increased by 50 percent as well. As shown in Table VII–8, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $5.5 million annually, or by about 6 percent, while net benefits would also decline by $5.5 million annually, from $754 million to $748 million annually.[17]

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 VII–8, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $22 million annually, or by about 23 percent, while net benefits would also decline by $22 million annually, from $754 million to $732 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 VII–8, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by $44 million annually, or by about 45 percent, while net benefits would also decline by $44 million annually, from $754 million to $710 million annually.

OSHA also performed sensitivity tests on several input parameters used to estimate the benefits of the proposed rule. In one sensitivity test on benefits, OSHA reduced its estimate of health and safety benefits of the proposed rule from 1 percent to 0.5 percent of the benefits estimated for the existing HCS. As shown in Table VII–8, if OSHA's estimates of other input parameters remained unchanged, the total estimated benefits of the proposed rule would decline by $133 million annually, or by about 16 percent, while net benefits would also decline by $133 million annually, from $754 million to $610 million annually.

In a second, parallel sensitivity test on benefits, OSHA increased its estimate of health and safety benefits of the proposed rule from 1 percent to 5 percent of the benefits estimated for the existing HCS. As shown in Table VII–8, if OSHA's estimates of other input parameters remained unchanged, the total estimated benefits of the proposed rule would increase by $1,064 million annually, or by about 125 percent, while net benefits would also increase by $1,064 million annually, from $754 million to $1,818 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 VII–8, if OSHA's estimates of other input parameters remained unchanged, the total estimated benefits of the proposed rule would decline by $8 million annually, or by about 1 percent, while net benefits would also decrease by $8 million annually, from $754 million to $746 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 VII–8, if OSHA's estimates of other input parameters remained unchanged, the total estimated benefits of the proposed rule would decline by $313 million annually, or by about 37 percent, while net benefits would also decrease by $313 million annually, from $754 million to $441 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 $73 million per year and increasing the benefits to $916 million per year. The result, as shown in Table VII–8, would be to increase net benefits by $89 million per year, from $754 million to $843 million per year.

OSHA also considered the sensitivity of its findings that the proposed rule is economically feasible and does not have a significant economic impact on a substantial number of small entities. Since the estimated potential negative impacts of the rulemaking are relatively small, these impacts would remain small even with relatively large changes in the input parameters. For example, even if the total estimated costs of compliance were increased by a factor of five, these costs would still represent less than 0.002 percent of revenues, and no industry or size class would have costs in excess of 5 percent of profits or 1 percent of revenues.

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 relatively large uncertainties in the estimates of compliance costs and benefits, 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 firms, and the conclusion that the benefits exceed the costs.

OSHA welcomes input from the public regarding all aspects of this sensitivity analysis, including any data or information regarding the accuracy of the preliminary estimates of compliance costs and benefit and how the estimates of costs, benefits, and economic impacts may be affected by varying assumptions and methodological approaches.

VIII. OMB Review Under the Paperwork Reduction Act of 1995

The proposed modifications to the Hazard Communication Standard would revise 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. The Paperwork Reduction Act defines ''collection of information'' as ''the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public of facts or opinions by or for an agency regardless of form or format.'' (44 U.S.C. 3502(3)(A).) OSHA has submitted the proposed revised Hazard Communication collection of information requirements identified in this NPRM to the OMB for review in accordance with 44 U.S.C. 3507(d).

As part of its continuing effort to reduce paperwork and respondent burden, the Department of Labor conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the PRA–95 (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collections instruments are clearly understood, and OSHA's estimate of burden is accurate. The Department notes that a Federal agency cannot conduct or sponsor a

[17] 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 VII–8, this effect would increase benefits by $8 million annually, more than offsetting the $5.5 million annual cost increase.

collection of information unless it is approved by OMB under the PRA, and displays a currently valid OMB control number, and the public is not required to respond to a collection of information unless it displays a currently valid OMB control number. Also, notwithstanding any other provisions of law, no person 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. OSHA will publish a notice of OMB's action at the final rule stage.

OSHA solicits comments on the modified collection of information requirements and the estimated burden hours associated with these collections, including comments on the following:

- Whether the proposed collection of information requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and cost) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply, for example, by using automated or other technological techniques for collecting and transmitting information.

The title, description of the need for and proposed use of the information, description of the respondents, and frequency of response of the information collections are described below, along with an estimate of the annual reporting burden and cost as required by 5 CFR 1320.5(a)(1)(iv) and 1320.8(d)(2).

Title: Proposed Changes to the Hazard Communications Standard (Globally Harmonized System of Classification and Labeling of Chemicals (GHS)).

Description and Proposed Use of the Collections of Information: The proposed Standard would modify existing information collection requirements that are currently approved under OMB Control Number 1218–0072 (Expiration Date: October 2009). OSHA has submitted the proposed modification of the Hazard Communication Standard to OMB and has requested a new OMB control number addressing the proposed modification. OSHA will maintain OMB approval of the existing collections of information contained in the Hazard Communication Standard, under OMB Control Number 1218–0072.

The proposed revisions to the OSHA Hazard Communication Standard would standardize the hazard communication requirements for products used in U.S. workplaces, and thus provide 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. The proposed revisions would harmonize the U.S. system with international norms and therefore would facilitate international trade. The proposed modifications to the 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 safety data sheets; and (4) related revisions to definitions of terms used in the Standard and to requirements for employee training on labels and safety data sheets.

Paragraph (d), ''hazard classification,'' requires chemical manufacturers and importers to evaluate chemicals produced in their workplaces or imported by them to classify their 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 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 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. A chemical manufacturer or importer of a mixture is responsible for the accuracy of the classification of the mixture even when relying on the classifications for individual ingredients received from the ingredient manufacturers or importers on the safety data sheets.

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);
(vi) Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party; and
(vii) Supplemental information as appropriate.

Information provided under (i) through (v) above must be in accordance with 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 containers of hazardous chemicals that do not fall into one of the new hazard classes, (f)(2) requires that the label include the name of the chemical, the name, address, and telephone number of the manufacturer, importer, or other responsible party, and, as supplementary information, a description of the unclassified hazards and appropriate precautionary measures to ensure the safe handling and use of the chemical.

For labels in the workplace, except as provided in paragraphs (f)(8) and (f)(9) 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 is also proposing 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 health 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 is proposing to modify the language to be compatible with GHS and consistent throughout the OSHA standards. The GHS classification process for a specific substance as proposed in this revision of the HCS will dictate the hazard warnings and the precautionary statements that will be required on the new GHS-compliant 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 proposal modifies the requirements for signs and labels found in the Agency's health standards listed below. Since OSHA is providing 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) product identifier and words, pictures, symbols, or combination thereof, which provide at least general information regarding the hazards of the chemicals.

GENERAL INDUSTRY

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

GENERAL INDUSTRY—Continued

1,3-Butadiene 1910.1051	1218–0170
Methylene Chloride 1910.1052	1218–0179
Hazard Communication 1910.1200	1218–0072

Construction Industry

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

Paragraph (g)(2) requires the chemical manufacturer or importer preparing the safety data sheet (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).

(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.

Note 1 to paragraph (g)(2): To be consistent with the GHS, an SDS must also include the following headings in this order:

Section 12, Ecological information;

Section 13, Disposal considerations;

Section 14, Transport information; and

Section 15, Regulatory information.

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.

(xii) Section 16, Other information, including date of preparation or last revision.

Paragraph (g)(5) requires the chemical manufacturer, importer or employer preparing the safety data sheet 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 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 must 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 must add the information to the safety data sheet before the chemical is introduced into the workplace again.

Paragraph (g)(11) requires that employers ensure the safety data sheets 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).

Affected Public: Business or other for-profit.

Number of Respondents: 90,801 firms producing Safety Data Sheets and labels.

Frequency: One time.

Average Time per Response: Time to convert Safety Data Sheets and labels to the new system ranges from 7 hours for establishments having between 1 to 19 employees; to 3 hours for establishments having greater than 500 employees.

Estimated Total Burden Hours: 2,125,414.

Estimated Costs (Operation and Maintenance): $32,055,258.

Submitting comments. Members of the public who wish to comment on the paperwork requirements in this proposal should send their written comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; *Attn:* OSHA Desk Officer (RIN 1218–AC20). The Agency encourages commenters also to submit their comments on these paperwork requirements to the rulemaking docket, along with their comments on other parts of the proposed rule. Comments may be submitted by using the Federal eRulemaking portal at *http://www.regulations.gov.* Comments and submissions are posted without change; therefore OSHA cautions commenters about submitting personal information such as social security numbers and date of birth. Information on using the *http://www.regulations.gov* Web site to submit comments and access the docket is available at the Web site's ''User Tips'' link. For instructions on submitting these comments to the rulemaking docket, see the sections of this **Federal Register** notice titled **DATES** and **ADDRESSES.**

Docket and inquiries. To access the docket in order to read or download comments and other materials related to this paperwork determination, including the complete Information Collection Request (ICR) (containing the Supporting Statement (describing the paperwork determinations in detail) and

attachments), use the procedures described under the section of this notice titled **ADDRESSES**. To make inquiries, or to request other information, contact Mr. Todd Owen, Directorate of Standards and Guidance, OSHA, Room N–3609, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2222.

IX. Federalism

The Agency reviewed the proposed Hazard Communication Standard according to the Executive Order on Federalism (Executive Order 13132, 64 FR 43255, August 10, 1999). This Executive Order requires that Federal agencies, to the extent possible, refrain from limiting State policy options, consult with States before taking 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 Executive Order 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. Section 18 of the Occupational Safety and Health Act (the ''Act'' or ''OSH Act''), 29 U.S.C. 667, expresses Congress' clear intent to preempt State laws with respect to issues for which OSHA has promulgated an occupational safety and health standard under section 6 of the Act. Under section 18 of the Act, a State may avoid preemption only if it submits and obtains OSHA approval of an occupational safety and health plan. *See Gade* v. *National Solid Wastes Management Association,* 112 S. Ct. 2374 (1992).

With respect to States that do not have OSHA-approved plans, the Agency concludes that this proposal falls under the preemption provisions of the Act. Additionally, section 18 of the Act prohibits States without approved plans from issuing citations for violations of OSHA standards; the Agency finds that this proposed rulemaking does not expand this limitation. OSHA has authority under Executive Order 13132 to propose a Hazard Communication Standard because the problems addressed by these requirements are national in scope.

Section 18(c)(2) of the Act permits State-plan states to develop their own requirements to deal with any special workplace problems or conditions, provided, inter alia, these requirements are at least as effective as the Federal standards promulgated under section 6 of the Act. Although a State standard becomes effective in accordance with State promulgation provisions, and is enforceable upon promulgation, OSHA must also review and approve the standard to assure that it is ''at least as effective'' as the Federal standard. OSHA intends to closely scrutinize State hazard communication standards submitted under current or future State plans to assure 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 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).

X. State Plans

The 26 States and territories with their own OSHA-approved occupational safety and health plans must adopt comparable provisions within six months after the Agency publishes a final standard. These States and territories 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, Virgin Islands, Washington, and Wyoming. Connecticut, New Jersey and New York have OSHA approved State Plans that apply to State and local government employees only. Each state-plan State's existing requirements will continue to be in effect until it adopts the required revisions.

XI. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532, an agency must prepare a written ''qualitative and quantitative assessment'' of any regulation creating a mandate that ''may result in the expenditure by the State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more'' in any one year before issuing a notice of proposed rulemaking. OSHA's proposal 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, the proposal would 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 of the expected impacts associated with a proposal, the proposal does not trigger the requirements of UMRA based on its impact on State, local, or tribal governments.

Based on the analysis presented in the Preliminary Economic Analysis (section VII above), OSHA concludes that the proposal would impose a Federal mandate on the private sector in excess of $100 million in expenditures in any one year. The Preliminary Economic Analysis constitutes the written statement containing a qualitative and quantitative assessment of the anticipated costs and benefits required under Section 202(a) of UMRA (2 U.S.C. 1532).

XII. Protecting Children From Environmental Health and Safety Risks

Executive Order 13045 requires that Federal agencies submitting covered regulatory actions to OMB's Office of Information and Regulatory Affairs (OIRA) for review pursuant to Executive Order 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. Executive Order 13045 defines ''covered regulatory actions'' as rules that may (1) be economically significant under Executive Order 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). The proposed HCS is economically significant under Executive Order 12866 (see section VII of this preamble). However, after reviewing the proposed HCS, OSHA has preliminarily determined that the standard would not impose environmental health or safety risks to children as set forth in Executive Order 13045.

XIII. Environmental Impacts

The Agency reviewed the proposed Hazard Communication Standard 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 made a preliminary determination that the proposed HCS 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 the proposed HCS would have no significant environmental impacts.

XIV. Public Participation

OSHA encourages members of the public to participate in this rulemaking by submitting comments on the proposal.

Written Comments. OSHA invites interested persons to submit written data, views, and arguments concerning this proposal. In particular, OSHA encourages interested persons to comment on the issues raised in section II of this preamble. When submitting comments, persons must follow the procedures specified above in the sections titled **DATES** and **ADDRESSES**. The comments must clearly identify the provision of the proposal you are addressing, the position taken with respect to each issue, and the basis for that position. Comments, along with supporting data and references, received by the end of the specified comment period will become part of the record, and will be available for public inspection and copying at the OSHA Docket Office as well as online at *www.regulations.gov* (Docket Number H022K–2006–0062).

Informal Public Hearing. Pursuant to section 6(b)(3) of the Act, members of the public will have an opportunity to provide oral testimony concerning the issues raised in this proposal at informal public hearings. The hearings will be announced in the **Federal Register**.

XV. Summary and Explanation of the Proposed Standard

The advance notice of proposed rulemaking (ANPR) published by OSHA on September 12, 2006 (71 FR 53617) included a series of questions to solicit information on a number of specific topics. The responses from more than 100 commenters have been used by the Agency to help prepare the required analyses for this rulemaking, as well as to make determinations regarding the proposed text. The discussion below on each paragraph of the proposed standard addresses the comments that were related to those subjects, and the discussion on the regulatory impact analysis in Section VII of this preamble refers to responses related to that topic.

In addition to the responses to specific questions in the ANPR, OSHA has also received general comments covering topics such as statements of support for the rulemaking, approaches or principles to follow in the rule, suggestions for outreach and compliance assistance, and other subjects of concern. Before addressing the specific paragraphs of the proposed rule, we would like to discuss these general comments.

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 out numbered those who opposed or questioned adoption (*see, e.g.,* Document ID #s 0003, 0007, 0047, 0050, 0052, 0062, 0106, 0011, 0033, 0038, 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 #s 0046, 0059, 0081, and 0038); will help to ensure that employees have reliable, consistent, comprehensive and comprehensible information (*e.g.,* Document ID #s 0054, 0030, 0037, and 0124); will help to enhance human health and the environment (improved worker safety) *(e.g.,* Document ID #s 0064, 0081, 0032, and 0128); and will reduce burdens associated with preparing multiple classifications and labels for the same product (*e.g.,* Document ID #s 0048, 0080, 0030, and 0123).

Support for implementation of the GHS by OSHA was expressed by both users and producers of chemicals. For example, the Aerospace Industries of America, Inc., representing companies that are generally large users of chemicals, identified many of these benefits in its statement of support (Document ID # 0054):

> AIA supports OSHA's current efforts to adopt the GHS and its past participation in the development of the UN's GHS for classification and communication of chemical hazards. We believe that the GHS adoption will help bring consistency and clarity to national and international regulation of hazardous chemicals and will help ensure that employers and employees have reliable, consistent, and comprehensive information on hazardous chemicals in the workplace. With the great diversity in the current systems of hazard communications globally, where MSDSs and chemical labels and classification systems vary in content details and length, type of information, format, and depth of hazard warnings and procedures, there is often inconsistency, redundancy, and incompatibility in labels developed by manufacturers and distributors. This often results in confusion for workers who try to interpret the MSDSs and labels, particularly across differing industry sectors and geographic areas where language, culture, and levels of experience and training may vary. OSHA's proposal to adopt applicable provisions of the GHS into the U.S. workplace is a positive step in working toward developing standardized, uniform, classification, labeling, and related procedures for worker hazard communications systems.

The United Parcel Service, Inc., also a user of chemicals as well as a transporter, supported implementation of the GHS too (Document ID # 0064):

> UPS is pleased to support OSHA's adoption of the GHS and applauds the publication of the ANPRM as an important step toward implementation. We believe that the implementation of the GHS has the potential to (1) contribute to the safety of workers through standardized and more easily understood Safety Data Sheets (''SDSs''); (2) streamline domestic hazard classification and labeling across all pertinent U.S. agencies (OSHA, EPA, DOT, CPSC); and (3) facilitate international trade in chemical-based products by harmonizing hazard communication requirements across national borders. UPS also recognizes that the current HAZCOM standard, while not perfect, has helped promote the safety and health of American workers. We believe that OSHA can reap the benefits of the GHS without compromising the substantial benefits of the existing HAZCOM regime.

The American Federation of Labor and Congress of Industrial Organizations (AFL–CIO), representing employees exposed to chemicals in the workplace, also recognized the value of revising the HCS to adopt the GHS provisions (Document ID # 0124):

> [T]he GHS offers a standardized and specific approach to the creation of labels and Safety Data Sheets (SDS), with a set format, content and order. Additionally, the GHS has an established set of hazard criteria and employs the use of standardized pictograms. We believe these elements of the GHS, when incorporated into the HCS, will assist greatly in generating labels and SDS's

that are vastly more consistent and comprehensible in comparison to the current MSDS's and labels. The improved consistency will also increase the ability to communicate the hazard information to workers. The AFL–CIO fully supports the efforts of OSHA to modify the HCS so that these objectives are realized.

Similarly, DuPont, a major chemical manufacturer, also expressed its support for pursuing harmonization through adoption of the GHS (Document ID # 0038):

DuPont supports OSHA adoption of the GHS and the publication of this ANPRM as a concrete step towards implementation of the GHS in the United States. DuPont urges OSHA to use the information received in response to this ANPRM and move quickly and judiciously to the next step towards a globally harmonized system—publication of a proposed rule. DuPont believes that implementation of the GHS will mean that workers who must handle hazardous chemicals will find hazard information presented in a standardized and more comprehensible manner. DuPont also believes that implementation of the GHS will ultimately reduce the costs to businesses of classifying chemicals as to their hazards and creating warning labels and safety data sheets.

While support for implementation of the GHS was widespread in the 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 #s 0032, 0111, 0155, 0157, and 0162). As will be addressed in other parts of this preamble, OSHA also recognizes the costs associated with implementation of the changes necessitated by adoption of the GHS, and has taken a number of steps to address them, including those recommended by these and other commenters.

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). The GHS was designed in this manner because the existing systems all had scope accommodations for different sectors. For example, the most notable difference among sectors involves transport of dangerous goods and the workplace. In the transport sector, only those hazards which involve the types of exposures expected to be encountered in transport are covered. In the area of health effects, this has been defined as acute health effects, and the transport sector does not include any chronic health hazards in its coverage. Representatives of transport authorities involved in the negotiations indicated that this coverage was considered appropriate, and the building block concept that allowed them to continue to have that scope was necessary to include transport within the GHS. On the other hand, workplace authorities are concerned about chronic health hazards occurring as a result of workplace exposures, and expected the GHS to include those types of effects. Thus the GHS does not specify that all provisions should be applied to all sectors.

However, as will be addressed below in specific paragraphs where this may be a concern, OSHA does not presently preclude employers from including additional information on labels and safety data sheets to address areas that are not covered by OSHA, and would not do so when implementing the proposed revisions. For example, where employers are preparing labels and SDSs for products that will be marketed in both the consumer and the workplace sector, additional information on acute toxicity at lower levels of concern may be included for the consumer sector without violating any current or proposed OSHA requirements. Similarly, information regarding transportation and environmental concerns may be included on SDSs required by OSHA. However, the Agency only enforces the standard with regard to the information required under its own provisions. The same situation would apply in implementation of the proposed revisions.

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 #s 0004, 0065, 0068, and 0108). These commenters argued that it would be too financially 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).

With regard to the costs and economic impacts, OSHA has prepared extensive analyses of the costs, benefits, and economic impacts of the rules, which are summarized in Section VII of this preamble. The Agency has preliminarily concluded that the draft proposed standard is an economically significant rule under E.O. 12866 in that the costs exceed $100 million in each of the first three years. However, OSHA will certify that a regulatory flexibility analysis is not necessary under the Regulatory Flexibility Act (RFA), because although the proposed standard will affect a substantial number of small firms, the impacts do not rise to the level of significance that would require a regulatory flexibility analysis under the RFA.

Section VI of the preamble addresses the legal authority of the Agency to pursue this rulemaking. OSHA believes that adoption of the GHS through rulemaking is the appropriate mechanism to achieve this increased protection for exposed employees as well as global harmonization, and that a treaty is not the only means to accomplish this goal. More importantly, however, adoption of the GHS through rulemaking does not delegate ''power to an international body'' as argued by the National Association of Home Builders (Document ID # 0065). NAHB also argues that the proposal would allow hazard determinations ''to be based on something other than fact and scientific evidence.''

This rulemaking process is the legal means to modify the current HCS requirements to make them consistent with GHS. Promulgation of the GHS modifications and implementation of the revised HCS will be by OSHA under the Agency's authority in the OSH Act. No international body will dictate the terms of the adoption. Moreover, there will be no international body with any authority in American workplaces with regard to hazard communication. Furthermore, the hazard determination process under the HCS is currently based on an evaluation of scientific facts and evidence, and would continue to be so under the revised HCS as proposed. The proposed revisions simply provide more extensive guidance on the scientific approach to hazard classification to help ensure a consistent evaluation process by multiple chemical manufacturers. As will be discussed in other parts of this preamble, OSHA believes that adoption of the GHS would lead to increased accuracy and reliability in evaluations of scientific evidence, and thus better information for employers and employees to use to protect them in the workplace.

OSHA believes that arguments presented in this preamble, and the accompanying analyses, indicate that pursuing modifications to the HCS will

enhance employee protection, as well as ultimately facilitate compliance for all companies including those in the construction industry that use hazardous chemicals.

Therefore, while OSHA did not include questions regarding the support of stakeholders for adoption of the GHS, it is clear that a majority of those responding to the ANPR support moving forward with the rulemaking. The arguments presented by those few who actively objected to adoption have been addressed in this preamble and the analyses for the rule, and have not been found persuasive. Other issues raised by supporters as concerns or suggestions for addressing concerns, have also been addressed in the proposed rule. While OSHA has addressed many of the identified issues in the proposal, the Agency recognizes that stakeholder input is needed to resolve some of the concerns, and these have been described in Section II.

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. 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 #s 0047, 0080, 0104, 0123, 0145, 0163, 0167, and 0170). For example, ORC Worldwide (Document ID # 0123) stated:

> * * *[O]SHA 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.

As will be described in greater detail below with regard to specific provisions, OSHA has made every effort to maintain the framework of the current HCS in the proposed revisions. The modifications proposed are believed by OSHA to be those that are required to align the current HCS with the GHS, but do not address provisions of the current standard that are not addressed in the GHS. Thus, for example, the scope and application paragraph remains largely unchanged, as does the paragraph addressing trade secret protection. The primary modifications proposed in these paragraphs are changes in terminology required to ensure consistency.

Many commenters 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 #s 0048, 0050, 0053, 0076, 0104, 0111, 0123, 0134, 0154, 0162, and 0170). Others mentioned the Mine Safety and Health Administration (MSHA) (Document ID #s 0049, 0101, and 0111). 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.

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 78595). EPA and CPSC have not initiated rulemaking on the GHS. Thus at this point, there is little to coordinate in terms of timelines. 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 also argued that OSHA should coordinate implementation with major U.S. trading partners (*see, e.g.,* Document ID #s 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 #s 0042, 0018, 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.

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 Subcommittee of Experts on the GHS, as well as the UNITAR Programme Advisory Group. There is increased emphasis in the Subcommittee on implementation issues as well as coordination. OSHA led a correspondence group that reviewed implementation of the mixture classification provisions, and modifications to address concerns raised were incorporated into Revision 3 of the GHS to help ensure consistency in approach. OSHA will continue to lead a correspondence group on practical classification and hazard communication issues. In addition, the Subcommittee has established a correspondence group to address broader implementation issues, and OSHA is participating in those deliberations as well.

The Agency has also had bilateral discussions in the past with Canada, as well as the European Union (EU), on issues related to implementation. These are two of the key trading partners for the U.S. The EU has recently revised its overall approach to the regulation of chemicals in a new European Community Regulation (EC 1907/2006) referred to as REACH: Registration, Evaluation, Authorization and Restriction of Chemical substances. The new law entered into force on June 1, 2007, and the provisions will be phased in over 11 years. REACH addresses chemical hazards over the life cycle of a chemical, and gives greater responsibility to industry to manage the risks from chemicals and to provide safety information on substances. Manufacturers and importers will be required to gather information on the properties of their chemical substances,

which will allow their safe handling, and to register the information in a central database run by the new European Chemicals Agency (ECHA). The Agency will act as the central point in the REACH system: it will manage the databases necessary to operate the system, coordinate the in-depth evaluation of suspicious chemicals, and run a public database in which consumers and professionals can find hazard information.

On September 3, 2008, the EU Parliament completed revisions to its longstanding chemical classification and labeling approach to align with the GHS (referred to now as the European Regulation on the Classification, Labelling, and Packaging of Substances and Mixtures). It applies to substances as of December 1, 2010, and mixtures as of June 1, 2015. The final version was published in the EU Official Journal on December 31, 2008.

In terms of these proposed provisions, OSHA examined the European Commission's regulation 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 is based on Revision 3 of the GHS. Revision 3 was adopted by the UN Subcommittee of Experts on the GHS (UNSCEGHS) in December 2008. A compilation of the approved changes is available on the UN Web site (ST/SG/AC.10/36/Add. 3), and the full text of Revision 3 will be accessible later this year. There are a number of clarifications and small modifications in Revision 3 that address inconsistencies or discrepancies in the previous text of the GHS, and these have been incorporated into this proposal.

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, OSHA has rulemaking options available that can be utilized to implement the changes and can be done 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 also 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.

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 commenters (*see, e.g.,* Document ID #s 0047, 0065, 0081, 0104, 0018, 0025, and 0154), OSHA will continue working with its partners, alliances and other 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.

With regard to the questions on the media through which to distribute materials, all of the methods mentioned in the ANPR received considerable support. In addition, a number of commenters indicated that all types of distribution systems should be used to reach the widest audience, including the Web site, electronic tools, PowerPoint presentations, flash videos, a dedicated web page, mail, train-the-trainer sessions, regional workshops, *etc.* All of the possible subjects suggested by OSHA (*e.g.,* hazard classification, labels, and safety data sheets) were also endorsed as being of interest.

Many commenters agreed with OSHA that training on understanding pictograms and symbols, as well as hazard statements, signal words, labels, and SDSs, would be useful for both small businesses and employees (*see, e.g.,* Document ID #s 0044, 0061, 0072, 0028, 0034, 0107, 0139, 0163, and 0170). There were also several recommendations that OSHA prepare a poster with the pictograms that can be displayed in workplaces (Document ID #s 0046, 0047, 0064, 0028, 0123, and 0171).

In addition, it was suggested that training on classification procedures, particularly for mixtures, would be useful, as would software that could complete mixture calculations (*see, e.g.,* Document ID #s 0046, 0054, 0032, 0038, 0128, 0140, and 0154). And a number of respondents believe that OSHA should develop a series of training modules on different aspects of the revised HCS (Document ID #s 0047, 0051, 0080, 0025, and 0135), and provide training online (Document ID #s 0059, 0032, 0125, 0129, 0155, and 0157).

Commenters also suggested that OSHA prepare a comprehensive comparison of the current standard to the revised HCS when completed (Document ID #s 0054, 0135, and 0145), as well as a reference table with different requirements around the world (Document ID #s 0047, 0080, 0123, and 0171). It was also noted that materials should be available in multiple languages (Document ID #s 0046 and 0080).

Other ideas presented included electronic seminars (Document ID # 0064); model programs (Document ID #s 0064, 0076, 0080, 0029, and 0124); toolbox talks (Document ID # 0065); Quick Cards (Document ID # 0065); online inventory lists (Document ID #s 0076 and 0178); Q and A document (Document ID #s 0072 and 0160); hotline (Document ID #s 0077, 0104, 0179, 0140, and 0163); GHS resource CD (Document ID #s 0021 and 0155); SDS template (Document ID #s 0144 and 0145); timely compliance directive (Document ID # 0124); and approximate conversion table for classifications (Document ID #s 0145 and 0163).

The proposed standard. The following is a description of the provisions of the proposed standard. Comments received that were related to the proposed provisions are also addressed.

(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 material 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 revision to HCS has essentially the same purposes, and OSHA is proposing only minor modifications to this paragraph. Paragraph (a)(1)would 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 is proposing 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'' has been modified to ''safety data sheet'' to reflect the terminology of the GHS.

The only modifications proposed to paragraph (a)(2) also address terminology, using ''classifying'' instead of ''evaluating'', and ''safety data sheet'' instead of ''material safety data sheet''.

There were no specific comments received in response to the ANPR regarding the Purpose paragraph of the HCS. 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 #s 0178, 0111, 0134, and 0164). 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. While the HCS itself requires 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. All information available to an employer when designing an appropriate protective program must be used, 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 hazards of chemicals based on 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 proposal 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 not generally result in a need to change engineering controls or respiratory protection.

It is possible that a chemical may be classified under the proposal 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 noted what they believed to be the continued need to address the preemption of State standards (*see, e.g.,* Document ID #s 0048, 0056, 0080, 0178, 0036, 0123, and 0135). 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 #s 0042, 0072, 0015, and 0038).

It was also indicated that changes in State laws should be coordinated with the Federal changes to facilitate implementation (Document ID # 0146). See Section IX and X of this preamble for a comprehensive discussion regarding Federalism and State plans.

(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. There was one comment received regarding this paragraph which indicated that hazard classification and labeling of steel for chronic health effects should not result from welding being considered a normal condition of use (Document ID # 0160). OSHA has made it clear in past interpretations of the rule that where such products are intended to be welded, this information must be provided for hazard communication purposes. That

interpretation does not change as a result of the proposed provisions in the revised rule.

In general, OSHA does not expect significant changes in the chemicals covered by the HCS under the proposed revisions 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 (ANSI Z129) that many manufacturers follow in their labeling programs, 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 proposal 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 a strict percentage cut-off of 1%. Other definitions of health hazards would maintain the current broad HCS scope.

In addition to the overall scope statement, the HCS provides for limited coverage in workplace situations that have special circumstances, including laboratories and work operations where employees only handle chemicals in closed containers.

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), or completely exempting the product (such as hazardous waste regulated by EPA). 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 has reviewed the current provisions of paragraph (b), and has determined that no significant changes are required to be consistent with the GHS. Several minor changes to revise terminology are proposed (involving the terms ''classifying'' and ''safety data sheets''), but OSHA is not proposing to modify 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). As is discussed elsewhere in this preamble, new outreach and compliance assistance materials are being prepared to replace this appendix and other existing outreach materials.

Several commenters 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 #s 0049, 0134, and 0164). All of these situations are already addressed in paragraph (b), and OSHA does not believe it is necessary to change them.

In terms of non-isolated intermediates, the overall scope provision in paragraph (b)(2) adequately addresses this situation. This was specifically addressed in the preamble to the 1983 final rule (48 FR 53335):

> 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).

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 proposed revised rule. As indicated in the ANPR, the Agency does not intend to change those parts of the HCS that are not affected by the GHS.

One commenter indicated that the revised HCS should indicate that it does not apply fully to State prison inmates because the GHS information would give them data that could be used illegally, and perhaps lead to harm (Document ID # 0069). Generally speaking, State prison inmates are not directly subject to Federal requirements under OSHA, although such requirements may be applied to them under State laws or the provisions of another Federal agency. This comment regarding limitations needed for inmates should be addressed in those jurisdictions, but nothing in these revisions would substantially change the application of the HCS to them.

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 #s 0072 and 0179). As OSHA indicated in the ANPR, it 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, in fact, continue to voluntarily include such data on their labels and safety data sheets to meet the requests of their domestic and international customers.

(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 has retained as many definitions as possible from the current HCS. Changes are proposed only when there is a new term used that needs to be defined, or there is a different definition in the GHS, and consistency with the international definition is needed for harmonization purposes. As with the preceding paragraphs, minor modifications have

been proposed to ensure terminology is appropriate—primarily the use of terms related to classification and safety data sheets.

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 maintain 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 proposed regulatory text, similar to the use of it in the current HCS. However, the proposed 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.

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.

OSHA is also proposing to maintain the term ''hazardous chemical'' 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, and to add the coverage of unclassified hazards as those terms are defined in a new definition explained below. This term will be used throughout the standard to indicate that the classification process is completed, and the chemical manufacturer has determined that the chemical poses a hazard—either by meeting the requirements for a physical or health hazard or by virtue of being considered an unclassified hazard under this section. Most of the substantive requirements of the rule apply to hazardous chemicals.

Another proposed modification to the definitions paragraph is to move the physical hazard definitions to an appendix. In the current HCS, health hazard definitions are addressed specifically in Appendix A to the rule, but the physical hazard definitions were included in paragraph (c). In the proposed revisions, health hazard definitions will continue to be addressed in Appendix A, but a new Appendix B will address physical hazards. Both of these appendixes will be discussed below under the summary and explanation of ''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 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 is proposing to add a definition for the term ''classification'' in order to ensure that the meaning of this term is clear. Consistent with the definition of classification in the GHS, the proposed definition of ''classification'' is ''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, and the degree of hazard where appropriate, by comparing the data with the criteria for health and physical hazards.'' 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.

In addition to the definition of classification, OSHA has proposed a definition 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, acute oral 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.'' These definitions are also taken from the GHS.

OSHA is proposing to modify the term ''health hazard'' to reflect the specific hazards defined in the GHS. While the overall scope of what is covered is expected to be 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'' is 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 toxicity. The criteria for determining whether a chemical is classified as a health hazard are detailed in Appendix A, Health Hazard Criteria.''

A revised definition of ''physical hazard'' is also 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 somewhat differently. The definition proposed for ''physical hazard'' is ''a chemical which 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 water-activated flammable gas.'' In addition, the definition refers to Appendix B, Physical Hazard Criteria, for details.

The definition of ''label'' in the GHS is slightly different than what is currently in the HCS, and OSHA is proposing to modify the HCS to be consistent. Thus the proposed definition of ''label'' 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 HCS, and includes certain core information that must be presented. Thus a definition for ''label elements'' is also proposed, and it would mean ''the specified pictogram, hazard statement, signal word, and precautionary statement for each hazard class and category.'' ''Safety data sheet (SDS)'' is defined 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 are also proposed to be added to the HCS. These include ''hazard statement'', ''pictogram,'' ''precautionary statement,'' ''product identifier,'' and ''signal word.'' These proposed 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.

''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.'' 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. The workplace pictograms will be a black symbol on a white background with a red diamond border frame. Some commenters noted that the frame should be permitted to be black for domestic shipments as allowed under the GHS (*see, e.g.,* Document ID #s 0032 and 0163). However, as described in Section V of this preamble, there are clear benefits associated with the use of the red frame in terms of recognition and comprehensibility. Thus OSHA is proposing to only allow the red frame to be used, whether the shipment is domestic or international.

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 are 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 employees will already be familiar with them.

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 revised HCS. 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 have not previously been required under the 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 Subcommittee, are assigned to the appropriate hazard class and category, and have been translated into six languages. Work continues on them in the Subcommittee to combine or edit the precautionary statements to reduce repetition and 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 has decided to use those currently 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.

Container labels will also be required to include a ''product identifier.'' The proposed definition for this term is ''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'' to maintain this approach.

Another new concept being proposed 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 is proposing 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 these criteria are sufficient to cover the hazards present in the workplace. While the Agency believes the scope of coverage is similar between the two approaches, OSHA wants to be sure that the new approach is as comprehensive as the existing standard. The primary hazard addressed by respondents to this question was combustible dust. As will be discussed later in this preamble, OSHA has proposed that the United Nations add criteria for combustible dust to the GHS, so this issue should be resolved in the future by having the necessary criteria. Another potential example is simple asphyxiation. The only specific reference to this effect in the GHS is in the part of the SDS that covers hazards that do not result in classification—suffocation is listed as an example. The definition of ''unclassified hazard'' could be used in this situation as well. Alternatively OSHA is considering proposing a definition and label elements as discussed in the issues section.

It is possible that there are other hazards that may not yet be specifically defined. The addition of the definition for unclassified hazards is 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 will capture those hazards to ensure that the modified HCS 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. Addition of the definition of ''unclassified hazards'', and specific recognition of the need to provide information when such effects arise, should help U.S. industry address its product liability concerns as well as protect exposed workers.

OSHA would require the chemicals posing unclassified hazards to be treated as hazardous chemicals under the rule. The Agency anticipates 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 it is included in Appendix D of this proposal as unclassified hazard. In terms of labeling, there would be no specified label elements for chemicals that pose unclassified hazards. The label for such hazards must describe the hazardous effects under supplementary information on the label, as well as provide any appropriate precautionary information. OSHA also expects that such hazards would be addressed in worker training programs.

The Agency anticipates that there will be relatively few situations where there will be scientific evidence or data indicating a hazard that is not currently classified, but wants to ensure that this information is captured and conveyed to employers and employees. It appears that it would also be appropriate to establish a feedback mechanism so in the future, classifiers can inform OSHA of these 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 is proposing 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 should be a temporary situation for these hazards, ensuring information is provided until such time as the criteria are added to the rule. OSHA is requesting additional input on this approach in the issues section.

OSHA is not proposing to revise the other terms currently defined in the HCS. In addition, the GHS includes a number of definitions that did not appear to be necessary for inclusion in the revised HCS and as a result have not been addressed here.

(d) Hazard classification.

Hazard determination under the current standard. Under the existing HCS, chemical manufacturers and importers are required to evaluate the scientific data available regarding the chemicals they produce or import, and determine whether they are 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 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 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 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 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 (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 includes 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 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. OSHA is proposing to reinstate the requirement and lift the stay, making the updating period consistent with that required for safety data sheets, and invites comments on this issue.

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 Annual Report on Carcinogens, 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 existing 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 is 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 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 existing 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 HCS does not require testing of chemicals to produce information where it is not available.

The hazard determination approach in the 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 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 HCS, including the definitions and Appendixes A and B, have been in place since the standard was promulgated in 1983. Therefore, the intent to design an approach that was dynamic and would remain current through changes in the workplace appears to have been accomplished.

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 existing 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., OSHA is proposing to modify the HCS as follows. First, paragraph (d) would be re-named ''hazard classification'' rather than the current ''hazard determination.'' This is to be consistent with the approach and terminology used in the GHS. Similarly, paragraph (d)(1) would be modified to indicate that chemical manufacturers and importers would be required to:

* * * [c]lassify their health and physical hazards in accordance with this section. For each chemical, the chemical manufacturer or importer shall determine which hazard classes, and the category of each class, that apply to the chemical being classified.

Paragraph (d)(1) would continue to allow employers to rely on information received from suppliers.

Paragraph (d)(2) would be similarly modified to use terminology regarding classification. However, the 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, new 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.

Proposed paragraph (d)(2) also refers to Appendixes A and B for further information on classification as in the current standard. However, the proposed Appendixes have been completely changed from the current text. New Appendix A would include the criteria for classification of health hazards, and new Appendix B would include the criteria for classification of physical hazards. These mandatory appendixes would have to be used for the hazard classification process under the proposed revised standard.

Reference to these appendixes is also included in new paragraph (d)(3), which addresses mixtures. This proposed paragraph re-emphasizes 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. In addition, this proposed paragraph indicates that chemical manufacturers or importers would maintain the overall responsibility for the accuracy of their hazard classifications for mixtures even if they rely on ingredient information received from a supplier.

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 is widely pursued, but it would not be permitted under the proposal. The revisions to the approach to classifying mixtures would not lend itself 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 proposed revisions because the hazard classification procedures have been specified, and thus all evaluators are following the same process.

Proposed 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 chemical and that chemical 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 proposed revisions only apply to chemical manufacturers and importers, unless an employer chooses not to rely on information received from them.

Appendix A, Health Hazards. Proposed Appendix A begins 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. 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. Generally speaking, OSHA has proposed the language from Chapter 3 regarding the criteria for classification to minimize deviations from the GHS approach. However, each of the hazard discussions has been reviewed carefully within the context of the HCS, and there has been some editing by OSHA. This has been primarily to shorten the discussions where possible to delete any portions that do not relate specifically to the method of classification for either individual substances or mixtures. Thus OSHA has removed the decision logics that are in the GHS from the proposed criteria, and is considering including them in a guidance document to be made available at the time a final rule is published. The hazard communication portions of the criteria chapters have also been removed since all of this information is already available in proposed Appendix C and is thus duplicative. In addition, as discussed further below, edits have been made where OSHA has not proposed to adopt all of the categories of a particular hazard class.

The chapters on Skin Corrosion/Irritation and Serious Eye Damage/Irritation 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 review these chapters to edit them and make them easier to follow. OSHA will be participating in this activity.

Each proposed hazard class discussion includes the criteria for classifying a substance or a mixture. Unlike the HCS, which defines across-the-board percentage cut-offs for all 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-off values/concentration 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 is related to the sensitivity of available test methods to detect these types of effects at small concentrations in the mixture as a whole.

This 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 1% of an acutely toxic material, regardless of the severity of that effect, and it is diluted with 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.

There are several hazard classes in the GHS that give competent authorities such as OSHA a choice of concentration limits to apply when classifying a mixture containing ingredients that pose these effects (*e.g.,* reproductive toxicity, sensitization, target organ effects). OSHA is proposing to use the most protective of the available concentration limits for these hazard classes, and require 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. 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.

In determining which categories to propose to adopt, OSHA employed two primary principles in reviewing them. First, the Agency tried to maintain a scope as consistent as possible with the current scope of the HCS, in particular to maintain the level of protection in keeping with that principle established to guide the harmonization process (*see* Section III)(an approach specifically supported by Document ID #s 0021, 0163, and 0170). Second, consistent with comments received and discussed previously in this preamble (*e.g.,* Document ID #s 0104, 0128, 0155, and 0171), OSHA reviewed what major trading partners of the U.S. have indicated they are proposing to adopt—in particular, the EU since they have already adopted an approach. Where possible, and appropriate in terms of maintaining protections and an appropriate scope for the workplace, OSHA has sought to be consistent with these other proposed approaches for the workplace.

All of the health hazard classes in the GHS have been proposed to be adopted in the HCS. However, for acute toxicity, OSHA is proposing to adopt Categories 1 through 4, but not 5. (See Appendix A.1 for a detailed explanation of acute toxicity categories and their corresponding cut-offs.) 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 3 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, those chemicals are already covered by the EU under their existing 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.

Coverage of 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, 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 #s 0046, 0047, 0077, 0104, 0021, 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 #s 0054, 0034, 0128, and 0141). Some argued that all categories should be adopted to ensure harmonization (*see, e.g.,* Document ID #s 0050, 0078, 0106, 0018, 0036, and 0116).

As indicated, OSHA believes that coverage of 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 of Category 5, OSHA would not preclude inclusion of information on Category 5 on the label or the SDS when implementing the proposed revisions. 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.

While OSHA has chosen not to adopt Category 5 for the reasons described, and it does not appear in the Table A.1.1, Paragraph A.1.3.6.1(a) requires that the calculation of acute toxicity for mixtures ''[i]nclude ingredients with a known acute toxicity, which fall into any of the GHS acute toxicity categories.'' The intent of this provision in the GHS was to include data on substances classified as Category 5 in the mixture calculation. The exclusion of Category 5 from the text of the acute toxicity table will likely mean that classifiers could overlook substances falling into this category in the mixtures calculation, resulting 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. The European Union GHS system excluded Category 5 for all sectors, and has explicitly excluded Category 5 data from the mixture calculation. OSHA invites comment on whether Category 5 data should be included in the calculation of the acute toxicity of mixtures, and whether exclusion of these data presents a significant difference in hazard classification.

OSHA is also not proposing to adopt Category 3 for skin corrosion/irritation. This particular category appears to cover much more than the current criteria for this hazardous effect under the 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 comments supporting such an approach (Document ID #s 0077, 0034, 0128, 0145, and 0171). This approach is also consistent with the European Union.

OSHA has also not proposed to adopt Category 2 for aspiration hazards covered by the GHS. This category appears 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 commenters suggested that Category 2 not be covered when aligning the HCS with the GHS (Document ID #s 0077, 0034, 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 #s 0102, 0104, and 0163). However, OSHA believes that accidental aspiration is possible in the occupational setting, and thus has proposed to adopt the criteria for Category 1.

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 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 as DOT has in this rulemaking will thus have the additional benefit of accomplishing substantial domestic harmonization.

As with Appendix A and the health hazard criteria, OSHA has edited Chapter 2 of the GHS to shorten the discussions and focus only on the criteria in the proposed revisions. Decision logics and hazard communication information are not included. OSHA is considering a guidance document with the decision logics to be made available when a final rule is completed, and the hazard communication information is already in proposed Appendix C, so to include it in Appendix A would be duplicative.

As with health hazards, OSHA is trying 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 proposing to adopt 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. Given the current coverage of the HCS, not covering Category 4 would be a reduction of protection that OSHA does not believe is appropriate. Thus we are proposing to include coverage of Category 4 in the 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.

While OSHA believes that harmonizing with DOT provides significant benefits, there are some concerns regarding this approach that have arisen in reviewing the physical hazard criteria. These concerns involve 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 invites comment on this issue, both in terms of the appropriateness of the criteria as drawn (including the test methods and references to packaging or volume), and any suggestions that interested parties have to address these issues. The criteria of particular interest involve those for self-reactive chemicals, organic peroxides, self-heating chemicals, and explosives.

OSHA raised as an issue for comment in the ANPR the impact of changing

some of the physical hazard criteria in other OSHA standards that rely on HCS definitions (for example, process safety management). Many comments were received on this issue (*see, e.g.,* Document ID #s 0042, 0076, 0077, 0015, 0024, 0108, 0128, 0145, and 0163). While opinions varied, generally the consensus was that OSHA needed to make the standards consistent.

OSHA has reviewed all of its other standards, and the possible impact of aligning the HCS with the GHS on those rules. The Agency is proposing changes to some of these other rules, and discusses elsewhere in this preamble the actions it has determined are appropriate to address this issue.

Combustible dust. In the ANPR, OSHA asked for comments on the scope of health and physical hazards covered by the HCS and the GHS. In response, several commenters addressed the issue of combustible dust. There is no specific definition of combustible dust in the HCS, nor is there one in the GHS. A number of explosions have occurred in workplaces due to an accumulation of combustible dust. The U.S. Chemical Safety and Hazard Investigation Board (CSB) has investigated these explosions, and made recommendations to OSHA regarding a number of actions it should undertake (Document ID # 0110). CSB found that hazard communication regarding such dusts was inadequate, and is recommending the following with regard to this rulemaking:

> 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.

The Phylmar Group (Document ID # 0080) noted that combustible dust is not specifically covered under the current HCS, but suggested that it should be a future revision to the GHS rather than an addition to the HCS at this point:

> Combustible dusts are not addressed in the current HCS or the GHS. Although we believe that combustible dusts should be addressed in future revisions of the GHS, we do not recommend that OSHA include them in this rulemaking, as it would not achieve the desired goal of global harmonization. We encourage OSHA to work with the UN to ensure that the hazards of combustible dusts are addressed in the future.

The American Petroleum Institute also suggested that OSHA discuss with the UN how to handle the classification of explosive organic dusts (Document ID # 0171). Both Dr. Michele Sullivan and Organization Resources Counselors had similar comments which highlighted the hazards of combustible dusts, but suggested that OSHA explore ways this can be addressed on SDSs or in future GHS revisions rather than suggesting modification of the current HCS (Document ID #s 0145 and 0123).

There are a number of activities ongoing in OSHA regarding combustible dust, including consideration of additional standards or regulations addressing this issue. Final decisions have not been made regarding such rulemaking. As noted by commenters, the HCS does not include an explicit definition of such dust. However, manufacturers and importers are required to perform a hazard evaluation and consider all scientific evidence to determine if their products present a hazard. 29 CFR 1910.1200(d)(1) The hazard determination must anticipate the full range of downstream uses of a product including any by-products that may be generated during normal conditions of use. It has been the longstanding position of the Agency that the hazard determination covers dusts known to be subject to deflagration and subsequent explosion, *i.e.,* combustible dusts. This information must be conveyed on the MSDS.

Likewise, the GHS specifically addresses inclusion of information on the hazards associated with explosive (combustible) dusts in the SDS. This information would appear in Hazard Identification (Section 2) on the SDS as a hazard that does not result in classification under the current provisions of the GHS. This provision in the GHS is consistent with OSHA's current coverage of combustible dusts and is included in the proposed modifications. In addition, as discussed above, OSHA has added a definition for unclassified hazards to the proposed rule to address hazards such as combustible dust that do not have specific criteria for classification in the current provisions. Under this definition, combustible dust would be covered as other hazardous chemicals are, including information on labels, SDSs, and in training.

Additionally, the United States has submitted a working paper to propose that the UN Subcommittee add combustible dusts to their program of work, and has volunteered to lead this work. At such time as specific classification criteria for combustible dusts are added to the GHS, OSHA would also add them to the modified HCS. At this point, there are no agreed U.S. criteria to propose to the UN Subcommittee. OSHA invites comments on this issue, and specifically would like to learn what stakeholders believe would be an appropriate definition for combustible dust to add to the GHS as a physical hazard.

Other comments related to hazard determination/classification. A number of commenters responded to OSHA's specific questions related to hazard determination and classification, but few commented generally on the approach in the GHS and the HCS. The Refractory Ceramic Fibers Coalition provided a general discussion on hazard determination, and reached the same conclusion as OSHA regarding the contrast in the approaches (Document ID # 0030):

> The GHS and HCS hazard determination/classification are self-classification processes, but the GHS process is more detailed and allows for closer scrutiny of the strengths and weaknesses of the available data. RCFC supports the GHS approach. While the HCS has a one positive study threshold, the GHS provides for the one positive study issue in the context of analysis of the weight of all of the available evidence. In vitro studies are treated specifically, and there is consideration of whether a substance is not bioavailable or is inextricably bound. Professional/expert judgment is included, human experience is taken into account, and negative findings and data which refute findings are considered.

As described above, the existing HCS includes reference to several lists of chemicals in the hazard determination provisions that the Agency considers a ''floor'' of chemicals that are to be considered hazardous under all circumstances. The lists were also referred to in the mixture provisions—requiring mixtures to be covered when components could exceed established or recommended exposure limits even when present in concentrations below the mixture cut-offs. Inclusion of the floor and the mixture provisions in the revised rule were raised as an issue for comment in the ANPR, and a number of responses were received. Opinions on these issues varied significantly.

A number of commenters thought the revised rule should take the same approach as the existing rule (*see, e.g.,* Document ID #s 0044, 0057, 0078, 0021, 0029, 0116, and 0149). On the other hand, some respondents did not support the inclusion of any additional lists, and several noted that the GHS does not include such an approach, and thus the revised rule should not either since it is being aligned with the GHS (*see, e.g.,* Document ID #s 0046, 0047, 0049, 0058, 0064, 0036, 0107, 0123, and 0171). Others objected to the process by which TLVs are determined and/or suggested

that it is not legal for OSHA to refer to TLVs (Document ID #s 0064, 0083, 0100, 0101, 0111, 0132, and 0141).

As OSHA noted in the ANPR, the more detailed hazard classification provisions in the GHS preclude the need for a floor and for the mixture provisions related to exposure limits. The current HCS does not provide a specific and detailed approach to hazard determination or classification of hazards, and thus there was concern during its promulgation about the relative ability of chemical manufacturers and importers to follow a performance-oriented approach and reach the same conclusions. The floor of chemicals, as well as the mixture provisions, reflected this concern by providing additional guidance regarding the types of chemicals that would be considered hazardous were an appropriate hazard determination conducted. The proposed modifications provide a specific and detailed approach, and thus this additional guidance is no longer necessary or appropriate. OSHA believes that the detailed and specific criteria would provide equal or improved protection for exposed employees since they would improve consistency in evaluations, as well as help to ensure a thorough and comprehensive classification. In addition, as noted by some commenters, the GHS itself does not include such lists, so including them in the revised HCS would be a deviation from the harmonized approach. Such a deviation would detract from the benefits of adopting a harmonized approach.

OSHA has thus decided to delete references to any lists in the hazard classification provisions being proposed. The Agency believes that the proposed revised criteria accomplish a similar purpose in ensuring a consistency in approach to classification by various manufacturers of the same product, and does not think these provisions are needed in the proposed standard for this purpose. Furthermore, the GHS does not include a floor list of this type, and maintaining such provisions in the proposed revisions would be a significant deviation from the harmonized approach.

A few commenters argued that the hazard classification approach in the GHS would result in chemical manufacturers testing or re-testing their products (Document ID #s 0061, 0178, 0022, and 0141). If manufacturers choose to test or re-test their products, it will not be a result of either the provisions of the GHS or those proposed for the revised HCS. The GHS does not require testing, and neither does the HCS. Both are based on available data. This has always been the case for the HCS, and is now explicitly addressed in the revised text to ensure it is understood by all stakeholders.

There were some other comments that noted concerns about the effects of the classification criteria on a specific chemical or product, or which noted the potential for a change in classification or the need for additional guidance or interpretation. Since OSHA had not actually proposed language or coverage for the rule in the ANPR, some of these concerns were based on assumptions about what requirements would be included in a revised HCS and thus should be re-considered in the context of this proposal. As noted in the discussion on outreach and compliance assistance, OSHA is open to suggestions regarding areas where help will be needed, and classification has already been highlighted as an area of concern.

One interesting comment that was submitted by a number of respondents involved development of a classification data base (Document ID #s 0047, 0050, 0053, 0054, 0038, 0155, 0160, and 0165). Opinions as to who would develop and maintain such a data base varied (OSHA, U.S. industry, and an international body were all mentioned). During the development of the GHS, chemical industry representatives did not generally support inclusion of such a list or data base of classified chemicals. It appears that the European Union will be making such a data base available for compliance with its requirements, as have Japan, Taiwan, Korea, and New Zealand. Concerns are now being raised by stakeholders that classifications in these data bases are different for the same chemical.

Development and maintenance of such a data base would be a significant undertaking for any entity, although the appeal of such an approach is obvious. The appearance of differing classifications in national data bases is certainly a concern. One development that impacts this issue is that the International Chemical Safety Cards distributed by the International Program on Chemical Safety are being updated to be consistent with the GHS, and will thus have classifications for over one thousand commodity chemicals. Several hundred have already been completed. NIOSH represents the U.S. in this activity (Document ID # 0082), and the cards are available on their Web site (which is linked on OSHA's Web site). These cards are available in multiple languages, and are internationally developed and peer reviewed. Thus they will provide a data base on an international level for a core group of widely available chemicals when the update is completed.

The issue of a data base is one which needs to be explored more fully, and the logistics and implications studied. It has been raised as an issue for consideration by the UN Subcommittee as well. OSHA invites further comment on how such an approach might be further developed.

(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 are intended to ensure that the approach to hazard communication in a given workplace is coordinated and comprehensive. The program includes a list of the hazardous chemicals known to be present in the workplace. This list is basically an inventory of the chemicals the employer must have safety data sheets for—and is accessible 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 can be kept by the ''identity'' of the chemicals (which would be the product identifier under the proposed 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.

In addition to the list, the HCS requires the employer's program to set forth how hazard communication will be implemented in the workplace. This includes how the standard's requirements for labels, SDSs, and training will be met; how the hazards of non-routine tasks will be addressed; and how hazard communication will be handled in a multi-employer workplace situation. 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 should have enough detail to provide the reader with a blueprint of the workplace-specific program.

Several comments 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 #s 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. Secondly, 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 the scope paragraph, OSHA does not believe that the scope of hazards covered by the GHS, and thus the proposal, is substantially different than the current HCS.

The most likely differences resulting from re-classification under the revised standard is 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 the program, it does not appear likely there would be many, if any at all. Written programs usually describe aspects 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 revised HCS need not affect these aspects at all. Therefore, OSHA does not believe that extensive revisions would have to be made to written programs, including the inventory, under the proposal.

Suggestions have been made by SBA and others for outreach products related to the written program, particularly for an online inventory tool (Document ID #s 0022 and 0027). Given that the inventory is a simple list, it does not appear that anything other than a word processing program would be required to generate this part of the program so OSHA is not certain what is being suggested by these stakeholders. OSHA does not believe that a tool that lists all hazardous chemicals, and allows employers to check off those they have in their workplace, would be feasible given the extensive number of products currently in use in American workplaces. Therefore, if this is what is being suggested, it is not likely to be provided.

OSHA is thus not proposing any substantive modifications to the written hazard communication program, and does not anticipate any significant new burdens associated with revising the program as a result of other modifications being proposed.

(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 thus 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 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.)''

Similarly, the requirements for in-plant containers specify an identity and appropriate hazard warning. 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 employers were able to continue using existing 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 V 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.

Paragraph (f) thus has more proposed modifications than most of the other paragraphs of the existing standard. The title of paragraph (f)(1) has been changed to indicate it addresses labels on shipped containers. The required information on these labels includes: 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.

The proposal thus would require that labels on shipped containers contain much more information than under 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 proposal, 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 proposal refer to this as supplemental information. Several commenters requested that this be permitted (Document ID #s 0132 and 0145).

Paragraph (f)(2) addresses labeling for unclassified hazards. As noted previously, the proposal ensures that unclassified hazards (such as combustible dusts and simple asphyxiants) will continue to be covered under the HCS. That means that hazard information will have to appear on the SDS, and in certain cases, the label. As there are, however, no harmonized labeling elements available for unclassified hazards, the agency requires the responsible party to determine what information will be included on the label. This evaluation is to be based on the product's hazards and exposures under normal conditions of use and foreseeable emergencies. Hazard information will be included on the label, as appropriate, under supplemental information, as well as appropriate precautionary measures for the safe handling and use of the chemical.

Paragraph (f)(3) elaborates the label requirements by stating that the required information will 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.

In addition to requiring that the information be taken from Appendix C, new paragraph (f)(4) also notes that the harmonized information must be located together on the label, tag, or mark, prominently displayed, and in English, although other languages may also be included if appropriate.

The rest of paragraph (f) in the current standard remains largely the same in the proposed modified text, although conforming changes to terminology are made throughout the paragraph. The current standard's accommodation for labels associated with solid metal is maintained in the revised text, as is the provision regarding conflicts with requirements of the U.S. Department of Transportation. 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 commenters specifically noted that OSHA should avoid conflict with DOT (Document ID #s 0064 and 0066). This is already addressed in the standard (currently paragraph (f)(3) and contained in proposed paragraph (f)(6)). They further noted that the exterior package should be for displaying DOT labels, rather than for OSHA labels. In general, this would be true, although there are some cases where the only 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 in Appendix C of this proposed rule.

Under new paragraph (f)(7), OSHA addresses workplace labeling in the proposed text. As noted previously, the current standard provides employers with flexibility regarding the type of system to be used in their workplaces. Some comments suggested that OSHA maintain this flexibility in the revised standard (*see, e.g.,* Document ID #s 0047, 0145, and 0157). OSHA agrees, and the revised text maintains this 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, the information must be consistent with the revised HCS. Hazard classifications must be revised as necessary to conform, and the other information provided must be revised to ensure the appropriate message is conveyed.

OSHA is not proposing 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 workshift, 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.

Several comments raised an issue regarding potential confusion resulting from the numbering of hazard categories in the GHS (*see, e.g.,* Document ID #s 0046, 0054, 0064, 0035, 0123, and 0146). As described in the GHS text, some of the hazard classes that are divided into categories use numbers to designate those categories. Chemicals posing the most serious hazards are assigned to Category 1, and higher category numbers denote less serious hazards. Labels prepared under the Hazardous Materials Information System (HMIS) and National Fire Protection Association (NFPA) systems, on the other hand, use higher numbers to indicate more severe hazards. It was argued that the different approaches would result in confusion and lead to hazardous conditions in the workplace.

OSHA recognizes that the approach to numbering hazard categories in the GHS differs from that used in the HMIS and

NFPA systems. However, the Agency does not believe that this will result in confusion. GHS category numbers determine the label elements that would be required for a chemical, but the category numbers themselves would not appear on labels. Where GHS category numbers would appear on the SDS (Section 2—Hazards identification), they would be accompanied by the label elements for the chemical, which would clearly indicate the degree of hazard. OSHA, therefore, does not anticipate that this information will cause employees to become confused. Moreover, the approach taken in the GHS (*i.e.,* assigning higher category numbers to denote less serious hazards) is consistent with the approach used in the DOT transport regulations for many years.

A few commenters also argued that a small package exemption, or some type of prioritization of information on small packages, should be permitted (Document ID #s 0043, 0046, and 0080). The current HCS does not have such an exemption or limitation, but the Agency has allowed practical accommodations in those situations where an issue has occurred. 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 is not proposing to adopt such a provision, and intends to continue its current approach regarding small packages. Very small packagings 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.

Some comments addressed objections to the specific labeling requirements for certain chemicals. For example, the National Propane Gas Association (Document ID # 0068) objected to labeling propane as being ''extremely'' flammable, stating that it is usually simply addressed as ''flammable'' in the U.S. In addition, The Fertilizer Institute (Document ID # 0045) objected to having the skull and crossbones on labels for anhydrous ammonia, stating that use of it in fertilizers is necessary for the food supply. Similarly, an argument is made by the Styrene Information and Research Center (Document ID # 0164) that no GHS Category 2 carcinogens should be labeled because it would result in more chemicals being classified as carcinogens than would be under the International Agency for Research on Cancer (IARC) criteria.

Adoption of the GHS is likely to result in a number of situations where current labeling practices are somewhat changed by the introduction of the concept of severity of hazard, and the use of different label elements to convey information. OSHA does not believe that it would be appropriate to designate substance-specific exemptions from classification for reasons unrelated to communication of hazards. In the case of propane, designating it as ''extremely flammable'' is actually already done by a number of manufacturers or distributors in the U.S., so it is not necessarily a departure from current practice. In addition, NPGA's argument that many propane distributors are small businesses who don't participate in international trade (Document ID # 0068), is not related to improving and enhancing the communication of hazards to employees in the U.S. Provision of an exemption for those engaged solely in domestic commerce would only increase employee confusion about hazardous chemicals in the workplace. Providing information about the degree of hazard will help to ensure that the material is handled with the proper care needed to prevent hazardous effects from occurring. Similarly, the fact that anhydrous ammonia is used for the food supply ignores the significant hazards this chemical poses to workers who handle it. The skull and crossbones will emphasize the degree of severity of the hazard, as well as communicate the hazard to individuals who do not read or speak English—many of whom work in the agriculture industry.

In addition, the mere fact that incorporation of the GHS criteria might change the number of chemicals classified is not a reason to disregard the carcinogens in Category 2. The IARC criteria were one of the primary sources used for development of the GHS criteria, so it does not appear that there is a significant difference in approach. OSHA has had an enforcement interpretation that would allow manufacturers of certain carcinogens, those in IARC Category IIB, to include information about their carcinogenicity on the safety data sheet but not the label. Such an interpretation would not be consistent with GHS, and is not included in the proposed provisions. Therefore, there may be some chemicals that will now have carcinogen labels in addition to SDS information as a result of implementation of the GHS. This will ensure that employees get consistent information about these chemicals from all suppliers. Furthermore, because the current HCS uses the one study criterion, it appears that more chemicals are currently covered under the HCS than under any other criteria applied.

A few comments were received 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), and also control the SDS content (Document ID # 0108). A commenter also argued that pesticide labels are more useful because they are risk-based rather than hazard-based (Document ID # 0108). OSHA believes these concerns are not related to the proposal. The revised HCS would maintain 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 under these proposed changes.

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. It was noted that GHS does not specify a location or size of core information on a shipment (Document ID # 0066). OSHA believes that this is best left in a performance-oriented provision, allowing accommodations to be made as long as the information is located together, and is prominently displayed as required.

Other commenters noted that changing labels will create confusion and additional burden (Document ID #s 0065 and 0146); that there may be two labels and SDSs during the transition period, and that would be confusing (Document ID # 0035); and that the diamond shape of the pictogram was similar to NFPA's diamond, and therefore confusing (Document ID # 0035). It is clear that a change in labels will require a period of transition where there may be some confusion, and there will be two types of labels in the workplace. However, when the GHS is completely implemented, the current widespread confusion resulting from allowing multiple labeling approaches will be eliminated. Comprehensibility and effectiveness of hazard

communication is expected to increase as a result. OSHA believes these long-term benefits outweigh the short-term transitional issues. As discussed above, commenters in general recognized the benefits of adoption of the GHS, including enhancement of current protections, and thus supported pursuing this rulemaking. (*See, e.g.,* Document ID#s 0046, 0047, 0054, 0059, 0064, 0081, 0034, 0038, 0158, and 0165).

There were a few commenters who wanted additional elements in the labeling system, such as the water-reactive pictogram so it could be posted on buildings for fire authorities (Document ID # 0029), and a numerical ranking system similar to those currently in use under voluntary systems (Document ID # 0013). In the case of the water-reactive pictogram, there is certainly nothing in the current HCS or in the GHS that precludes its use to mark buildings, but that is a purpose that is outside the scope of the system at this point. In terms of the numerical ranking system, the GHS was developed based on consideration of existing national and regional hazard communication systems, and none of those currently employ a numerical ranking system. Thus, such an approach was not considered in the process.

(g) Safety data sheets. The proposed revisions to this paragraph are 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, this was largely based on 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 an order of information or a format. In particular, stakeholders such as emergency responders were concerned that not being able to find information 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 consensus standard that included a 16-section SDS (ANSI Z400). The titles of each section were established, as was the order of presentation. The standard sought to address 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. They also responded to comments that indicated 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.

In 1990, OSHA published a Request for Information (RFI) that addressed the issues of comprehensibility of labels and SDSs (55 FR 20580). There were nearly 600 comments 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, the ANSI format has been acceptable for many years, as long as the SDS includes the required information (*see* CPL 2–2.38D, the compliance directive for the HCS). As explained in Section V 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 Labor 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 to put hazard information before the chemical names of ingredients. This change has subsequently been adopted by ANSI and other groups to be consistent.

Since the 16-section SDS was initiated in the U.S. by industry, many companies have been using it. This will reduce the impact of adopting the GHS requirements since the major changeover to that approach has already been made by those companies. Others who continued to use different formats will need to change their SDSs to conform. There is already software available in the 16-section format, and it is expected that more tools will be available as the effective dates for compliance approach.

OSHA is proposing 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 is being 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, there are several sections of the SDS that address information that is 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 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 regarding 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 workshift; and access for OSHA and NIOSH, remain as they are in the current standard.

As was the case with labels, relatively few comments were submitted in response to the ANPR on the specific provisions for SDSs in the GHS. Those provisions are generally consistent with the current HCS, with the exception of the standardized approach described above that OSHA is proposing to include in the revised text.

Comments were received on inclusion of exposure limits on SDSs, and a number of different opinions were expressed, particularly regarding TLVs being required. Many commenters argued that TLVs should be included on the SDSs as currently required under the HCS (see, *e.g.,* Document ID #s 0042, 0179, 0021, 0038, 0124, and 0149). Others suggested they should not be required (see, *e.g.,* Document ID #s 0058, 0064, 0036, 0129, 0151, and 0163). There were also a number of commenters that 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.,* 0044, 0077, 0018, 0024, 0109, 0147, and 0171). OSHA has decided 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 will 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.

Several commenters appear to believe that the GHS requires disclosure of all ingredients in a mixture, unlike the current rule that has percentage cut-offs (Document ID #s 0048, 0056, and 0064), and argue that the current rule's approach should be maintained. In fact, the GHS approaches ingredient disclosure in a manner consistent with the current HCS, although the cut-offs may be different for the various health hazards covered. Similarly, it was suggested that there be a de minimis level below which SDSs would not be required (Document ID # 0178). This is already addressed by the cut-offs in the mixture classification provisions for each health hazard class. It was suggested that the GHS approach to ingredient disclosure would lead to more testing of chemicals (Document ID #s 0048 and 0056). This is not true as neither the current HCS nor the GHS require testing of any kind to be performed.

A number of comments suggested specific information to be included on the SDS, such as the Chemical Abstracts Service Registry Number (Document ID # 0044); whether a chemical is an EPA hazardous waste (Document ID # 0059 and 0108); control banding recommendations (Document ID # 0081); lethal dose data (Document ID # 0015); a miscellaneous section (Document ID # 0019); NFPA and HMIS ratings (Document ID # 0019); storage requirements (Document ID # 0019); reference to the DOT Emergency Response Guide (Document ID # 0019); and more spill cleanup and disposal information (Document ID # 0028). Much of this information is already included in the proposed SDS (such as the CAS Registry Number and lethal dose data). The other information noted could certainly be included in the SDS as additional information to that which is required by OSHA. The information referenced by these comments that falls under sections of the SDS that are not workplace-related (*e.g.,* environmental and transport information) cannot be required by OSHA. The Agency would certainly not preclude inclusion of such information by SDS preparers voluntarily, or as a result of requirements at some time in the future by the other Agencies that do have responsibility for those subject areas.

Several commenters noted that SDSs need to be written in plain language (Document ID #s 0044, 0010, and 0035). In general, the Agency agrees that SDSs should be written as plainly as possible while still conveying the required information to the intended audiences. 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 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.

A number of the comments received dealt with the management of SDSs, rather than the specific requirements for preparing them. For example, one commenter said that there would be a large burden associated with sending letters to obtain new SDSs, tracking their receipt, and updating workplace data bases (Document ID # 0178). The proposal would employ the same approach as the current HCS for distribution of SDSs. During the phase-in period for the standard, chemical manufacturers, importers, and distributors will be required to send a new SDS with their next shipment of a chemical to their customers. In other words, employers should automatically receive new SDSs, just as they do now when an SDS is updated. There will still be a burden associated with updating workplace records, but since users are not required to solicit new SDSs, there will not be a burden of sending letters to suppliers and tracking receipt of the responses. Furthermore, the phase-in period should be long enough that there will be turnover of chemical supplies that necessitate a new shipment in most cases.

Several commenters suggested that an online library of SDSs be created by OSHA (Document ID #s 0019, 0028, and 0146). This is an approach that was investigated by OSHA in the past, and at that time, it was determined that it would not be feasible for the Agency to maintain a complete and up-to-date data base of all the SDSs in use in American workplaces. The number of SDSs involved is very large, and there is no way for the Agency to know about each SDS or when each is updated. OSHA believes this approach is still infeasible for the Agency.

There appeared to be some concern about having two SDSs for the same product during the phase-in period, and how an employer would decide which takes precedence (Document ID # 0146). OSHA believes that the most recent version would be the one that takes precedence, and should be maintained in the workplace. It would not be necessary to maintain two versions for purposes of the proposed standard.

There was also a comment regarding SDS management for construction sites, and the use of a FAXback system (Document ID # 0022). This is an issue that has long been addressed by OSHA in its compliance directive (CPL 2–2.38D), as well as in the standard itself (see paragraph (g)(8) of the existing HCS), with provisions for what would

be considered effective electronic access to SDSs. The proposed revisions to the rule do not change these requirements.

(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, as well as addressing 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 V 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 is proposing 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 this has always been required in the HCS, OSHA believes that modifying the text slightly will 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. So the revised text would read:

> 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.

In addition, OSHA is proposing 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. Comment is invited on this approach.

Some commenters 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 #s 0178 and 0153). 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 #s 0042, 0072, 0077, and 0030).

Marshfield Clinic (Document ID # 0028) noted that communication of information about chemicals and other hazardous substances:

> * * *[I]s 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 that: ''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 #s 0065 and 0078). Another noted that the current approach is fine for companies that are domestic only (Document ID # 0026).

There were also many comments related to outreach that suggested compliance assistance in the area of employee training. As OSHA noted in the ANPR, the Agency is considering the development of generic training on symbols to make available to employers (71 FR 53624). OSHA has been working with NIOSH to prepare training on symbols and pictograms in particular (addressed by NIOSH in their comment at Document ID # 0082). However, it is expected that there will be other products related to training as well, both from OSHA and from the private sector.

(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 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:

> 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 the issue, and provide principles for countries to follow when adopting the provisions. These principles are consistent with the approach already incorporated into the HCS.

First, 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 claims to specific chemical identities. This is the primary difference between the current rule and the proposed revisions to HCS. To be consistent with GHS, OSHA is proposing 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 revises 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 revised rule as previously promulgated. The proposed revisions simply conform terminology, and add 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 #s 0072 and 0179), and that the current trade secret position should be retained (Document ID # 0049). There was also a comment that indicated 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 noted, 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.

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.

(j) Effective dates. OSHA is proposing to require implementation of the revisions to the HCS in 3 years after the final rule is completed. Training would be required two years after the final rule, and all provisions would be implemented in 3 years. During the transition period, employers would be required to be in compliance with either the existing HCS or the modified GHS, or both. OSHA recognizes 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. This will be considered acceptable, and employers are not 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.

Many comments were received 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 #s 0022, 0144, 0146, and 0151), many more indicated that this would not be appropriate (*see, e.g.,* Document ID #s 0042, 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 they would need information from them in order to comply themselves (Document ID #s 0080 and 0123).

There were also those who thought the phasing should be coordinated with other trading partners, particularly the European Union (Document ID #s 0072, 0080, 0081, 0179, 0024, 0163, and 0171). The European phasing is taking place over a long period of time because of the REACH requirements for chemicals that are going into effect. The long time periods being considered do not necessarily reflect a determination that the amount of time is needed just for compliance with GHS. Another suggestion that had support was to phase in substances first, and then cover mixtures, or to have a 3-step phase-in that includes intermediates before mixtures (*see, e.g.,* Document ID #s 0104, 0021, 0024, 0034, 0036, 0122, 0141, and 0154).

A number of other phasing approaches were also mentioned, including selecting the 200 most produced chemicals by weight and then sort them by hazard (Document ID # 0139); examining the data available on the chemicals in determining which to do first (Document ID #s 0081 and 0036); basing it on the time to use up stockpiles (Document ID # 0022); and ''sufficient'' time to work through the supply chain (Document ID #s 0068 and 0122).

There were also suggestions for a specific number of years, or a range of years. Some of these suggested less than 3 years (*see, e.g.,* Document ID #s 0064, 0019, and 0028). A number suggested 3 to 5 years, or in some cases, 6 years (*see, e.g.,* Document ID #s 0042, 0046, 0104, 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 #s 0050, 0077, 0078, 0018, 0116, 0129, 0141, and 0164).

OSHA decided on the 3-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. This work is already underway, and by the time this rulemaking is finalized, it is expected that much of it will be completed. And there were commenters that indicated that work is already being done in their companies to comply, particularly those that are multinational. (*See* Section VII for an analysis of activities already underway.)

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 the new GHS labels will co-exist is inevitable, the longer this period continues, the less effective the communication to employees will be. It is therefore important to minimize the effects of the

transition on the effectiveness of hazard communication by ensuring that 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. Waiting till the end of an extensive time period to complete their work may not allow them to 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. Further comment on this issue would be helpful to determine whether the final rule should include such phasing by type of product.

Other Standards Affected by the GHS Modification to the HCS

OSHA has reviewed all its standards and is proposing to modify standards in General Industry (29 CFR part 1910), Construction (29 CFR part 1926), and Shipyards, Marine Terminals and Longshoring (29 CFR parts 1915, 1917 and 1918) that contain hazard classification and communication provisions in order that they will be internally consistent and aligned with the GHS modifications to the HCS. There is strong support in the record for including these OSHA standards in this rulemaking.

The issue of how to deal with OSHA's existing standards was raised in the ANPR. (71 FR 53617; Sept. 12, 2006). OSHA specifically requested input on how GHS provisions addressing classification of physical hazards such as flammable liquids would impact other OSHA standards. OSHA also asked whether physical hazard definitions in other standards should be changed at the same time as HCS (71 FR at 53623, 53626).

In response to 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 (Document ID #s 0046, 0050, 0054, 0072, 0077, 0179, 0031, 0038, 0107, 0116, 0145, 0147, 0154, 0155, 0163, 0165, and 0171). Abbott Laboratories addressed the issue in terms of substance specific standards:

> OSHA should conduct a complete review of substance specific standards and determine how they need to be changed in order to be consistent with GHS. These changes should be made concurrent with the implementation of GHS. (Document ID # 0046)

Other commenters agreed, urging OSHA to complete these revisions in one rulemaking. (Document ID #s 0079, 0123, 0137, 0154, and 0157). For example, the National Paint & Coatings Association, whose members produce up to 70,000 formulated products, urged OSHA to update the standards impacted by the GHS modification to the HCS to ''minimize discrepancies and inconsistency''. (Document ID # 0050). Similar views were expressed by the Marshfield Clinic, the Hazard Communication Group and BASF (Document ID #s 0028, 0154, 0119, 0145, and 0155). NIOSH supported OSHA's plan to ''adopt the specific labeling requirement and the safety data sheet (SDS) order of information'' in the GHS, which, if substance specific standards were not included, would lead to internal inconsistencies (Document ID # 0081). The American Chemical Society noted that it would be best if OHSA identifies and updates all affected OSHA standards at once, otherwise industry may not realize all potential benefits (Document ID # 0165). The Association of Occupational Health Professionals in Healthcare (AOHP) stated:

> The standardization needs to be applied from the beginning until the end of the production, through distribution and use by the end user. We would recommend that any other OSHA standards that would be affected by the adoption of the HCS be changed to coincide with the implementation of the HCS'' (Document ID # 0051)

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 #s 0050, 0072, 0104, 0105, 0018, 0012, 0144, 0139 and 0140). 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).

However, several of the commenters pointed out some of the difficulties with adoption of the GHS physical hazards criteria (Document ID #s 0077, 0031, 0034, 0038, 0145, and 0166). MRS Associates stated that ''flammability is the key physical hazard that needs to have consistent definition and criteria because it affects other standards'' (Document ID # 0145). Other commenters agreed with MRS associates (Document ID #s 0072, 0105, 0179, 0145, and 0163). Manufacturer 3M posited that ''consistent classification between HCS and storage and handling requirements is the most critical potential problem'' (Document ID # 0128). However, some commenters recommended OSHA limit changes in order to facilitate GHS implementation. (Document ID #s 0047, 0064, 0077, 0104, and 0115). Dow Chemical wrote:

> Dow believes that OSHA should implement only those changes needed to facilitate GHS implementation. While this may necessitate some duplicative information on SDSs (for example, listing both GHS and NFPA flammability classifications), this would cause less disruption and confusion than trying to make changes i[n] associated standards that might then be in conflict with other current standards outside OSHA's control (for example, State and local building and fire codes) (Document ID # 0047).

OSHA's proposal reflects the advantages of harmonizing, but takes 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.

OSHA reviewed all its standards and has proposed changes to ensure that they are internally harmonized to facilitate safety and health for the employer and employee. To that end, OSHA is proposing to apply the GHS elements it is adopting in the modified HCS to its other standards. Provisions in OSHA standards, such as the substance-specific standards that set forth hazard and precautionary statements will be changed to be consistent with GHS terminology. Also, OSHA is proposing to modify provisions of the standards that reference the HCS definitions to maintain coverage or consistency with the modified HCS, and to change provisions in standards that affect the information requirements of the safety data sheet (SDS). OSHA will also maintain the current HCS definitions in the several standards that reference the HCS for which the adoption of GHS definitions could potentially impact the scope of those standards.

Some standards are not being included in this rulemaking. As explained in more detail below, OSHA is not proposing at this time to change

certain standards that reference consensus standards such as National Fire Protection Association (NFPA) standards. In addition, OSHA is not proposing any changes in 29 CFR 1910.109 Explosives and Blasting Agents and 29 CFR 1926.914 definitions for Blasting in Excavation Work Under Compressed Air.

Substance Specific Health Standards

OSHA proposes to update substance-specific health standards in General Industry, Construction, and Maritime, whether they specifically reference HCS or contain their own hazard communication requirements. OSHA is proposing to modify these standards in the following areas:

- 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, but for which GHS modifications contain no equivalent statements at this time;
- Maintain or specify language for contaminated clothing and debris;
- Update most 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.

OSHA is proposing 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 health 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 is proposing to modify the language to be compatible with GHS and consistent throughout the OSHA standards.

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. For example, many of the substance-specific health standards were regulated as carcinogens; however, the hazard statements required on signs and labels range from ''Cancer Hazard'' in Inorganic Arsenic (29 CFR 1910.1018) to ''Cancer—Suspect agent'' in Vinyl Chloride (29 CFR 1910.1017) to ''May Cause Cancer'' in Methylenediamiline (MDA) (29 CFR 1910.1050). The GHS revision to HCS will standardize the warning language to ''May Cause Cancer'' for each standard regulated as a carcinogen. NAHB addressed this issue, 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). OSHA believes that the signal words and hazard statements in its substance-specific standards would be more consistent if they are changed to reflect the GHS modification to HCS.

Currently, OSHA standards appear to suggest gradations of cancer hazards with ''cancer hazard'' seeming to signal the greatest hazard. However, there is no gradation of hazard. The standards were promulgated at different times and reflect the language used at the time and not relative degrees of hazard. With GHS harmonization, the potential misperception of degree of carcinogenic hazard is alleviated and the process is simplified with one statement warning that the chemical is carcinogenic. ''May Cause Cancer'' means ''carcinogen,'' is equivalent to any of the warnings for the current standards, and communicates the serious adverse health effects caused by carcinogens. Nevertheless, NAHB's concerns with potential confusion over hazard statements and signal words are well taken. This highlights the need for training. OSHA believes that after hazard communication training ''May Cause Cancer'' and other GHS compliant warnings will be quickly recognized and easily understood, leading to more effective avoidance of the various hazards to which workers are exposed. See Table XV–1 for a comparison of the language on current signs to signs modified to be consistent with the modified HCS.

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Table XV-1 Proposed Regulated Area Signs

Standard	Substance	Original signs	Proposed Changes
1910.1001	Asbestos Regulated areas Where the use of respirators and protected clothing is required	DANGER, ASBESTOS, CANCER AND LUNG DISEASE HAZARD, AUTHORIZED PERSONNEL ONLY, RESPIRATORS AND PROTECTIVE CLOTHING ARE REQUIRED IN THIS AREA	DANGER ASBESTOS MAY CAUSE CANCER CAUSES DAMAGE TO LUNGS AUTHORIZED PERSONNEL ONLY WEAR RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING IN THIS AREA
1910.1003	4-Nitrobiphenyl: Regulated areas Regulated areas covered by paragraph (C) (5)	CANCER-SUSPECT AGENT AUTHORIZED PERSONNEL ONLY 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 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
1910.1010	4-Aminodiphenyl:		See 1910.1003
1910.1011	Ethyleneimine:		See 1910.1003
1910.1012	beta-Propiolactone:		See 1910.1003

Standard	Substance	Original signs	Proposed Changes
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 Hazardous operations	CANCER-SUSPECT AGENT AREA AUTHORIZED PERSONNEL ONLY CANCER-SUSPECT AGENT IN THIS AREA PROTECTIVE EQUIPMENT REQUIRED AUTHORIZED PERSONNEL ONLY	DANGER VINYL CHLORIDE MAY CAUSE CANCER 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	Proposed 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	Proposed 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 AUTHORIZED PERSONNEL ONLY

Standard	Substance	Original signs	Proposed Changes
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 RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN THIS AREA AUTHORIZED PERSONNEL ONLY
1926.62	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
1926.1101	Asbestos Regulated areas Where the use of respirators and protected clothing is required	DANGER, ASBESTOS, CANCER AND LUNG DISEASE HAZARD, AUTHORIZED PERSONNEL ONLY, RESPIRATORS AND PROTECTIVE CLOTHING ARE REQUIRED IN THIS AREA	DANGER ASBESTOS MAY CAUSE CANCER CAUSES DAMAGE TO LUNGS AUTHORIZED PERSONNEL ONLY 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 would result in all the substance-specific health standards making reference to the HCS and would remove the specific language that must be included on a label for raw materials, mixtures, and products. Currently, OSHA substance-specific standards are inconsistent in that some have their own hazard communication requirements while others reference the HCS and still others are silent, but still are covered by HCS. The new paragraph that will reference the modified HCS in each substance specific standard states:

( ) *Hazard communication.* The employer shall include *(insert name of chemical)* in the workplace hazard communication program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer shall ensure that each employee has access to labels on containers of *(insert name of chemical)* and safety data sheets, and is trained in accordance with the provisions of HCS and paragraph () of this section. The employer shall provide information on at least the following hazards: *(insert hazards)*

Requiring standards to reference HCS will ensure consistency with the GHS revisions and consistency among the standards, and consistency when the specific chemical is part of a mixture. Removal of the current specific warning language is essential for adoption of the GHS language. To leave 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 modifications. Moreover, the hazard statements specified for the chemical in the standard may no longer be correct when the chemical is part of the mixture. As for the standards that now simply reference HCS, labeling will no longer be performance-oriented where producers and employers could choose any language and format that conveyed the necessary information. The GHS revision to HCS requires specific GHS elements, including pictograms, hazard and precautionary statements and signal words on labels.

OSHA recognizes that employers have relied upon the warning language for labels in the substance-specific standards and that the absence of language where it had been in the standard could cause some initial confusion as to what, if anything, is required. Therefore, OSHA is proposing to provide guidance on the potential health outcomes that must be reviewed when classifying a substance. The Agency is not attempting to formally classify each substance; rather, OSHA is proposing to provide a list of health effects that will assist the classifier in determining what must be considered for inclusion on the new labels. The GHS classification process for a specific substance as proposed in this revision of the HCS will dictate the hazard warnings and the precautionary statements that will be required on the new GHS-compliant labels. In determining which hazards to include in the substance specific standards, the Agency's primary sources on health effects were its own information gained in rulemaking and subsequent experience, the NIOSH Pocket Guide to Chemical Hazards (2005), and the International Chemical Safety Cards (ICSC), which are an undertaking of the International Programme on Chemical Safety (a joint activity of three cooperating International Organizations: namely the United Nations Environment Programme (UNEP), the International Labor Office (ILO) and the World Health Organization (WHO)), and which are peer reviewed by a group of internationally recognized experts. 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, labelling 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 that were to be included in the substance-specific health standards based on two criteria: (1) the health hazard was the basis for the original rulemaking; or (2) the health hazard was asserted by OSHA, NIOSH or ICSC, and confirmed by a second source. For example, acrylonitrile (AN) 1910.1045 was regulated based on its carcinogenicity. Skin sensitization was acknowledged by OSHA, ICSC, and EU; skin irritation by OSHA, NIOSH, and EU; respiratory tract irritation by ICSC and EU; eye irritation by OSHA, NIOSH, and ICSC; liver effects and central nervous system effects by ICSC and NIOSH; acute toxicity by OSHA, ICSC, and EU; and flammability by ICSC, NIOSH and EU. Because all these effects met the criteria for inclusion, skin irritation, respiratory irritation, eye irritation, liver effects, central nervous system effects, acute toxicity, and flammability were added as potential hazards to AN. See Table XV–2 for the proposed list of health effects for each substance-specific health standard.

OSHA is proposing to maintain specific language for labels in its substance-specific health standards for containers of contaminated clothing or waste and debris even though these labels may not be consistent with the GHS. This is to ensure that protection gained from communicating these hazards to the downstream recipients of the materials is not lessened. Substances found on contaminated clothing and waste and debris often occur in unknown and frequently small quantities. In order to ensure and maintain protection for employees in the receiving workplaces, labeling of these hazards is essential.

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Table XV-2 Health Effects Determined for the Substance Specific Standards

Standard Number	Substance	Health effects	Source
1910.1001	Asbestos	Cancer and lung effects	OSHA/NIOSH/ICSC/EU
1910.1003	4-Nitrobiphenyl:	Cancer	OSHA/NIOSH/ICSC/EU
1910.1003	Alpha-Naphthylamine:	Cancer: skin irritation, and acute toxicity effects	OSHA/NIOSH/ICSC/EU
1910.1003	Methyl chloromethyl ether:	Cancer; skin ,eye and respiratory effects; acute toxicity effects; and flammability	OSHA/NIOSH/ICSC/EU
1910.1003	3,3'-Dichlorobenzidine (and its salts):	Cancer and skin sensitization	OSHA/NIOSH/ICSC/EU
1910.1003	Bis-Chloromethyl ether:	Cancer; skin, eye, and respiratory tract effects; acute toxicity effects; and flammability	OSHA/NIOSH/ICSC/EU
1910.1003	Beta-Naphthylamine,:	Cancer and acute toxicity effects	OSHA/NIOSH/ICSC/EU
1910.1003	Benzidine:	Cancer and acute toxicity effects	OSHA/NIOSH/ICSC/EU
1910.1003	4-Aminodiphenyl:	Cancer	OSHA/NIOSH/ICSC/EU
1910.1003	Ethyleneimine:	Cancer; mutagenicity; skin and eye effects; liver effects; kidney effects; acute toxicity effects; and flammability	OSHA/NIOSH/ICSC/EU
1910.1003	Beta-Propiolactone:	Cancer; skin irritation; eye effects; and acute toxicity effects	OSHA/NIOSH/ICSC/EU
1910.1003	2-Acetylaminofluorene:	Cancer	OSHA/NIOSH
1910.1003	4-Dimethylaminoazo-benzene:	Cancer; skin effects; and respiratory tract irritation	OSHA/NIOSH/ICSC
1910.1003	N-Nitrosodimethylamine:	Cancer; liver effects; and acute toxicity effects	OSHA/NIOSH/ICSC/EU

Standard Number	Substance	Health effects	Source
1910.1017	Vinyl chloride	Cancer; central nervous system effects; liver effects; blood effects; and flammability	OSHA/NIOSH/ICSC
1910.1018	Inorganic arsenic	Cancer; liver effects; skin effects; respiratory irritation; nervous system effects; and acute toxicity effects	OSHA/NIOSH/ICSC
1910.1025	Lead	Reproductive/developmental toxicity; central nervous system effects; kidney effects; blood effects; and acute toxicity effects	OSHA/NIOSH/ICSC
1910.1026	Chromium VI	Cancer; skin sensitization; and eye irritation	OSHA/NIOSH/EU
1910.1027	Cadmium	Cancer; lung effects; kidney effects; and acute toxicity effects	OSHA/NIOSH/ICSC/EU
1910.1028	Benzene	Cancer; central nervous system effects; blood effects; aspiration; skin, eye, and respiratory tract irritation; and flammability	OSHA/NIOSH/ICSC/EU
1910.1029	Coke oven emissions	Cancer	OSHA/NIOSH
1910.1043	Cotton Dust	Lung effects	OSHA/NIOSH
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	OSHA/NIOSH/ICSC/EU
1910.1045	Acrylonitrile (AN)	Cancer; central nervous system effects; liver effects, skin sensitization, skin, respiratory, and	OSHA/NIOSH/ICSC/EU

Standard Number	Substance	Health effects	Source
		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	OSHA/NIOSH/ICSC/EU
1910.1048	Formaldehyde	Cancer; skin and respiratory sensitization; eye, skin and respiratory track irritation; acute toxicity effects; and flammability	OSHA/NIOSH/ICSC/EU
1910.1050	Methylenedianiline (MDA)	Cancer; liver effects; and skin sensitization	OSHA/NIOSH/ICSC/EU
1910.1051	1,3 Butadiene (BD)	Cancer; eye and respiratory tract irritation; center nervous system effects; and flammability	OSHA/NIOSH/ICSC/EU
1910.1052	Methylene chloride	Cancer; cardiac effects; central nervous system effects; liver effects; and skin and eye irritation.	OSHA/NIOSH/ICSC/EU

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In addition, OSHA has determined that the hazard and precautionary statements that address creating dust in the substance-specific health standards

must be maintained even though there is no GHS equivalent. At this time, a work group formed under the UN Subcommittee of Experts for the GHS is *working to finalize* issues related to hazard and precautionary statements. As indicated in Section II of this preamble, this work is likely to be accomplished prior to the promulgation of the *Hazard Communication* final standard (See UN/SCEGHS/15/INF.26). If the UN subcommittee adopts a precautionary statement for creating dust, the paragraphs in the substance-specific standards can be removed and protection will be attained by the GHS modifications to HCS. However, if this does not occur, OSHA intends to continue to require them in the standards.

OSHA's Cadmium Standard provides an example of this issue. In paragraphs 1910.1027(m)(3)(i) and (ii), containers must be labeled in accordance with HCS and the label must include the phrase ''Avoid Creating Dust.'' In this case, there is no equivalent statement in GHS. Therefore, OSHA would continue to require this statement on labels. That said, OSHA believes inclusion in GHS would be the best way to require this information and if the UN subcommittee has completed its work in time, the statements could be removed from the standards, and the GHS modification to HCS would be relied upon to require the warning.

OSHA is proposing to modify most definitions in § 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories (the laboratory standard), in order to maintain compatibility with HCS. This 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)

There is one exception in the laboratory standard and that is the definition of ''select carcinogens.'' (§ 1910.1450(b)). In this rulemaking, OSHA is proposing 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, 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 the preamble to the final rule 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 is also proposing to change the name of the ''material safety data sheets'' for the substance specific standards to ''safety data sheets.'' As discussed above, this change is being proposed to reflect the GHS terminology.

Safety Standards

OSHA is proposing to modify safety standards that either directly reference the HCS or provide information pertinent to the Safety Data Sheets (SDSs), in particular regarding the storage and handling of chemicals. As noted above, some commenters supported standardizing physical hazard criteria across all applicable OSHA standards (Document ID #s 0104, 0105, 0034, 0155, 0170, and 0171). 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 (PSM) Standard; and potential conflicts with widely accepted consensus standards (Document ID #s 0104, 0038, 0077, and 0163). OSHA is addressing all of these concerns in this proposal. OSHA's proposed integration of the physical hazards criteria would:

- Incorporate the current HCS definitions of flammable liquid and gas into PSM and health hazard into Hazardous Waste Operations and Emergency Response (HAZWOPER);
- Change paragraphs on flammable and combustible liquids to conform in categories, terminology, flashpoints (FP) and boiling points (BP) to the GHS modifications to HCS;
- Update the acceptable methods for determining flashpoints;
- Modify the welding standard § 1910.252 requirements on labeling welding consumables to be consistent with GHS modifications to HCS; and
- Incorporate the modified-HCS definition of flammable aerosols into the Flammable and Combustible Liquids Standard § 1910.106 [35]; but
- Leave unchanged electrical standards in Subpart S for general industry and Subpart K for construction, and explosive standards § 1910.109 for general industry and § 1926.914 for construction.

OSHA agrees with the commenters who urged the Agency to ensure consistency in its standards while maintaining their scope (Document ID #s 0049, 0050, 0077, 0105, 0123, 0145, 0163, and 0170). Two standards, PSM and HAZWOPER, rely on definitions from the HCS to define their scope. If OSHA did not modify these standards during this rulemaking, there would be unintended coverage changes. For example, PSM covers processes that involve ''flammable liquids'' as currently defined by reference to the HCS which are limited to liquids with a flashpoint below 100 °F. However, the proposal incorporates the GHS definitions for physical hazards and defines flammable liquids as liquids with a flashpoint below 199.4 °F, potentially increasing the coverage of PSM by adding flammable liquids with flashpoints between 100 °F and 199.4 °F to the chemicals PSM already covers. Therefore, OSHA is proposing to change the PSM standard to define ''flammable liquid'' by the specific flashpoint set forth in the current HCS, rather than referencing HCS's definition of flammable liquid. Similarly for ''flammable gas,'' OSHA is proposing to change the definition to only include Category 1 flammable gas to maintain coverage of PSM. Therefore, OSHA would delete the reference to HCS for flammable liquid and insert the current definition in paragraph 1910.119(a)(1)(ii). The current PSM standard states:

> (ii) A process which involves a flammable liquid or gas (as defined in 1910.1200(c) of this part) on site in one location, in a quantity of 10,000 pounds (4535.9 kg) * * *

The new proposed paragraph would state:

> (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) * * *

[35] 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.

Likewise, OSHA is proposing to update the definition of health hazard in HAZWOPER 1910.120 so the terminology is aligned with the GHS health hazards in Appendix A. The new definition would read:

> 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 which 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; target organ specific systemic toxicity (single or repeated dose); or aspiration toxicity. The criteria for determining whether a chemical is classified as a health hazard can be found in Appendix A to 29 CFR 1910.1200.

OSHA was concerned that some of the terminology in HAZWOPER, such as neurotoxin and nephrotoxin (see definitions in ''health hazard'') which are partly defined by reference to the HCS would no longer be consistent with the modified HCS. OSHA has not dropped these health hazards, but instead, consistent with the GHS modifications to HCS, such terms are recatagorized under specific target organ toxicity, thus maintaining the same requirements for hazard communication. If OSHA did not update the definition in HAZWOPER then employers would not have the proper guidance on how to classify a health hazard consistent with the GHS.

Flammable and Combustible Liquids

OSHA is proposing to align the definitions of flammable and combustible liquids to conform to the GHS modifications to HCS in categories, terminology, flashpoints, and boiling points, in the general industry, construction, and maritime standards. (See Table XV–3 for comparison of the current HCS definitions and the GHS flammable liquid definitions.) OSHA believes that most of the changes in the definitions are not significant. OSHA is proposing to make nominal changes to the flashpoint values for flammable and combustible liquids from 22.8 ° C to 23 °C and 93.3 °C to 93 °C to be consistent with the GHS modifications to HCS. OSHA believes these changes represent simple rounding to the closest significant value and that they will have no effect on the scope of its standards or safety, but will enable users to work in whole numbers, which OSHA believes will benefit affected employers and employees.

However, other changes are potentially significant. The boiling points used to define the threshold for the current Flammable Class IA will shift from the cut-point of 37.8 °C to a cut-point of 35 °C for Category 1 in the modified HCS. Flammable Class IA is currently defined as any liquid with a FP of greater than (>) 22.8 °C and a BP of less than (<) 37.8 °C; the new definition will adopt a BP of less than or equal to (≤) 35 ° C. Likewise, the BP will shift for the current definition of Flammable Class IB from equal to or greater than (≥) 37.8 °C to (>) 35 °C for Category 2. These changes are necessary to make OSHA standards internally consistent and consistent with the GHS modifications to HCS. However, OSHA is concerned that changing the boiling point cut-off for the highly flammable liquids currently 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, a facility could increase the size of its storage tanks for the liquids with boiling points between 37.8 °C and 35 °C. It is possible that increasing the size for these chemicals could decrease the safety of their storage. OSHA has 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 current Flammable and Combustible Liquids Standard Class IA liquids on this list. This is an instance where the benefits of harmonization could be in conflict with the measure of safety currently provided.

How the storage and handling of chemicals would be affected by the changes in classification of chemicals generated significant comments to the ANPR. Some commenters urged the Agency to change criteria in the standards, but acknowledged that the storage and handling requirements for flammable liquids would present the most critical potential problems (Document ID #s 0072, 0102, 0179, 0034, 0145, and 0163). Other commenters were concerned that changing the definitions, including flammability criteria, would require facilities to modify their storage facilities to maintain compliance with § 1910.106, with some worried that storage receptacles would have to be smaller, leading to less storage and greater costs. For example, BASF wrote:

> The flammable and combustible liquid standard, 29 CFR 1910.106, includes definitions within the standard. Changing these to be consistent with the GHS definitions could require storage facilities to be modified or the amount of storage inventory limited, all of which impacts the cost of implementation. (Document ID # 0119)

OSHA disagrees with this statement. Because the GHS change from OSHA's flammable and combustible classes to GHS Categories involves a lowering of the boiling point cut-offs by 2.8 °C, all current handling and storage would be permitted. In addition, storage and handling of chemicals whose boiling points fall between 37.8 °C and 35 °C would be allowed to be stored according to the lesser flammability Category 2. Category 2 chemicals could be stored in larger containers but, as noted above, it is possible that safety could be compromised. OSHA is proposing the GHS changes to the safety standards because it believes safety will be enhanced by the standardization of the GHS modifications. However, OSHA is seeking comment on the resulting handling and storage of chemicals after the standards have incorporated GHS definitions, and the Agency has included this topic in Section II (Issues) of this preamble.

Table XV-3 Flammable Liquid definitions

GHS			Flammable and Combustible Liquids Standard (29 CFR 1910.106)		
Category	Flashpoint (ºC)	Boiling Point (ºC)	Class	Flashpoint (ºC)	Boiling Point (ºC)
Flammable 1	< 23	≤ 35	Flammable Class IA	< 22.8	< 37.8
Flammable 2	< 23	> 35	Flammable Class IB	< 22.8	≥ 37.8
Flammable 3	≥ 23 and ≤ 60		Flammable Class IC Combustible Class II	≥ 22.8 and < 37.8 ≥ 37.8 and < 60	
Flammable 4	> 60 and ≤93		Combustible Class IIIA	≥ 60 and <93.3	
None			Combustible Class IIIB	≥ 93.3	

OSHA is also proposing to adopt the terminology in the GHS modifications to HCS so that all liquids covered by § 1910.106 will be redefined as flammable liquids in Categories 1–4, as appropriate, and the term ''Combustible Liquids'' in §§ 1910.106, 1910.107, 1910.123, 1910.125, 1926.152, and 1926.155 will be deleted. Instead of using the term Combustible Class IIIB, flammable liquids with a flashpoint of ≥ 93 °C will be called ''Flammable Liquids with a Flashpoint of > 93 °C.'' The GHS does not classify flammable liquids with flashpoints > 93 °C and, in fact, does not use the term combustible liquid for classification. However, other OSHA standards, such as § 1910.107, Spray Finishing Using Flammable and Combustible Materials, relying on the current § 1910.106 definitions of flammable and combustible liquids, which cover liquids with a flashpoint over 93 °C as ''combustible liquids.'' OSHA believes it needs to maintain this non-GHS category in order to preserve the coverage of combustibles in standards such as Spray Finishing. However, these chemicals will be known by the new term ''Flammable Liquids with a Flashpoint of Greater Than 93°C,'' which means that protection provided by the current standards remains in force.

Updating the Method To Determine Flashpoint

Currently, OSHA references only ASTM D–56–70 or ASTM D–93–71 for testing methods to determine flashpoints for liquids and these are the only methods allowed. However, these methods, which were developed in 1970 and 1971, have been updated and are incompatible with GHS. To remedy this situation, OSHA is proposing to reference the methods set forth in the GHS that can be used to determine flashpoints. These methods include updated ASTM methods, ISO methods, as well as British, French, and German national standards for the testing. A complete list of methods is in the *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)* (second revision, 2007). OSHA is seeking comment on this approach, and the Agency has included this topic in Section II (Issues) of this preamble.

Welding, Cutting and Brazing

OSHA is proposing to modify the labeling requirements for welding consumables in the Welding, Cutting and Brazing Standard, paragraphs 1910.252(c)(iv)(A), (B), and (C). These paragraphs contain the labeling requirements for filler metals, fusible granular materials and fluxes. The standard sets forth the responsibility for labeling in paragraph 1910.252(c)(iv):

The suppliers of welding materials shall determine the hazard, if any associated with the use of their materials in welding, cutting, *etc.*

Similar to the substance-specific health standards, OSHA is proposing to require these labels to be consistent with the GHS modifications to HCS.

Flammable Aerosols

OSHA is proposing to harmonize its existing standards with the GHS modifications to HCS on flammable aerosols. Currently OSHA references CPSC regulations for its definition of flammable aerosol. The current HCS definition is:

''Aerosol, flammable'' means 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.

OSHA defines and regulates flammable aerosols in its Flammable and Combustible Liquids standard at 29 CFR 1910.106. The definitions there are:

Aerosol shall mean a material which is dispensed from its container as a mist, spray, or foam by a propellant under pressure. § 1910.106(a)(1).

Flammable aerosol shall mean 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 paragraph (d) of this section, such aerosols are considered Class IA liquids. § 1910.106(a)(13).

Appendix B.3 of GHS modifications to HCS begins its definition with what an aerosol is:

* * * 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. (Appendix B)

Aerosols are then further classified into one of two categories if it contains a flammable liquid, gas or solid (Appendix B.3.2.1).

OSHA's decision to change the definition of aerosols to be consistent with the GHS is based not only upon harmonizing its own standards with those followed by other countries who have or are considering adopting GHS, but also with making OSHA standards internally consistent. OSHA believes that the classification resulting from the various methods are similar enough 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. Thus, OSHA is proposing to remove the current definitions from its Flammable and Combustible Liquids standards and insert its GHS consistent definitions along with references to Appendix B.3 of the HCS. While the Agency believes the effect of these changes will be minimal, it nevertheless seeks comment on this change which will primarily affect the Flammable and Combustible Liquids standards.

Standards Not Included in This Rulemaking

At this time, OSHA is not proposing 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 HCS for applicable scope or incorporation into the SDS. These standards would include subpart S—Electrical in part 1910 (General industry) and Subpart K—Electrical in part 1926 (Construction). Many commenters were particularly concerned that a change in OSHA's definitions would create an incompatibility with local building codes (Document ID #s 0047, 0075, 0076, 0104, 0113, 0145 and 0163). 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.

In addition OSHA is not proposing to update standards that pertain to explosives at this time. A separate rulemaking to revise the Explosive and Blasting Agents standard § 1910.109 is currently in progress.

XVI. References

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XVII. Authority and Signature

This document was prepared under the direction of Jordan Barab, Acting 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. 5–2007 (72 FR 31160); and 29 CFR part 1911.

Signed at Washington, DC, this 10th day of September 2009.

Jordan Barab,

Acting Assistant Secretary of Labor.

XVIII. Proposed Amendments

List of Subjects

29 CFR Part 1910

Asbestos, Blood, Chemicals, Diving, Fire prevention, Gases, Hazard communication, Hazardous substances, Health records, 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.

For the reasons discussed in the preamble, the Occupational Safety and Health Administration proposes to amend 29 CFR parts 1910, 1915 and 1926 as set forth below:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS [AMENDED]

Subpart A—[Amended]

1. The authority citation for subpart A of part 1910 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), 5–2002 (67 FR 65008), or 5–2007 (72 FR 31159), 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); and OMB Circular A–25 (dated July 8, 1993) (58 FR 38142, July 15, 1993).

2. Amend § 1910.6 by adding new paragraphs (h)(22) through (h)(28), (q)(36), (x), and (y) to read as follows:

§ 1910.6 Incorporation by reference.

* * * * *

(h) * * *

(22) ASTM D 56–93, Standard Test Method for Flash Point by Tag Closed Cup Tester, IBR approved for Appendix B to § 1910.1200, (see B.6).

(23) ASTM D 3278–96, Standard Test Method for Flash Point of Liquids by Small Scale Closed-Cup Apparatus, IBR approved for Appendix B to § 1910.1200.

(24) ASTM D 3828–93 Standard Test Method for Flash Point by Small Scale Closed Cup Tester, IBR approved for Appendix B to § 1910.1200,.

(25) ASTM D 93–96, Standard Test Methods for Flash Point by Pensky-Martens Closed Cup Tester, IBR approved for Appendix B to § 1910.1200.

(26) ASTM D 240–2007 Standard Test Method for Heat of Combustion of Liquid Hydrocarbon Fuels by Bomb Calorimeter, IBR approved for Appendix B to § 1910.1200.

(27) ASTM D 86–07a Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure, IBR approved for Appendix B to § 1910.1200.

(28) ASTM D 1078–05 Standard Test Method for Distillation Range of Volatile Organic Liquids, IBR approved for Appendix B to § 1910.1200.

* * * * *

(q) * * *

(36) NFPA 30B–2006 Code for the Manufacture and Storage of Aerosol

Products, IBR approved for Appendix B to § 1910.1200.

* * * * *

(x) The following material is available for purchase from the International Standards Organization (ISO) through ANSI, 25 West 43rd Street, Fourth Floor New York, NY 10036–7417.

(1) ISO 10156–1996; ''Gases and Gas Mixtures—Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets,'' IBR approved for Appendix B to § 1910.1200.

(2) EN/ISO 13943–2000, 86.1 to 86.3—Fire Safety—Vocabulary, IBR approved for Appendix B to § 1910.1200

(3) ISO 10156–2–2005 ''Gas cylinders—Gases and Gas Mixtures—Part 2: Determination of Oxidizing Ability of Toxic and Corrosive Gases and Gas Mixtures,'' IBR approved for Appendix B to § 1910.1200.

* * * * *

(y) The following document is available for purchase from United Nations Publications, 2 United Nations Plaza, Room DC2–853, New York, NY 10017, USA.

(1) The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Edition, 2003, IBR approved for Appendix B to § 1910.1200.

(2) [Reserved]

(z) The following is available from Verein Deutscher Ingeniere (VDI)(Association of German Engineers). The guidelines can be ordered at: Beuth Verlag GmbH, 10772 Berlin.

(1) 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 (176 °F) above the reference temperature for a volume of 1 l, IBR approved for Appendix B to § 1910.1200, (see B.11).

(2) [Reserved]

(aa) The following journal article can be obtained on-line though Wiley InterScience, at Journal Customer Services, John Wiley & Sons, Inc., 350 Main Street, Malden, MA 02148.

(1) 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) (Copyright 1992 American Institute of Chemical Engineers) with an onset temperature 60°K (140°F) above the reference temperature for a volume of 1 l, IBR approved for Appendix B to § 1910.1200, (see B.11).

(2) [Reserved]

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), 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. 655 NOTE. Section 1910.120 also issued under Section 126, Superfund Amendments and Reauthorization Act of 1986 as amended (29 U.S.C. 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 it appears.

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*), (b)(4)(iv)(*e*), (d)(1)(ii)(*b*), (d)(2)(iii) and (d)(2)(iii)(*a*)(*2*), (d)(3)(i), (d)(4)(iii), (d)(4)(iv), (d)(7)(i)(*b*), (e)(2), (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), (e)(7)(i)(*c*), (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), (f)(8), (g)(1)(i)(*c*), (g)(1)(i)(*e*), (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*)(*1*), (g)(3)(iv)(*b*)(*2*), (g)(3)(iv)(*c*), (g)(3)(v)(*a*), (g)(3)(vi)(*a*), (g)(4)(iii)(*d*), (g)(5)(i), (g)(6)(iv), (g)(7), (h)(3)(i)(*a*), (h)(3)(iii)(*b*), (h)(3)(iv), (h)(5), (h)(7)(i)(*b*), (h)(7)(iii)(*c*), (j), and Tables H–12, H–14 through H–17, and H–19;

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 Sec. 1910.6, shall be used or an equivalent test method as defined in Appendix B to § 1910.1200—Physical Hazard Criteria.

(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) shall be used or an equivalent method as defined by Appendix B to § 1910.1200—Physical Hazard Criteria, 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 standards are 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*) 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.

Exemption: Tanks of 3,000 bbls. 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 (vi) (*b*) of this section.)

(*g*) Flame arresters or venting devices required in paragraph (*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

* * * * *

(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.

* * * * *

(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 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.

* * * * *

(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 Category 3 flammable liquids with a flashpoint at or above 100 °F (37.8 °C) or Category 4 flammable liquids only 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) * * *

(a) * * *

* * * * *

(*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 Cagetory 1 or 2 flammable liquids or Category 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 below 199.4 °F (93 °C) unless otherwise noted. This section does not apply to:

* * * * *

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).

BILLING CODE 4510–26–P

TABLE H-14 - INDOOR CONTAINER STORAGE

Category liquid	Storage level	Gallons	
		Protected storage maximum per pile	Unprotected storage maximum per pile
1	Ground and upper floors.....	2,750	660
		(50)	(12)
	Basement.....	Not permitted	Not permitted
2	Ground and upper floors.....	5,500	1,375
		(100)	(25)
	Basement.....	Not permitted	Not permitted
3 ..... FP<100F	Ground and upper floors.....	16,500	4,125
		(300)	(75)
	Basement.....	Not permitted	Not permitted
3 .... FP≥100F	Ground and upper floors.....	16,500	4,125
		(300)	(75)
	Basement.....	5,500	Not permitted
		(100)	
4 ...	Ground and upper floors.....	55,000	13,750
		(1,000)	(250)
	Basement.....	8,250	Not permitted
		(450)	

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. (Number in parenthesis indicate corresponding number of 55-gal. drums.)

NOTE 4: FP means Flashpoint

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.

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 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 °(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

BILLING CODE 4510–26–C

* * * * *

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'' and replacing them with the phrase ''flammable liquids or liquids with a flashpoint greater than 199.4 °F (93 °C)'' and;

B. Revise paragraphs (e) introductory text 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) *Definitions.* * * *

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 which are classified in accordance with the Hazard Communication Standard, 29 CFR 1910.1200 as posing one of the following 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; target organ specific systemic toxicity (single or repeated dose); or aspiration toxicity. 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 term ''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 a liquid having a flashpoint 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 a flashpoint greater than 199.4 °F (93 °C) is:

* * * * *

10. Amend § 1910.125 introductory text (including the table) to read as follows:

§ 1910.125 Additional requirements for dipping and coating operations that use flammable or combustible liquids.

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 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.

* * * * *

Subpart Q—[Amended]

11. Continue the authority citation for subpart Q 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), or 5–2007 (72 FR 31159), as applicable; and 29 CFR part 1911.

12. Amend § 1910.252 as follows;

A. Revise paragraph (c)(1)(iv);

B. Add new paragraph (c)(1)(v).

§ 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) (29 CFR 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 29 CFR 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 the hazard as required by § 1910.1200, if any, associated with the use of their materials in welding, cutting, and brazing.

(B) 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 containing fluorine compounds, the labels shall indicate the hazards associated with fluorine compounds including eye and respiratory tract effects.

* * * * *

Subpart Z—[Amended]

13. Revise the authority citation for subpart Z to read as follows:

Authority: Secs. 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), or 5–2007 (72 FR 31159), 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, Section 1910.1000 Tables Z–1, Z–2, and Z–3 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.

14. 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 (j)(6).

D. Add new paragraph (j)(1);

The revisions, with new designations, 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.* The employer shall include asbestos in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer 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 provisions of HCS and paragraph (j)(7) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer and lung effects.

* * * * *

(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

(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 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

(6) The provisions for labels and for safety data sheets required by paragraph (j) of this section do not apply where:

* * * * *

15. Amend § 1910.1003 as follows:

A. Amend the last sentence in paragraph (c)(4)(v) to 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);

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.* The employer shall include the carcinogens listed below in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer shall ensure that each employee has access to labels on containers of the carcinogens listed below and to safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (e)(3) of this section. The employer shall ensure that at least the hazards listed for the following chemicals are addressed:

4-Nitrobiphenyl: Cancer;

alpha-Naphthylamine: Cancer: skin irritation, and acute toxicity effects;

Methyl chloromethyl ether: Cancer; skin, eye and respiratory effects; acute toxicity effects; and flammability;

3,3'-Dichlorobenzidine (and its salts): Cancer and skin sensitization;

Bis-Chloromethyl ether: Cancer; skin, eye, and respiratory tract effects; acute toxicity effects; and flammability;

Beta-Naphthylamine: Cancer and acute toxicity effects;

Benzidine: Cancer and acute toxicity effects;

4-Aminodiphenyl: Cancer

Ethyleneimine: Cancer; mutagenicity; skin and eye effects; liver effects; kidney effects; acute toxicity effects; and flammability;

Beta-Propiolactone: Cancer; skin irritation; eye effects; and acute toxicity effects;

2-Acetylaminofluorene: Cancer;

4-Dimethylaminoazo-benzene: Cancer; skin effects; and respiratory tract irritation;

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) 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.

* * * * *

16. Amend § 1910.1017 by revising paragraph (l) to read as follows:

§ 1910.1017 Vinyl chloride.

* * * * *

(l) *Communication of hazards.* (1) *Hazard communication.* The employer shall include vinyl chloride in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer 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 provisions of HCS and paragraph (j) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer; central nervous system effects; liver effects; blood effects; and flammability.

(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

(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

(4) 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.

* * * * *

17. Amend § 1910.1018 by revising paragraphs (j)(2)(vii) and (p) as follows:

§ 1910.1018 Inorganic arsenic.

* * * * *

(j) * * *

(2) * * *

(vii) In addition to the communication requirements in paragraph (p) of this section, 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 EAT, DRINK, OR SMOKE. DO NOT REMOVE DUST BY BLOWING OR SHAKING.

* * * * *

(p) *Communication of hazards.* (1) *Hazard communication.* (i) The employer shall include inorganic arsenic in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer 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 provisions of HCS and paragraph (o) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer; liver effects; skin effects; respiratory irritation; nervous system effects; and acute toxicity effects.

(ii) The employer shall ensure that no statement appears on or near any sign or label required by this paragraph 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) The employer shall ensure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible.

* * * * *

18. Amend § 1910.1025 to revise paragraph (g)(2)(vii) and paragraph (m) to read as follows:

§ 1910.1025 Lead.

* * * * *

(g) * * *

(2) * * *

(vii) The employer shall ensure that labels of bags or containers of contaminated protective clothing and equipment include the following information: DANGER: COTHING 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

* * * * *

(m) *Communication of hazards.* (1) *Hazard communication.* The employer shall include lead in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer 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 provisions of HCS and paragraph (l) of this section. The employer shall ensure that at least the following hazards are addressed: Reproductive/developmental toxicity; central nervous system effects; kidney effects; blood effects; and acute toxicity effects.

(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 which contradicts or detracts from the meaning of the required sign.

(iii) The employer shall ensure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible.

* * * * *

19. Amend § 1910.1026 to revise paragraphs (h)(2)(iv), (j)(3)(ii) 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, 29 CFR 1910.1200.

* * * * *

(j) * * *

(3) * * *

(ii) The employer shall ensure that bags or containers of waste, scrap, debris, and any other materials contaminated with chromium (VI) that are consigned for disposal are labeled in accordance with the Hazard Communication Standard, 29 CFR 1910.1200.

* * * * *

(l) * * *

(1) *Hazard communication.* The employer shall include chromium (VI) in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer 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 provisions of HCS and paragraph (l)(2) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer, eye irritation, and skin sensitization.

* * * * *

20. Amend § 1910.1027 to revise paragraphs (i)(2)(iv), (k)(7), (m)(1), (m)(2)(ii), (m)(3)(i), and (m)(3)(ii) to read as follows:

§ 1910.1027 Cadmium.

* * * * *

(i) * * *

(2) * * *

(iv) The employer shall ensure that bags or 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 are labeled in accordance with paragraph (m) of this section. As a minimum, the employer shall ensure that labels on containers of contaminated protective clothing and equipment include the following information:

DANGER

CONTAINS CADMIUM

MAY CAUSE CANCER

CAUSES DAMAGE TO LUNGS AND KIDNEYS

AVOID CREATING DUST

* * * * *

(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.* The employer shall include cadmium in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer 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 provisions of HCS and paragraph (m)(4) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer; lung effects; kidney effects; and acute toxicity effects.

(2) * * *

(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

(3) * * *

(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 waste, scrap, or debris shall include at least the following information:

DANGER

CONTAINS CADMIUM

MAY CAUSE CANCER

* * * * *

21. Amend § 1910.1028 to revise the heading of paragraph (j) and the regulatory text of paragraphs (j)(1) and (j)(2) to read as follows:

§ 1910.1028 Benzene.

* * * * *

(j) *Communication of hazards.* (1) *Hazard communication.* The employer shall include benzene in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer 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 provisions of HCS and (j)(3) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer; central nervous system effects; blood effects; aspiration; skin, eye, and respiratory tract irritation; and flammability.

Note to paragraph (j)(1) of this section: There is no requirement to label pipes.

(2) *Signs.* 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

* * * * *

22. Amend § 1910.1029 to revise paragraph (l) to read as follows:

§ 1910.1029 Coke oven emissions.

* * * * *

(l) *Communication of hazards.* (1) *Hazard communication.* The employer shall include coke oven emissions in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 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 which contradicts or detracts from the effects of the required sign.

(iv) The employer shall ensure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible.

(3) *Labels.* In addition to the requirements in (l)(1) of this paragraph, 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 EAT, DRINK, OR SMOKE

DO NOT REMOVE DUST BY BLOWING OR SHAKING

* * * * *

23. Amend § 1910.1043 to revise paragraph (j) as follows:

§ 1910.1043 Cotton dust.

* * * * *

(j) *Signs.* 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

* * * * *

24. Amend § 1910.1044 to revise paragraphs (j)(2)(v), (k)(1)(iii)(*b*), and (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 in accordance with paragraph (o) of this section. As a minimum, the employer shall ensure that labels for containers of contaminated protective devices or work clothing include 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 (o) of this section.

* * * * *

(o) *Communication of hazards.* (1) *General.* (i) *Hazard communication.* The employer shall include DBCP in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer 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 provisions of HCS and paragraph (n) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer; reproductive effects; liver effects; kidney effects; central nervous system effects; skin, eye and respiratory tract irritation; and acute toxicity effects.

(ii) The employer shall ensure that no statement appears on or near any sign or label required by this paragraph which contradicts or detracts from the meaning of the required sign or label.

(2) *Signs.*

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

(3) The employer shall ensure that the precautionary labels required by this paragraph are readily visible and legible.

* * * * *

25. Amend § 1910.1045 to revise paragraphs (p)(1)(i), (p)(2)(i), and (p)(3) to read as follows:

§ 1910.1045 Acrylonitrile.

* * * * *

(p) *Communication of hazards.* (1) General. (i) *Hazard communication.* The employer shall include AN in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer shall ensure that each employee has access to labels on containers of AN and to safety data sheets, and is trained in accordance with the provisions of HCS and paragraph (o) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer; central nervous system effects; liver effects, skin sensitization, skin, respiratory, and eye irritation; acute toxicity effects; and flammability.

* * * * *

(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

* * * * *

(3) *Labels.* The employer shall ensure that precautionary labels 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.

* * * * *

26. Amend § 1910.1047 to revise the heading of paragraph (j) and paragraphs (j)(1) and (j)(2) to read as follows:

§ 1910.1047 Ethylene oxide.

* * * * *

(j) *Communication of hazards.* (1) *Hazard communication.* The employer shall include EtO in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer 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 provisions of HCS and paragraph (j)(3) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer; reproductive effects; mutagenicity; central nervous system; skin sensitization; skin, eye and respiratory tract irritation; acute toxicity effects; and flammability.

(2) *Signs and labels.*

(i) *Signs.* 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

(ii) *Labels.* 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, reaction vessels, storage tanks, and pipes or piping systems are not considered to be containers.

Note to paragraph (j)(2): 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.

* * * * *

27. Amend § 1910.1048 to revise paragraphs (e)(1); (h)(2)(ii); (j)(4) and (m) to read as follows:

§ 1910.1048 Formaldehyde.

* * * * *

(e) * * *

(1) 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

* * * * *

(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 and storage areas are labeled in accordance with the Hazard Communication standard, 29 CFR 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

* * * * *

(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.* The employer shall include formaldehyde in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer 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 provisions of HCS and paragraph (n) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer; skin and respiratory sensitization; eye, skin and respiratory tract irritation; acute toxicity effects; and flammability.

(i) The employer must include chemicals and substances 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, in the hazard communication program.

(ii) 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) In addition to the requirements in paragraphs (m)(1) introductory text and (m)(1)(i) of this section, for materials listed in paragraph (m)(1)(i) of this section 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.''

* * * * *

28. Amend § 1910.1050 as follows:

A. Revise paragraph (i)(2)(v) and 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 a new paragraph (k)(3).

The revisions and additions read as follows:

§ 1910.1050 Methylenedianiline.

* * * * *

(i) * * *

(2) * * *

(v) Containers of MDA-contaminated protective work clothing or equipment, which are to be taken out of change rooms or the workplace for cleaning, maintenance, or disposal, shall bear labels warning of the hazards of MDA. The employer shall ensure that labels are consistent with requirements in paragraph (k) of this section and that labels include at least the following information:

DANGER

CONTAINS METHYLENEDIANILINE (MDA)

MAY CAUSE CANCER

CAUSES DAMAGE TO THE LIVER

* * * * *

(k) *Communication of hazards.*

(1) *Hazard communication.* The employer shall include MDA in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer 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 provisions of HCS and paragraph (k)(4) of this section. The employer shall ensure that at least the following hazards are addressed:

Cancer; liver effects; and skin sensitization.

(2) *Signs.* 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

(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 .

* * * * *

29. Amend § 1910.1051 to revise paragraph (l)(1) as follows:

§ 1910.1051 1,3-Butadiene.

* * * * *

(l) * * *

(1) *Hazard communication.* The employer shall include BD in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer 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 provisions of HCS and paragraph (l)(2) of this section. The employer shall ensure that at least the following hazards are addressed: Cancer; eye and respiratory tract irritation; center nervous system effects; and flammability.

* * * * *

30. Amend § 1910.1052 to revise paragraph (k) as follows:

§ 1910.1052 Methylene chloride.

* * * * *

(k) *Hazard communication.* The employer shall include MC in the workplace hazard communication program established to comply with the Hazard Communication Standard (HCS) (29 CFR 1910.1200). The employer 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 provisions of HCS and paragraph (l) of this section. The employer shall provide information on at least the following hazards: Cancer, cardiac effects (including elevation of carboxyhemoglobin), central nervous system effects, liver effects, and skin and eye irritation.

* * * * *

31. Amend § 1910.1200 as follows:

A. Remove the word ''material'' before the word ''safety'' in the phrase ''material safety data sheet'' wherever it appears in paragraphs (b)(3)(ii) and (iv), (b)(4)(ii) five times, (e)(1) introductory text, (e)(1)(i), (e)(2)(i), (g)(heading), (g)(1) two times, (g)(4), (6)(i) two times, (g)(6)(ii) through (iv), (g)(7)(i) two times, (g)(7)(ii), (g)(7)(iii) two times, (g)(7)(iv) two times, (g)(7)(v) two times, (g)(7)(vi) and (vii), (g)(8) two times, (g)(9), (g)(10), (h)(l), (h)(2)(iii),and (i)(1)(ii);

B. Remove the following definitions in paragraph (c) *Combustible liquid, Compressed gas, Explosive, Flammable, Flashpoint, Hazard warning, Identity, Material Data Safety Sheet (MSDS), Organic peroxide, Oxidizer, Pyrophoric, Unstable (reactive),* and *Water reactive;*

C. Revise the following definitions in paragraph (c) *Chemical, Chemical name, Health hazard, Label, Mixture, Physical hazard,* and *Trade secret;*

D. Revise the definition of the term ''Hazardous chemical'' and relocate it in alphabetical order in paragraph (c).

E. Add the following definitions in alphabetical order in paragraph (c) in alphabetical order *Classification, Hazard category, Hazard class, Hazard statement, Label element, Pictogram, Precautionary statement, Product identifier, Safety Data Sheet (SDS), Signal word, Substance and Unclassified Hazard;*

F. Revise paragraphs (a)(1), (a)(2), (b)(1), (d) (heading), (d)(1) through (d)(3), (f), (g)(2), (g)(3), (g)(5), (g)(11), (h)(3)(iv), (i)(1), (i)(1)(iii) and (iv), (i)(2), (i)(3), (i)(3)(iii), (i)(7), (i)(7)(iii), (i)(7)(v), (i)(9)(i), (i)(10)(i), (i)(10)(ii), (i)(11), and (i)(13), and (j);

G. Remove Appendices A, B, and E to § 1910.1200; redesignate Appendix D to § 1910.1200 as Appendix E to § 1910.1200 and 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 Labeling 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 legal requirements 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, through any court or agency, 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.)

* * * * *

(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, and 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 4 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 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, or an unclassified hazard as defined in this section.

* * * * *

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; 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 required list of hazardous chemicals, the label and the SDS.

* * * * *

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.

* * * * *

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.

Unclassified hazard means a chemical for which there is scientific evidence identified during the classification process that it may pose an adverse physical or health effect when present in a workplace under normal conditions of use or in a foreseeable emergency, but the evidence does not currently meet the specified criteria for physical or health hazard classification in this section. This does not include adverse physical and health effects for which there is a hazard class addressed in this section.

* * * * *

(d) *Hazard classification.*

(1) Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported by them to classify their health and physical hazards in accordance with this section. For each chemical, the chemical manufacturer or importer shall determine the hazard classes, and 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 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 this section.

(ii) A chemical manufacturer or importer of a mixture shall be

responsible for the accuracy of the classification of the mixture even when relying on the classifications for individual ingredients received from the ingredient manufacturers or importers on the safety data sheets.

* * * * *

(f) *Labels and other forms of warning.*

(1) *Labels on shipped containers.* The chemical manufacturer, importer, or distributor shall ensure that each 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.

(2) For unclassified hazards, the label shall include the name of the chemical, the name, address, and telephone number of the manufacturer, importer, or other responsible party, and, provide as supplementary information, a description of the unclassified hazards and appropriate precautionary measures to ensure the safe handling and use of the chemical.

(3) The chemical manufacturer, importer, or distributor shall ensure that the information provided under (f)(1)(i) through (v) is in accordance with 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).

(4) The chemical manufacturer, importer, or distributor shall ensure that the information provided under (f)(1)(ii) through (iv) is located together on the label, tag, or mark.

(5)(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).

(6) 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.

(7) *Workplace labeling.* Except as provided in paragraphs (f)(8) and (f)(9) 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 (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.

(8) 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)(7) 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.

(9) 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.

(10) 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.

(11) 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.

(12) 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 three 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) * * *

(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 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.

Note 1 to paragraph (g)(2): To be consistent with the GHS, an SDS must also include the following headings in this order:

Section 12, Ecological information;

Section 13, Disposal considerations;

Section 14, Transport information; and

Section 15, Regulatory information.

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.

(xii) Section 16, Other information, including date of preparation or last revision.

(g)(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.

* * * * *

(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 29 CFR 1910.1020(e).

(h) * * *

(3) * * *

(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 the 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 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.

(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.

* * * * *

(13) Nothing in this paragraph (i) shall be construed as requiring the disclosure under any circumstances of process information which is a trade secret.

(j) *Effective dates.* (1) Employers shall train employees regarding the new labels and safety data sheets by [date 2 years after the publication of the final rule].

(2) Chemical manufacturers, importers, distributors, and employers shall be in compliance with all modified provisions of this section no later than

[date 3 years after the publication of the final rule].

(3) Chemical manufacturers, importers, distributors, and employers may comply with either 29 CFR 1910.1200 revised as of October 1, 2009, or the modified version of this standard, or both during the 3-year 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 procedures.

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.

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 assembled 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 assembled 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 that 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;

For health hazards,

(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 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 Concentration Limits

A.0.4.3.1 When classifying an untested mixture based on the hazards of its ingredients, concentration limits for the classified ingredients of the mixture are used for several hazard classes. While the adopted concentration limits adequately identify the hazard for most mixtures, there may be some that contain hazardous ingredients at lower concentrations than the specified concentration limits that still pose an identifiable hazard. There may also be cases where the concentration limit is considerably lower than could be expected on the basis of an 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 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 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 commercial product, when produced by or under the control of the same 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.

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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: Notes (a)(b)*	≤ 5	>5 and ≤ 50	>50 and ≤ 300	>300 and ≤ 2000
Dermal (mg/kg bodyweight) *see: Notes (a)(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: Gases concentration are expressed in parts per million per volume (ppmV).

Notes to Table A.1.1:

(a) The acute toxicity estimate (ATE) for the classification of a substance is derived using the LD_{50}/LC_{50} where available ;

(b) The acute toxicity estimate (ATE) for the classification of a substance or ingredient in a mixture is derived using:

(i) the LD_{50}/LC_{50} where available. Otherwise,

(ii) the appropriate conversion value from Table 1.2 that relates to the results of a range test, or

(iii) the appropriate conversion value from Table 1.2 that relates to a classification category;

(c) Inhalation cut-off values in the table are based on 4 hour testing exposures. Conversion of existing inhalation toxicity data which has been generated according to 1 hour exposure is achieved by dividing by a factor of 2 for gases and vapors and 4 for dusts and mists;

(d) For some chemicals the test atmosphere may consist of a vapor which is near the gaseous phase. In these 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.

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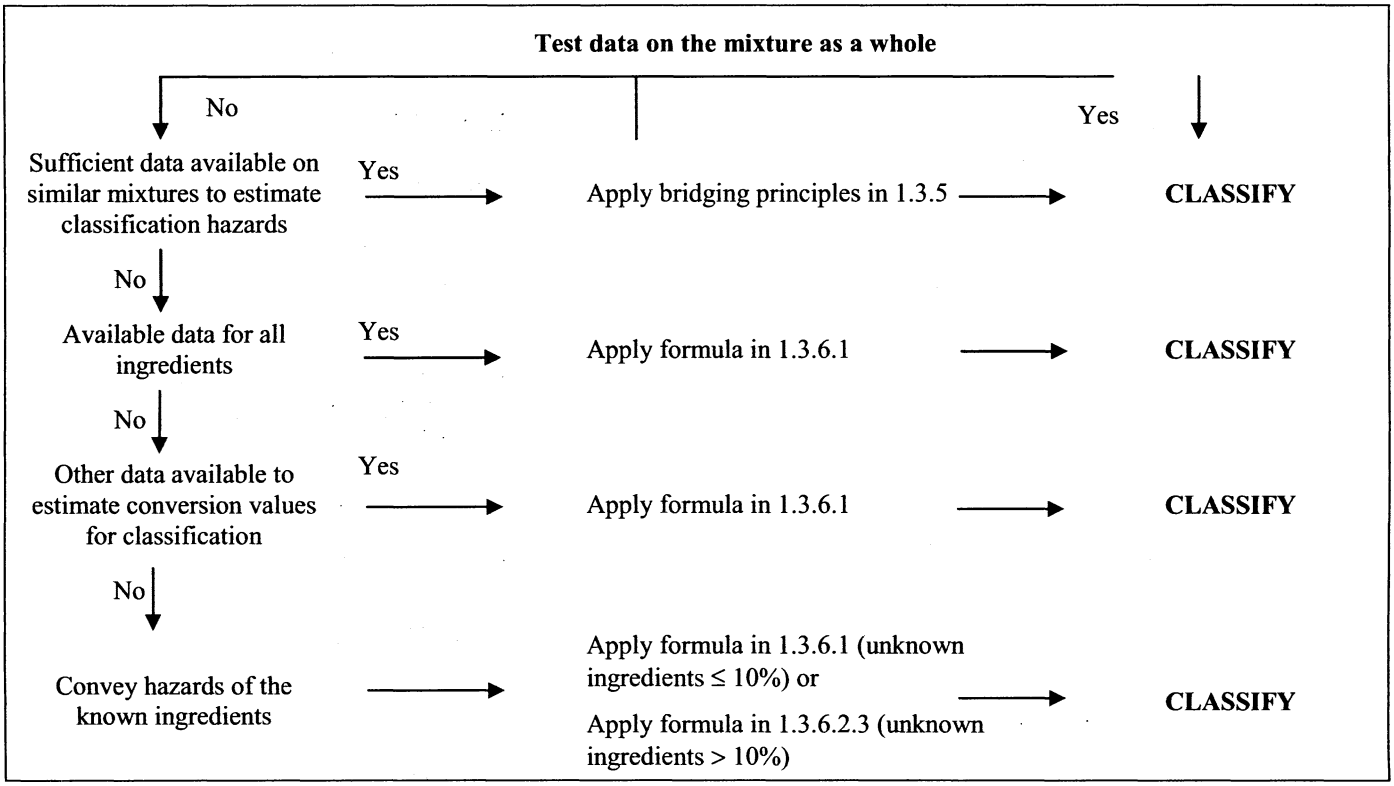
A.1.2.3 The preferred test species for evaluation of acute toxicity by the oral and inhalation routes is the rat, while the rat or rabbit are preferred for evaluation of acute

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 can be carried out for each route of exposure, but is only needed 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 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.1.3.6.2.3.

(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.1.3.6.2.3.

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;

(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.1.3.6.2.3.''.

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:

$$\frac{100}{\text{ATEmix}} = \sum_{n} \frac{Ci}{\text{ATE}_i}$$

Where:

C^i = concentration of ingredient i

n ingredients and i is running from l 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%, 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, Allocation of Label Elements and Appendix D, Safety Data Sheets.)

A.1.3.6.2.4 If the total concentration of the 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 ingredient(s) with unknown toxicity is > 10%, the formula presented in A.1.3.6.1 is corrected to adjust for the total percentage of the unknown ingredient(s) as follows:

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$$\frac{100 - \left(\sum C_{\text{unknown}} \text{ if } >10\%\right)}{\text{ATE}_{\text{mix}}} = \sum_{n} \frac{Ci}{\text{ATE}_i}$$

Table A.1.2: Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for use in the formulas for the classification of mixtures

Exposure routes	Classification category or experimentally obtained acute toxicity range estimate	Converted Acute Toxicity point estimate
Oral (mg/kg bodyweight)	0 < Category 1 ≤ 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: Gases concentration are expressed in parts per million per volume (ppmV).

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A.2 SKIN CORROSION/IRRITATION

A.2.1 Definitions

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.2.2 Classification Criteria for Substances Using Test Data

A.2.2.1 Corrosion

A.2.2.2 A single harmonized corrosion category is provided in Table A.2.1, using the results of animal testing. A corrosive is a substance 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.2.2.3 Three sub-categories of Category 1 are provided in Table A.2.1, all of which will be regulated as Category 1.

TABLE A.2.1—SKIN CORROSION CATEGORY AND SUB-CATEGORIES [a]

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] *The use of human data is discussed in Appendix A.0.2.6.*

A.2.3 Irritation

A.2.3.1 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 [a]

	Criteria
Irritant (Category 2)	(1) Mean value of ≥ 2.3 ≤ 4.0 for erythema/eschar or for oedema 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] The use of human data is discussed in Appendix A.0.

A.2.3.2 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.2.3.3 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 material should be considered to be an irritant.

A.2.4 Classification Criteria for Substances Using Other Data Elements

A.2.4.1 Several factors must be considered in determining the corrosion and irritation potential of substances when no clear data exist for those substances:

- Solid substances (powders) may become corrosive or irritant when moistened or in contact with moist skin or mucous membranes.
- Existing human experience and data including from single or repeated exposure and animal observations and data shall be the first line of analysis, as they give information directly relevant to effects on the skin.
- In some cases enough information may be available from structurally related compounds to make classification decisions.
- pH extremes ≤ 2 and ≥ 11.5 may indicate skin effects, especially when buffering capacity is known, although the correlation is not perfect. Generally, such agents are expected to produce significant effects on the skin.
- If a chemical is highly toxic by the dermal route, data from dermal testing for skin irritation/corrosion may not be available 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.
- *In vitro* alternatives that have been validated and accepted may also be used to help make classification decisions.

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 (see A.2.4), 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. Primary 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.

A.2.4.2 A *tiered approach* to the evaluation of initial information shall be considered, where applicable (Figure A.2.1), recognizing that all elements may not be relevant in certain cases.

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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 experience	Corrosive	Category 1
	↓ Not corrosive or no data		
1b	Existing human or animal experience	Irritant	Category 2
	↓ Not irritant or no data		
1c	Existing human or animal experience	Not corrosive or irritant	Not classified
	↓ No data		
2a	Structure-activity relationships	Corrosive	Category 1
	↓ Not corrosive or no data		
2b	Structure-activity relationships	Irritant	Category 2
	↓ Not irritating or no data		
3	pH with buffering [(a)]	pH ≤ 2 or ≥ 11.5	Category 1
	↓ Not pH extreme or no data		
4	Valid and accepted *in vitro* skin corrosion test	Positive response	Category 1
	↓ Negative response or no data		
	↓		
5	Valid and accepted *in vitro* skin irritation test [(b)]	Positive response	Category 2
	↓ Negative response or no data	→	Not classified

(a) Measurement of pH alone may be adequate, but assessment of acid or alkali reserve is preferable; methods are needed to assess buffering capacity;

(b) Presently there are no validated and accepted in vitro test methods for skin irritation.

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A.2.5 Classification Curiteria for Mixtures

A.2.5.1 Classification of Mixtures When Data Are Available for the Complete Mixture

A.2.5.1.1 The mixture shall be classified using the criteria for substances (see A.2.2 to A.2.4).

A.2.5.2 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

A.2.5.2.1 Where the mixture itself has not been tested to determine its skin irritation/corrosion, 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.2.5.3 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

A.2.5.3.1 In order to make use of all available data for purposes of classifying the skin irritation/corrosion hazards of mixtures, the following assumption has been made and is applied where appropriate in the tiered approach:

The ''relevant ingredients'' of a mixture are those which are present in concentrations ≥ 1% (w/w for solids, liquids, dusts, mists and vapors and v/v for gases), unless there is a presumption (*e.g.* in the case of corrosive ingredients) that an ingredient present at a concentration < 1% can still be relevant for classifying the mixture for skin irritation/corrosion.

A.2.5.3.2 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.2.5.3.3 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.2.5.3.4 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.2.5.3.1 and A.2.5.3.2 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.2.5.3.5 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 3.2.3 and 3.2.4. In these cases the mixture could be classified according to those data (see *Use of concentration limits*, paragraph A.0.4.3 of this Appendix).

A.2.5.3.6 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 concentration limits,* paragraph A.0.4.3 of this Appendix).

TABLE A.2.3—CONCENTRATION OF INGREDIENTS OF A MIXTURE CLASSIFIED AS SKIN CATEGORY 1 OR 2 THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE AS HAZARDOUS TO SKIN (CATEGORY 1 OR 2)

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Skin corrosive	Skin irritant
		Category 1
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

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.3.2 Classification Criteria for Substances Using 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 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.

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Table A.3.1: Irreversible eye effects [a]

An eye irritant Category 1 (irreversible effects on the eye) is a substance that produces:
(a) at least in one animal effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days; and/or
(b) 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 installation of the substance.

[a] *The use of human data is discussed in paragraph A.0.2.6.*

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

An eye irritant Category 2A (irritating to eyes) is a substance that produces:
(a) 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
calculated as the mean scores following grading at 24, 48 and 72 hours after installation of the substance, and which fully reverses within an observation period of normally 21 days.

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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 A tiered evaluation scheme that combines pre-existing information on serious ocular tissue damage and on eye irritation (including data relating to historical human or animal experience) as well as considerations on structure-activity relationships (SAR) or structure-property relationships (SPR) and the output of validated in vitro tests shall be used for substances where no clear test data exist for those substances:

A.3.3.2 All existing information on a substance shall be reviewed and several factors considered in determining the serious eye damage or irritation potential of substances:

- Accumulated human and animal data shall be the first line of analysis, as it gives information directly relevant to effects on the eye.
- In some cases enough information may be available from structurally related compounds to make hazard decisions.
- Likewise, pH extremes like ≥ 2 and > 11.5 may produce serious eye damage, especially when associated with significant buffering capacity. Such agents are expected to produce significant effects on the eyes.
- Possible skin corrosion has to 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 validated and accepted may be used to make classification decisions.

A.3.3.3 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. Generally, primary emphasis shall be placed upon expert judgment, considering human experience with the substance, followed by the outcome of skin irritation testing and of well validated alternative methods.

A.3.3.4 A tiered approach to the evaluation of initial information shall be considered where applicable, recognizing that all elements may not be relevant in certain cases (Figure A.3.1).

A.3.3.5 The proposed tiered testing approach provides good guidance on how to organize existing information on a substance and to make a weight-of-evidence decision, where appropriate, about hazard assessment and hazard classification.

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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	Findings	Conclusions
1a	Data relating to historical human or animal experience	→ Serious eye damage	→ Category 1
		→ Eye irritant	→ Category 2
	↓ No or No Evaluation		
1b	Data relating to historical human or animal experience	→ Skin corrosive	→ Category 1
	↓ No or No Evaluation		
1c	Data relating to historical human or animal experience	→ Skin irritant	→ Category 2
	↓ No or No Evaluation		
2a	Structure activity relationships (SAR)	→ Severe damage to eyes	→ Category 1
	↓ No or don't know		
2b	Structure activity relationships (SAR)	→ Eye irritant	→ Category 2
	↓ No or No Evaluation		
2c	Structure activity relationships (SAR)	→ Skin corrosive	→ Category 1
	↓ No or No Evaluation		
3a	pH/acid or alkaline reserve	→ pH ≥ 11.5 or pH ≤ 2 (considering acid or alkaline reserve)	→ Category 1
	↓		
3b	2 < pH < 11.5 (no buffering potential)		
	↓		
4	Other information indicating the material is a skin corrosive	→ Yes	→ Category 1
	↓ No		

(Cont'd on next page)

Figure A.3.1 *(cont'd)*: Evaluation strategy for serious eye damage and eye irritation (see also Figure A.2.1)

Step	Parameter	Findings	Conclusions
5	Is a valid *in vitro* test available to assess severe damage to eyes	No	Go to step 6
5a	*In vitro* test for severe eye irritation	Severe damage to eyes	Category 1
	Not a severe eye irritant		
6	Is a valid *in vitro* test for eye irritation available	No	Not Classified
	Yes		
6a	*In vitro* eye irritation test	Eye irritant	Category 2
	No indication of eye irritant properties		Not Classified

Notes to Figure A.3.1:

Step 1a/b: Data relating to historical human or animal experience: pre-existing information on eye irritation and skin corrosion are shown separately because evaluation of skin corrosion has to be considered if there is no information on local effects on eyes. Analysis of pre-existing experience with the substance may identify serious eye damage, corrosion and irritation potential for both skin and eye effects:

(i) Step 1a - reliable determination of eye irritancy basing on human or animal experience - depends on expert judgment: in most cases human experience is based on accidental events and thus, the local effects detected after an accident have to be compared with classification criteria created for evaluation of animal test data;

(ii) Step 1b - evaluation of data on skin corrosivity - skin corrosive substances shall be considered as leading to serious damage to the eyes as well (Category 1).

Step 2a/b/c: SAR (Structure Activity Relationships) for eye irritation and skin corrosion are shown separately but in reality would probably be done in parallel. Scientifically validated and accepted SAR approaches shall be used. The SAR analysis may identify serious eye damage, corrosion and irritation potential for both skin and eye effects:

(i) Step 2a - reliable determination of eye irritancy only by theoretical evaluations - in most cases it will only be appropriate for substances that are homologous to agents with very well known properties;

(ii) Step 2c - theoretical evaluation of skin corrosivity - skin corrosive substances shall be considered as leading to serious damage to the eyes as well (Category 1).

Step 3: pH extremes like ≤ 2 and ≥ 11.5 may indicate strong local effects, especially in combination with assessment of acid or alkaline reserve, substances exhibiting such physico-chemical properties should be considered as leading to serious damage to eyes (Category 1).

Step 4: All attainable information shall be used, including human experience.

Step 5: These must be scientifically validated, alternative methods for the assessment of eye irritation/ or serious damage to eyes (e.g. irreversible corneal opacity)

Step 6: At present this step seems not to be achievable in the near future. If such methods are developed, they must be scientifically, validated alternative methods for the reliable assessment of (reversible) eye irritation.

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A.3.4 Classification Criteria for Mixtures

A.3.4.1 Classification of Mixtures When Data Are Available for the Complete Mixture

A.3.4.1.1 The mixture will be classified using the criteria for substances, and taking into account the testing and evaluation strategies used to develop data for these hazard classes.

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, 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. A mixture is considered to cause serious eye damage (Eye Category 1) if it has a pH ≤ 2 or ≥ 11.5. If consideration of alkali/acid 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 testing needs to be carried out to confirm this, preferably by use of an appropriate validated *in vitro* test.

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 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 In order to make use of all available data for purposes of classifying the eye irritation/serious eye damaging properties of the mixtures, the following assumption has been made and is applied where appropriate in the tiered approach:

The ''relevant ingredients'' of a mixture are those which are present in concentrations ≥ 1% (w/w for solids, liquids, dusts, mists and vapours and v/v for gases), unless there is a presumption (*e.g.,* in the case of corrosive ingredients) that an ingredient present at a concentration < 1% can still be relevant for classifying the mixture for eye irritation/serious eye damage.

A.3.4.3.2 In general, the approach to classification of mixtures as eye irritant or seriously damaging to the eye 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 an irritant or as seriously damaging to the eye.

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 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 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%.
Eye Category 2		≥ 10%.
(10 × eye Category 1) + eye Category 2		≥ 10%.
Skin Category 1 + eye 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
10 × (skin Category 1 + eye Category 1) + eye Category 2	.....	≥ 10%.

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.

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.[19]
Sub-category 1A	Substances showing a high frequency of occurrence in humans; or a probability of occurrence of a high sensitization rate in humans based on animal or other tests.[1] Severity of reaction may also be considered.
Sub-category 1B	Substances showing a low to moderate frequency of occurrence in humans; or a probability of occurrence of a low to moderate sensitization rate in humans based on animal or other tests.[1] Severity of reaction may also be considered.

A.4.2.1.2 *Human evidence*

A.4.2.1.2.1 Evidence that a substance can lead to specific respiratory hypersensitivity will normally be based on human experience. In this context, hypersensitivity is normally seen as asthma, but other hypersensitivity reactions such as rhinitis/conjunctivitis and alveolitis are also considered. The condition will have the clinical character of an allergic reaction. However, immunological mechanisms do not have to be demonstrated.

A.4.2.1.2.2 When considering the human evidence, it is necessary that in addition to the evidence from the cases, the following be taken into account:

(a) the size of the population exposed;

(b) the extent of exposure.

A.4.2.1.2.3 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);

[19] 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.

(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 [1] which may be indicative of the potential of a substance to cause sensitization by inhalation in humans [20] 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.

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 (HRIPT, 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.[21]

A.4.2.2.3.2 Animal test results for sub-category 1A can include data with values indicated in Table A.4.3.

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* ≥60% responding at >0.2% to ≤20% topical induction dose.

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:

[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.

[20] The mechanisms by which substances induce symptoms of asthma are not yet fully known. For preventative 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 hyperreactivity, they should not be considered as respiratory sensitizers.

[21] 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.4.4—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.

A.4.2.2.4 *Specific Considerations*

A.4.2.2.4.1 For classification of a substance, evidence should include any or all 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 may also be considered.

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 can 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%.

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—Continued

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
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.

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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/genotoxic tests in germ cells in vivo, or by demonstrating the ability of the substance or its metabolite(s) to interact with the genetic material of germ cells; or

(c) Positive results from tests showing mutagenic effects in the germ cells of humans, without demonstration of transmission to progeny; for example, an increase in the frequency of aneuploidy in sperm cells of exposed people.

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.

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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.[1] Evaluation of the test results shall be done using expert judgment and all the available evidence shall be weighed for classification.

A.5.2.2.4 The classification of substances shall be based on the total weight of evidence available, using expert judgment. In those instances where a single well-conducted test is used for classification, it shall provide clear and unambiguously positive results. The relevance of the route of exposure used in the study of the substance compared to the route of human exposure should also be taken into account.

A.5.3 Classification Criteria for Mixtures [22]

A.5.3.1 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

A.5.3.1.1 Classification of mixtures shall be based on the available test data for the individual ingredients of the mixture using cut-off values/concentration limits for the ingredients classified as germ cell mutagens.

A.5.3.1.2 The mixture will be classified as a mutagen when at least one ingredient has been classified as a Category 1A, Category 1B or Category 2 mutagen and is present at or above the appropriate cut-off value/concentration limit as shown in Table A.5.1 below for Category 1 and 2 respectively.

[22] It should be noted that the classification criteria for the GHS 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 or additivity. However, this approach is not used for Germ Cell Mutagenicity. These criteria for Germ Cell Mutagenicity consider the cut-off levels 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.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.

Examples of *in vivo* heritable germ cell mutagenicity tests are:

- Rodent dominant lethal mutation test (OECD 478)
- Mouse heritable translocation assay (OECD 485)
- Mouse specific locus test

Examples of *in vivo* somatic cell mutagenicity tests are:

- Mammalian bone marrow chromosome aberration test (OECD 475)
- Mouse spot test (OECD 484)
- Mammalian erythrocyte micronucleus test (OECD 474)

Examples of mutagenicity/genotoxicity tests in germ cells are:

(a) Mutagenicity tests:

a. Mammalian spermatogonial chromosome aberration test (OECD 483)

b. Spermatid micronucleus assay

(b) Genotoxicity tests:

a. Sister chromatid exchange analysis in spermatogonia

b. Unscheduled DNA synthesis test (UDS) in testicular cells

Examples of genotoxicity tests in somatic cells are:

- Liver Unscheduled DNA Synthesis (UDS) *in vivo* (OECD 486)
- Mammalian bone marrow Sister Chromatid Exchanges (SCE)

Examples of *in vitro* mutagenicity tests are:

- *In vitro* mammalian chromosome aberration test (OECD 473)
- *In vitro* mammalian cell gene mutation test (OECD 476)
- Bacterial reverse mutation tests (OECD 471)

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 [23]

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.

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[23] See Non-mandatory Appendix F for further guidance regarding hazard classification for carcinogenicity. This appendix is consistent with the GHS and is provided as guidance excerpted from monographs of the International Agency for Research on Cancer (IARC) Monographs programme on the evaluation of the strength and evidence of carcinogenic risks to humans.

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 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. 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.

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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 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 [24]

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 1: If a Category 2 carcinogen ingredient is present in the mixture at a concentration between 0.1% and 1%, information is required on the SDS for a product, however, a label warning is optional If a Category 2 carcinogen ingredient is present in the mixture at a concentration of ≥ 1%, both an SDS and a label is required and the information must be included on each.

A.6.3.2 Classification of Mixtures When Data Are Available for the Complete Mixture

A mixture may be classified based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (*e.g.*, statistical analysis, test sensitivity) of carcinogenicity test systems.

A.6.3.3 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

Where the mixture itself has not been tested to determine its carcinogenic hazard, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution; Batching; and Substantially similar mixtures.

A.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 lactation shall be classified in a separate hazard category in accordance with Figure A.7.1(b).

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[24] It should be noted that the classification criteria for the GHS 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 or additivity. However, this approach is not used for Carcinogenicity. These criteria for Carcinogenicity consider the cut-off levels 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.

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
(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.

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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 assembled together into 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 useful indicators 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 should 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 [25]

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.

[25] It should be noted that the classification criteria for the GHS 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 or additivity. However, this approach is not used for Reproductive Toxicity. These criteria for Reproductive Toxicity consider the cut-off levels 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.

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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 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 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

		Guidance value ranges for:		
Route of exposure	**Units**	**Category 1**	**Category 2**	**Category 3**
Oral (rat)	mg/kg body weight	$C \leq 300$	$2000 \geq C > 300$	Guidance values do not apply
Dermal (rat or rabbit)	mg/kg body weight	$C \leq 1000$	$2000 \geq C > 1000$	
Inhalation (rat) gas	ppmV/4h	$C \leq 2500$	$20{,}000 \geq C > 2500$	
Inhalation (rat) vapor	mg/l/4h	$C \leq 10$	$20 \geq C > 10$	
Inhalation (rat) dust/mist/fume	mg/l/4h	$C \leq 1.0$	$5.0 \geq C > 1.0$	

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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 (typical of new substances, but also true for many existing substances), 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 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 track irritation;

(d) There are currently no 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, in accordance with the principles of A.0.2.1 in this Appendix.

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. See A.0.2.1.

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, *i.e.,* 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).

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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 incidence, 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/incidence 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 that is for humans.

A.9.2.9.3 Thus, in animal studies, when significant toxic effects are observed that indicate classification, consideration of the duration of experimental exposure and the dose/concentration at which these effects were seen, in relation to the suggested guidance values, provides useful information to help assess the need to classify (since the toxic effects are a consequence of the hazardous property(ies) and also the duration of exposure and the dose/concentration).

A.9.2.9.4 The decision to classify at all can be influenced by reference to the dose/concentration guidance values at or below which a significant toxic effect has been observed.

A.9.2.9.5 The guidance values refer to effects seen in a standard 90-day toxicity study conducted in rats. They can be used as a basis to extrapolate equivalent guidance values for toxicity studies of greater or lesser duration, using dose/exposure time extrapolation similar to Haber's rule for inhalation, which states essentially that the effective dose is directly proportional to the exposure concentration and the duration of exposure. The assessment should be done on a case-by-case basis; for example, for a 28-day study the guidance values below would be increased by a factor of three.

A.9.2.9.6 Thus for Category 1 classification, significant toxic effects observed in a 90-day repeated-dose study conducted in experimental animals and seen to occur at or below the (suggested) guidance values (C) as indicated in Table A.9.1 would justify classification:

TABLE A.9.1—GUIDANCE VALUES TO ASSIST IN CATEGORY 1 CLASSIFICATION

[Applicable to a 90-day study]

Route of exposure	Units	Guidance values (dose/ concentration)
Oral (rat)	mg/kg body weight/day	$C \leq 10$.
Dermal (rat or rabbit)	mg/kg body weight/day	$C \leq 20$.
Inhalation (rat) gas	ppmV/6h/day	$C \leq 50$.
Inhalation (rat) vapor	mg/liter/6h/day	$C \leq 0.2$.
Inhalation (rat) dust/mist/fume	mg/liter/6h/day	$C \leq 0.02$.

A.9.2.9.7 For Category 2 classification, significant toxic effects observed in a 90-day repeated-dose study conducted in experimental animals and seen to occur within the (suggested) guidance value ranges as indicated in Table A.9.2 would justify classification:

TABLE A.9.2—GUIDANCE VALUES TO ASSIST IN CATEGORY 2 CLASSIFICATION

[Applicable to a 90-day study]

Route of exposure	Units	Guidance value range (dose/ concentration)
Oral (rat)	mg/kg body weight/day	$10 < C \leq 100$.
Dermal (rat or rabbit)	mg/kg body weight/day	$20 < C \leq 200$.
Inhalation (rat) gas	ppmV/6h/day	$50 < C \leq 250$.
Inhalation (rat) vapor	mg/liter/6h/day	$0.2 < C \leq 1.0$.
Inhalation (rat) dust/mist/fume	mg/liter/6h/day	$0.02 < C \leq 0.2$.

A.9.2.9.8 The guidance values and ranges mentioned in A.2.9.9.6 and A.2.9.9.7 are intended only for guidance purposes, *i.e.,* to be used as part of the weight of evidence approach, and to assist with decisions about classification. They are not intended as strict demarcation values.

A.9.2.9.9 Thus, it is feasible 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 or 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 (typical of new substances, but also true for many existing substances), 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 incidence 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 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 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.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 in accordance with A.0.2.1.

TABLE A.9.3—CUTOFF 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. See A.0.2.1.

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:

$$\frac{\text{Dynamic viscosity (mPa}\cdot\text{s)}}{\text{Density}\left(\text{g/cm}^3\right)} = \text{Kinematic viscosity } \left(\text{mm}^2/\text{s}\right)$$

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 1); or (b) If it is a hydrocarbon and has a kinematic viscosity ≤ 20.5 mm^2/s, measured at 40 °C.

Note 1: 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 Hazard Criteria (Mandatory)

B.1 EXPLOSIVES

B.1.1 Definitions and General Considerations

B.1.1.1 An explosive chemical is a solid or liquid chemical which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings. Pyrotechnic chemicals are included even when they do not evolve gases.

A *pyrotechnic chemical* is a chemical designed to produce an effect by heat, light, sound, gas or smoke or a combination of these as the result of non-detonative self-sustaining exothermic chemical reactions.

An *explosive item* is an item containing one or more explosive chemicals.

A *pyrotechnic item* is an item containing one or more pyrotechnic chemicals.

An *unstable explosive* is an explosive which is thermally unstable and/or too sensitive for normal handling, transport, or use.

An *intentional explosive* is a chemical or item which is manufactured with a view to produce a practical explosive or pyrotechnic effect.

B.1.1.2 The class of explosives comprises:

(a) Explosive chemicals;

(b) Explosive items, except devices containing explosive chemicals in such quantity or of such a character that their inadvertent or accidental ignition or initiation shall not cause any effect external to the device either by projection, fire, smoke, heat or loud noise; and

(c) Chemicals and items not included under (a) and (b) 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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition.* 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.1.3.3 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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition*) 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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition;* 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;

(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. 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:

less than 15%, by mass, if the oxidizing substance is assigned to Category 1 or 2;

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 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 methods adopted by ISO (see ISO 10156:1996 ''Gases and gas mixtures—Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets''). Where insufficient data are available to use these methods, 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% of 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, or (b) for foam aerosols, in the aerosol foam flammability test. (i) the flame height is ≥ 20 cm and the flame duration ≥ 2 s; or (ii) the flame height is ≥ 4 cm and the flame duration ≥ 7 s.
2	Contains > 1% flammable components, or the heat of combustion is ≥ 20 kJ/g; and

TABLE B.3.1—CRITERIA FOR FLAMMABLE AEROSOLS—Continued

Category	Criteria
	(a) for spray aerosols, in the ignition distance test, ignition occurs at a distance ≥ 15 cm, 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:

$$\Delta Hc\ (product) = \sum_{i}^{n} [wi\% \times \Delta Hc(i)]$$

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(2007)—Standard Test Methods for Heat of Combustion of Liquid Hydrocarbon Fuels by Bomb Calorimeter, ISO/FDIS 13943:1999, 86.1 to 86.3—Fire safety—Vocabulary, and NFPA 30B—Code for the Manufacture and Storage of Aerosol Products, 2007 Edition).

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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition.*

B.4 OXIDIZING GASES

B.4.1 Definition

Oxidizing gas means any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.

Note: ''Gases which cause or contribute to the combustion of other material more than air does'' means pure gases or gas mixtures with an oxidizing power greater than 23.5% (as determined, by a method specified in ISO 10156:1996 or 10156–2:2005 or an equivalent testing method.)

B.4.2 Classification Criteria

An oxidizing gas shall be classified in a single category for this class in accordance with Table B.4.1:

TABLE B.4.1—CRITERIA FOR OXIDIZING GASES

Category	Criteria
1	Any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.

B.4.3 Additional Classification Considerations

Classification shall be in accordance with tests or calculation methods as described in ISO 10156:1996 ''Gases and gas mixtures—Determination of fire potential and oxidizing ability for the selection of cylinder valve outlet'' and ISO 10156–2:2005 ''Gas cylinders, Gases and gas mixtures. Part 2: Determination of oxidizing ability of toxic and corrosive gases and gas mixtures''.

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 (−58 °F); including all gases with a critical temperature[1] ≤ −50 °C (−58 °F).
Liquefied gas	A gas which when under pressure is partially liquid at temperatures above −50 °C (−58 °F). A distinction is made between: (a) High pressure liquefied gas: a gas with a critical temperature[1] between −50 °C (−58 °F) and +65 °C (149 °F); and (b) Low pressure liquefied gas: a gas with a critical temperature[1] above +65 °C (149 °F).
Refrigerated liquefied gas	A gas which is made partially liquid because of its low temperature.
Dissolved gas	A gas which when under pressure is dissolved in a liquid phase solvent.

(1) The critical temperature is the temperature above which a pure gas cannot be liquefied, regardless of the degree of compression.

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).

B.6.2 Classification Criteria

A flammable liquid shall be classified in one of four categories in accordance with Table B.6.1:

TABLE B.6.1—CRITERIA FOR FLAMMABLE LIQUIDS

Category	Criteria
1	Flash point <23 °C (73.4 °F) and initial boiling point ≤ 35 °C (95 °F).
2	Flash point <23 °C (73.4 °F) and initial boiling point > 35 °C (95 °F).
3	Flash point ≥ 23 °C (73.4 °F) and ≤ 60 °C (140 °F).
4	Flash point > 60 °C (140 °F) and ≤ 93 °C (199.4 °F).

B.6.3 Additional Classification Considerations

The flash point shall be determined in accordance with Standard Method of Test for Flash Point by Tag Closed Tester (ASTM D 56–93), Standard Methods of Test for Flash Point of Liquids by Setaflash Closed Tester (ASTM D 3278–96), Standard Methods of Test for Flash Point by Small Scale Closed Tester (ASTM D 3828–93), Standard Method of Test for Flash Point by Pensky-Martens Closed Tester (ASTM D 0093–96), or any other method specified in GHS Revision 3, Chapter 2.6.

The initial boiling point shall be determined in accordance with ''Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure (ASTM D86–07a) or Standard Test Method for Distillation Range of Volatile Organic Liquids (ASTM D1078–05).

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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition*, Part III, sub-section 33.2.1, is less than 45 s or the rate of burning is more than 2.2 mm/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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition,* 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 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:

(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;

will be defined as self-reactive chemical TYPE D;

(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 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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition.*

B.8.3.2 Self-accelerating decomposition temperature (SADT) shall be determined in accordance with the *UN Recommendations for the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition,* Part II, section 28.

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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition;* 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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition*).

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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition,* 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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition* 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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition,* 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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition,* 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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and*

Criteria, Fourth Revised Edition, in accordance with Table B.13.1:

TABLE B.13.1—CRITERIA FOR OXIDIZING LIQUIDS

Category	Criteria
1	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, spontaneously ignites; or the mean pressure rise time of a 1:1 mixture, by mass, of chemical and cellulose is less than that of a 1:1 mixture, by mass, of 50% perchloric acid and cellulose;
2	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 40% aqueous sodium chlorate solution and cellulose; and the criteria for Category 1 are not met;
3	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 65% aqueous nitric acid and cellulose; and the criteria for Categories 1 and 2 are not met.

B.13.3 Additional Classification Considerations

B.13.3.1 For organic chemicals, the classification procedure for this class shall not be applied if:

(a) The chemical does not contain oxygen, fluorine or chlorine; or

(b) The chemical contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.

B.13.3.2 For inorganic chemicals, the classification procedure for this class shall not be applied if the chemical does not contain oxygen or halogen atoms.

B.13.3.3 In the event of divergence between tests 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.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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition* 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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition,* 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 tests 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:

(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; shall be defined as organic peroxide TYPE D;

(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 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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition.*

B.15.3.2 Self-accelerating decomposition temperature (SADT) shall be determined in accordance with the *UN Recommendations for the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition,* 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 Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition*, 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 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. For unclassified hazards, the label shall include a description of the hazards and appropriate precautions for safe handling and use under supplementary information.

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.2.3 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.

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.

BILLING CODE 4510–26–P

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

BILLING CODE 4510–26–C

C.2.3.3 Where a label required by the Department of Transportation under Title 49 of the Code of Federal Regulations appears on a container, the pictogram specified in C.4 for the same hazard shall not appear.

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 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 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 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.2.4.6 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 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.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, or when it provides information about unclassified hazards.

C.3.2 Where the manufacturer, importer, or distributor chooses to add supplementary information on the label, the placement of supplemental information shall not impede identification of information required by this section.

C.3.3 Where an ingredient with unknown acute toxicity is used in a mixture at a concentration $\geq 1\%$, a statement that $\times$ percent of the mixture consists of ingredient(s) of unknown toxicity is required on the label.

BILLING CODE 4510–26–P

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. ... 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 or doctor/physician.** **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)

Pictogram
Skull and crossbones

Hazard category	Signal word	Hazard statement
3	Danger	Toxic if swallowed

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash ... thoroughly after handling. ... 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 or doctor/physician.** **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)

Pictogram
Exclamation mark

Hazard category	Signal word	Hazard statement
4	Warning	Harmful if swallowed

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash ... thoroughly after handling. ... 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 or doctor/physician if you feel unwell.** **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.** **...** 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.** Manufacturer, importer, or distributor to specify type of equipment.	**If on skin: Gently wash with plenty of soap and water.** **Immediately call a poison center or doctor/physician.** **Specific measures (see ... on this label)** ... Reference to supplemental first aid instruction. - *if immediate measures such as specific cleansing agent is advised.* **Remove/Take off immediately all contaminated clothing.** **Wash contaminated clothing 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)

Pictogram
Skull and crossbones

Hazard category	Signal word	Hazard statement
3	Danger	Toxic in contact with skin

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear protective gloves/protective clothing. Manufacturer, importer, or distributor to specify type of equipment.	**If on skin: Wash with plenty of soap and water.** **Call a poison center or doctor/physician if you feel unwell.** **Specific measures (see ... on this label)** ... Reference to supplemental first aid instruction. *- if measures such as specific cleansing agent is advised.* **Remove/Take off immediately all contaminated clothing.** **Wash contaminated clothing 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)

Pictogram
Exclamation mark

Hazard category	Signal word	Hazard statement
4	Warning	Harmful in contact with skin

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear protective gloves/protective clothing Manufacturer, importer, or distributor to specify type of equipment.	**If on skin: Wash with plenty of soap and water.** **Call a poison center or doctor/physician if you feel unwell.** **Specific measures (see ... on this label)** ... Reference to supplemental first aid instruction. - *if measures such as specific cleansing agent is advised.* **Wash contaminated clothing 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)

Pictogram
Skull and crossbones

Hazard category	Signal word	Hazard statement
1	Danger	Fatal if inhaled
2	Danger	Fatal if inhaled

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/ vapors/spray. Manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.** **Wear respiratory protection.** Manufacturer, importer, or distributor to specify equipment.	**If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing.** **Immediately call a poison center or doctor/physician.** **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)

Pictogram
Skull and crossbones

Hazard category	Signal word	Hazard statement
3	Danger	Toxic if inhaled

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/vapors/spray. Manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.**	**If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing.** **Call a poison center or doctor/physician.** **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)

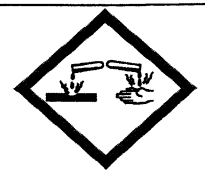
Pictogram
Exclamation mark

Hazard category	Signal word	Hazard statement
4	Warning	Harmful if inhaled

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/ vapors/spray. Manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.**	**If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing.** **Call a poison center or doctor/physician if you feel unwell.**		

C.4.4 SKIN CORROSION/IRRITATION
(CLASSIFIED IN ACCORDANCE with appendix A.2)

Pictogram
Corrosion



Hazard category	Signal word	Hazard statement
1A to 1C	Danger	Causes severe skin burns and eye damage

Precautionary statements

Prevention	Response	Storage	Disposal
Do not breathe dusts or mists. *- if inhalable particles of dusts or mists may occur during use.* **Wash ...thoroughly after handling.** ...Manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Wear protective gloves/protective clothing/eye protection/face protection.** Manufacturer, importer, or distributor to specify type of equipment.	**If swallowed: Rinse mouth. Do NOT induce vomiting.** **If on skin (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.** **Wash contaminated clothing before reuse.** **If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing.** **Immediately call a poison center or doctor/physician.** **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)

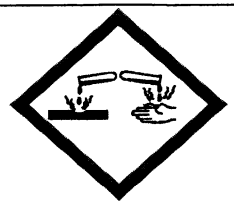
Pictogram
Exclamation mark

Hazard category	Signal word	Hazard statement
2	Warning	Causes skin irritation

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash ... thoroughly after handling. ... Manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Wear protective gloves.** Manufacturer, importer, or distributor to specify type of equipment.	**If on skin: Wash with plenty of soap and water.** **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 before reuse.**		

C.4.5 EYE DAMAGE/IRRITATION
(CLASSIFIED IN ACCORDANCE with appendix A.3)

Pictogram
Corrosion



Hazard category	Signal word	Hazard statement
1	Danger	Causes serious eye damage

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear eye protection/face protection. 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 or doctor/physician.**		

C.4.5 EYE DAMAGE/IRRITATION (CONTINUED) (CLASSIFIED IN ACCORDANCE with appendix A.3)

Hazard category	Signal word	Hazard statement
2A	Warning	Causes serious eye irritation

Pictogram

Exclamation mark

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash ... thoroughly after handling. ... Manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Wear eye protection/face protection.** 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. ... 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)

Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
1 (including both sub-categories 1A and 1B)	Danger	May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/vapors/spray. Manufacturer, importer, or distributor to specify applicable conditions. **In case of inadequate ventilation wear respiratory protection.** Manufacturer, importer, or distributor to specify equipment	**If inhaled: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.** **If experiencing respiratory symptoms: Call a poison center or doctor/physician.**		**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)

Pictogram

Exclamation mark

Hazard category	Signal word	Hazard statement
1 (including both sub-categories 1A and 1B)	Warning	May cause an allergic skin reaction

Precautionary statements

Prevention	Response	Storage	Disposal
Avoid breathing dust/fume/gas/mist/vapors/spray. Manufacturer, importer, or distributor to specify applicable conditions. **Contaminated work clothing must not be allowed out of the workplace.** **Wear protective gloves.** Manufacturer, importer, or distributor to specify type of equipment.	**If on skin: Wash with plenty of soap and water.** **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.** **Use personal protective 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)

Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
1A and 1B	Danger	May cause cancer <...>
2	Warning	Suspected of causing cancer <...>
		(state route of exposure if no other routes of exposure cause the hazard).

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not handle until all safety precautions have been read and understood.** **Use personal protective 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)

Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
1A and 1B	Danger	May damage fertility or the unborn child <...> <<...>>
2	Warning	Suspected of damaging fertility or the unborn child <...> <<...>>
		(state specific effect if known)
		(state route of exposure if no other routes of exposure cause the hazard)

Precautionary statements

Prevention	Response	Storage	Disposal
Obtain special instructions before use. **Do not handle until all safety precautions have been read and understood.** **Use personal protective 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	*No signal word*	May cause harm to breast-fed children

(See Table A.7.1 in Appendix A.7)

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.** ...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. Manufacturer, importer, or distributor to specify applicable conditions. **Wash ...thoroughly after handling.** ... 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 or doctor/physician.** **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)

Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
2	Warning	May cause damage to organs <...> <<...>> *(or state all organs affected, if known)* *(state route of exposure if no other routes of exposure cause the hazard)*

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/ vapors/spray. Manufacturer, importer, or distributor to specify applicable conditions. **Wash ... thoroughly after handling.** ... 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 if you feel unwell: Call a poison center or doctor/physician.**	**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)

Pictogram

Exclamation mark

Hazard category	Signal word	Hazard statement
3	Warning	May cause respiratory irritation; or May cause drowsiness or dizziness

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/ vapors/spray. Manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.**	**If Inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing.** **Call a poison center or doctor/physician if you feel unwell.**	**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)

Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
1	Danger	Causes damage to organs <...> through prolonged or repeated exposure <<...>> *(state all organs affected, if known)* *(state route of exposure if no other routes of exposure cause the hazard)*

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/ vapors/spray. Manufacturer, importer, or distributor to specify applicable conditions. **Wash ... thoroughly after handling.** ...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)

Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
2	Warning	May cause damage to organs <...> through prolonged or repeated exposure <<...>> *(state all organs affected, if known)* *(state route of exposure if no other routes of exposure cause the hazard)*

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/ vapors/spray. 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)

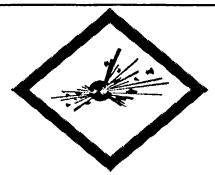
Pictogram
Health hazard

Hazard category	Signal word	Hazard statement
1	Danger	May be fatal if swallowed and enters airways

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
	If Swallowed: Immediately call a poison center or doctor/physician. **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.** **Use personal protective 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)

Pictogram
Exploding bomb

Hazard category	Signal word	Hazard statement
Division 1.1	Danger	Explosive; mass explosion hazard
Division 1.2	Danger	Explosive; severe projection hazard
Division 1.3	Danger	Explosive; fire, blast or projection hazard

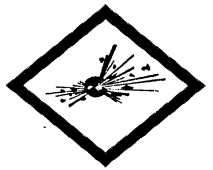
Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep wetted with...** ... 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.** ...Manufacturer, importer, or distributor to specify applicable rough handling. **Wear face protection.** 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
Exploding bomb[26]



Hazard category	Signal word	Hazard statement
Division 1.4	Warning	Fire or projection hazard

Precautionary statements[1]			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Manufacturer, importer, or distributor to specify applicable ignition source(s). **Ground/bond container and receiving equipment.** *- if the explosive is electrostatically sensitive.* **Do not subject to grinding/shock/.../friction.** Manufacturer, importer, or distributor to specify applicable rough handling. **Wear face protection.** Manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Evacuate area.** **Explosion risk in case of fire.** - except if explosives are 1.4S ammunition and components thereof. **Do NOT fight fire when fire reaches explosives.** **Fight fire with normal precautions from a reasonable distance** - if explosives are 1.4S ammunition and components thereof.	**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]

[26] Except if explosives are 1.4S small arms ammunition and components thereof. Labels for 1.4S small arms ammunition and components shall include appropriate precautionary statements.

C.4.14 EXPLOSIVES (CONTINUED)
(CLASSIFIED IN ACCORDANCE with Appendix B.1)

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. Manufacturer, importer, or distributor to specify applicable ignition source(s). Keep wetted with... ... 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.** ...Manufacturer, importer, or distributor to specify applicable rough handling. **Wear face protection.** 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)

Pictogram
Flame

Hazard category	Signal word	Hazard statement
1	Danger	Extremely flammable gas

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. -No smoking. 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. 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. 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 °C/122 °F.**	

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. ...Manufacturer, importer, or distributor to specify other incompatible materials. **Keep reduction valves free from grease and oil.**	**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)

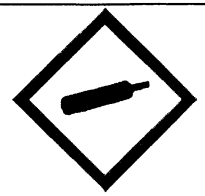
Pictogram
Gas cylinder

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)

Pictogram
Gas cylinder



Hazard category	Signal word	Hazard statement
Refrigerated liquefied gas	Warning	Contains refrigerated gas; may cause cryogenic burns or injury

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear cold insulating gloves/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. 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.** ... 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** Manufacturer, importer, or distributor to specify type of equipment.	**If on skin (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.** **In case of fire: Use ... for extinction.** ... 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** Manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... for extinction.** ... 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)

Pictogram
Flame

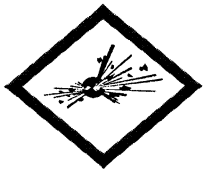
Hazard category	Signal word	Hazard statement
1	Danger	Flammable solid
2	Warning	Flammable solid

Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. 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.** ... Manufacturer, importer, or distributor to specify other equipment. - *if dust clouds can occur.* **Wear protective gloves/eye protection/face protection** Manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... for extinction** ... 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

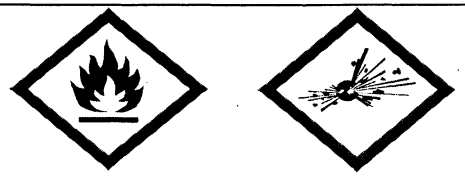
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep/Store away from clothing/.../combustible materials.** ... Manufacturer, importer, or distributor to specify other incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... for extinction** ... 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.** ... 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. Manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep/Store away from clothing/.../combustible materials.** ... Manufacturer, importer, or distributor to specify other incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... for extinction.** ... 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.** ... 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. Manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep/Store away from clothing/.../combustible materials.** ...Manufacturer, importer, or distributor to specify other incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... for extinction** ... 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.** ...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)

Pictogram
Flame

Hazard category	Signal word	Hazard statement
1	Danger	Catches fire spontaneously if exposed to air

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Manufacturer, importer, or distributor to specify applicable ignition sources(s). **Do not allow contact with air.** **Wear protective gloves/eye protection/face protection.** 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 ... for extinction** ... Manufacturer, importer, or distributor to specify appropriate media. - *if water increases risk.*	**Store contents under ...** ... Manufacturer, importer, or distributor to specify appropriate liquid or inert gas.	

C.4.23 PYROPHORIC SOLIDS
(CLASSIFIED IN ACCORDANCE with Appendix B.10)

Pictogram
Flame

Hazard category	Signal word	Hazard statement
1	Danger	Catches fire spontaneously if exposed to air

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Manufacturer, importer, or distributor to specify applicable ignition source(s). **Do not allow contact with air.** **Wear protective gloves/eye protection/face protection** 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 ... for extinction** ... Manufacturer, importer, or distributor to specify appropriate media. - *if water increases risk.*	**Store contents under ...** ...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.** 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.** ... 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)

Pictogram
Flame

Hazard category	Signal word	Hazard statement
1	Danger	In contact with water releases flammable gases, which may ignite spontaneously
2	Danger	In contact with water releases flammable gas

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from any possible contact with water, because of violent reaction and possible flash fire. **Handle under inert gas. Protect from moisture.** **Wear protective gloves/eye protection/face protection.** 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 ... for extinction** ... 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)

Pictogram
Flame

Hazard category	Signal word	Hazard statement
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.** Manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... for extinction.** ... 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)

Pictogram
Flame over circle

Hazard category	Signal word	Hazard statement
1	Danger	May cause fire or explosion; strong oxidizer

Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat. **Keep/Store away from clothing and other combustible materials.** **Take any precaution to avoid mixing with combustibles/...** ... Manufacturer, importer, or distributor to specify other incompatible materials. **Wear protective gloves /eye protection/face protection.** 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 ... for extinction.** ... 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.** ...Manufacturer, importer, or distributor to specify other incompatible materials. **Take any precaution to avoid mixing with combustibles/...** ... Manufacturer, importer, or distributor to specify other incompatible materials. **Wear protective gloves/eye protection/face protection.** Manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... for extinction.** ... 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)

Pictogram
Flame over circle

Hazard category	Signal word	Hazard statement
1	Danger	May cause fire or explosion; strong oxidizer

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat. **Keep away from clothing and other combustible materials.** **Take any precaution to avoid mixing with combustibles/...** ...Manufacturer, importer, or distributor to specify other incompatible materials. **Wear protective gloves/eye protection/face protection.** 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 ... for extinction.** ... 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)

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.** ... Manufacturer, importer, or distributor to specify incompatible materials. **Take any precaution to avoid mixing with combustibles/...** ...Manufacturer, importer, or distributor to specify other incompatible materials. **Wear protective gloves/eye protection/face protection.** Manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... for extinction.** ... 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)

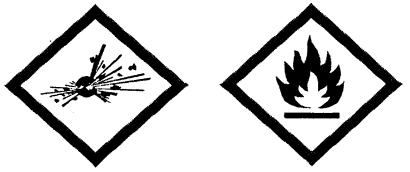
Pictogram
Exploding bomb

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. Manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep/Store away from clothing/.../combustible materials.** ... Manufacturer, importer, or distributor to specify incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Manufacturer, importer, or distributor to specify type of equipment.		**Store at temperatures not exceeding ...°C/...°F. Keep cool.** ... 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)

Pictograms
Exploding bomb and flame



Hazard category	Signal word	Hazard statement
Type B	Danger	Heating may cause a fire or explosion

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep /Store away from clothing/.../combustible materials.** ... Manufacturer, importer, or distributor to specify incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Manufacturer, importer, or distributor to specify type of equipment.		**Store at temperatures not exceeding ...°C/...°F. Keep cool.** 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. Manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep/Store away from clothing/.../ combustible materials** ... Manufacturer, importer, or distributor to specify incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Manufacturer, importer, or distributor to specify type of equipment.		**Store at temperatures not exceeding ...°C/...°F. Keep cool.** ... 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)

Pictogram
Corrosion

Hazard category	Signal word	Hazard statement
1	Warning	May be corrosive to metals

Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep only in original container.	**Absorb spillage to prevent material damage.**	**Store in corrosive resistant/... container with a resistant inner liner.** ... Manufacturer, importer, or distributor to specify other compatible materials.	

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, 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

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 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 this section; (b) Signal word, hazard statement(s), symbol(s) and precautionary statement(s) in accordance with paragraph (f) of this section. (Hazard symbols may be provided as graphical reproductions or the name of the symbol, *e.g.,* flame, skull and crossbones); (c) Unclassified hazards (*e.g.,* combustible dust or dust explosion hazard); (d) Where an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥ 1%, a statement that × percent of the mixture consists of ingredient(s) of unknown toxicity is required.
3. Composition/information on ingredients	Except as provided for in paragraph (i) of this section 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* The chemical name and concentration or concentration ranges of all ingredients which are classified as health hazards in accordance with paragraph (d) of this section. *For All Chemicals Where a Trade Secret is Claimed* Where a trade secret is claimed in accordance with paragraph (i) of this section, a statement that the specific chemical identity and/or percentage 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) and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet. (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; (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);

TABLE D.1—MINIMUM INFORMATION FOR AN SDS—Continued

	(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).
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 are found in Chapter A.6. However, as noted in Footnote 5 of that chapter, the GHS also included as guidance for classifiers the following information taken from the International Agency for Research on Cancer (IARC) *Monographs programme on the evaluation of the strength and evidence of carcinogenic risks to humans*. This guidance is consistent with Chapter A. 6, and should help in evaluating information to determine carcinogenicity.

Background Guidance

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, mixture or exposure circumstance 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; or,

(b) *Limited evidence of carcinogenicity:* A positive association has been observed between exposure to the agent, mixture or exposure circumstance 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:

(a) *Sufficient evidence of carcinogenicity:* A causal relationship has been established between the agent or mixture and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms in (i) two or more species of animals or (ii) in two or more independent studies in one species carried out at different times or in different laboratories or under different protocols;

(b) Exceptionally, a single study in one species 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,

(c) *Limited evidence of carcinogenicity:* The data suggest a carcinogenic effect but are limited for making a definitive evaluation because, for example, (i) the evidence of carcinogenicity is restricted to a single experiment; or (ii) there are unresolved questions regarding the adequacy of the design, conduct or interpretation of the study; or (iii) the agent or mixture increases the incidence only of benign neoplasms or lesions of uncertain neoplastic potential, or of certain neoplasms which may occur spontaneously in high incidences in certain strains.

*Guidance on How to Consider Important Factors in Classification of Carcinogenicity**

This section provides some considerations and an approach to analysis, rather than hard-and- fast rules. The weight of evidence analysis called for in GHS is an integrative approach which 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), the 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 the IARC (Preamble section 12(b)) provide a basis for systematic assessments which 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 available 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 behaviour 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). Even when a particular tumor type may be discounted, expert judgment must be used in assessing the total tumor profile in any animal experiment.

**References:*

Cohen, S.M., J. Klaunig, M.E. Meek, R.N. Hill, T. Pastoor, L. Lehman-McKeeman, J. Bucher, D.G. Longfellow, J. Seed, V. Dellarco, P. Fenner-Crisp, and D. Patton. 2004. Evaluating the human relevance of chemically induced animal tumors. Toxicol. Sci., 78(2): 181–186.

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Meek, M.E., J.R. Bucher, S.M. Cohen, V. Dellarco, R.N. Hill, L. Lehman-McKeeman, D.G. Longfellow, T. Pastoor, J. Seed, D.E. Patton. 2003. A framework for human relevance analysis of information on carcinogenic modes of action. Crit. Rev. Toxicol., 33(6), 591–653.

Sonich-Mullin, C., R. Fielder, J. Wiltse, K. Baetcke, J. Dempsey, P. Fenner-Crisp, D. Grant, M. Hartley, A. Knapp, D. Kroese, I. Mangelsdorf, E. Meek, J.M. Rice, and M. Younes. 2001. The Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogenesis. Reg. Tox. Pharm. 34, 146–152.

International Programme on Chemical Safety Harmonization Group. 2004 Report of the First Meeting of the Cancer Working Group. World Health Organization. Report IPCS/HSC–CWG–1/04, Geneva.

International Agency for Research on Cancer. IARC Monographs on the Evaluation of Carcinogenic Risks to Human. Preambles to volumes. World Health Organization. Lyon, France.

S.M. Cohen, P.A. Fenner-Crisp, and D.E. Patton. 2003. Special Issue: Cancer Modes of Action and Human Relevance. Critical Reviews in Toxicology, R.O. McClellan, ed., Volume 33/Issue 6. CRC Press.

C.C. Capen, E. Dybing and J.D. Wilbourn. 1999. Species differences in Thyroid, Kidney and Urinary Bladder Carcinogenesis. International Agency for Research on Cancer, Scientific Publication N° 147.

32. 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); and

D. Amend paragraphs (f)(3)(v), (h)(1), (h)(1)(ii) and (h)(2)(iii) by removing the phrase ''material safety data sheets'' and inserting the phrase ''safety data sheets'' in its place.

The revisions and additions read as follows:

§ 1910.1450 Occupational exposure to hazardous chemicals in laboratories.

* * * * *

(b) * * *

Hazardous chemical means any chemical that is defined as a hazardous chemical in accordance with the Hazard Communication Standard (29 CFR 1910.1200). Appendices A and B of the Hazard Communication Standard provide criteria for classification of health hazards and physical hazards.

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); or 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 (29 CFR 1910.1200).

* * * * *

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 (29 CFR 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 (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; or in contact with water emits flammable gas. The criteria for determining whether a chemical is classified as a physical hazard are in Appendix B of the Hazard Communication Standard (29 CFR 1910.1200).

* * * * *

Reproductive toxins means 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 (29 CFR 1910.1200) shall be considered reproductive toxins for purposes of this section.

* * * * *

PART 1915—OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR SHIPYARD EMPLOYMENT

33. 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), or 5–2007 (72 FR 31160) as applicable; 29 CFR Part 1911.

Section 1915.120 and 1915.152 of 29 CFR also issued under 29 CFR part 1911.

Subpart Z—[Amended]

34. Amend § 1915.1001 to revise 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) (29 CFR 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) The provisions for labels required in this paragraph 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 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 this paragraph. 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.

* * * * *

35. Amend § 1915.1026 to revise 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, 29 CFR 1910.1200.

* * * * *

(j) * * *

(1) *Hazard communication.* The employer shall include chromium (VI) in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 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]

36. 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), or 5–2007 (72 FR 31159), 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 1926.62 of 29 CFR also issued under section 1031 of the Housing and Community Development Act of 1992 (42 U.S.C. 4853).

Section 1926.65 of 29 CFR 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.

37. Amend § 1926.60 to revise paragraph (j)(2)(v), (l)(1), and (l)(2) to read as follows:

§ 1926.60 Methylenedianiline.

* * * * *

(j) * * *

(2) * * *

(v) Containers of MDA-contaminated protective work clothing or equipment that are to be taken out of decontamination areas or the workplace

for cleaning, maintenance, or disposal, shall bear labels warning of the hazards of MDA. The employer shall ensure that labels are consistent with requirements in paragraph (l) and that labels include at least the following information:

DANGER

CONTAINS METHYLENEDIANILINE (MDA)

MAY CAUSE CANCER

CAUSES DAMAGE TO THE LIVER

* * * * *

(l) * * *

(1) *Hazard communication*. The employer shall include MDA in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 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) 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

* * * * *

38. Amend § 1926.62 to revise paragraph (g)(2)(vii), the heading of paragraph (l) and paragraph (l)(1)(i) and paragraph (m) to read as follows:

§ 1926.62 Lead.

* * * * *

(g) * * *

(2) * * *

(vii) 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

* * * * *

(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) (29 CFR 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). The employer shall ensure that at least the following hazards are addressed: Reproductive/developmental toxicity; central nervous system effects; kidney effects; blood effects; and acute toxicity effects.

* * * * *

(m) *Signs*.

(1) *General*.

(i) The employer shall post the following warning signs in each work area where an employees exposure to lead is above 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

(ii) The employer shall ensure that no statement appears on or near any sign required by this paragraph that contradicts or detracts from the meaning of the required sign.

(iii) The employer shall ensure that signs required by this paragraph 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.

(2) [Reserved]

* * * * *

39. Amend § 1926.64 to revise paragraphs (a)(1)(ii) introductory text and (a)(1)(ii)(B) 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.

* * * * *

40. Amend § 1926.65 (a)(3) to revise 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, 29 CFR 1910.1200, as posing one of the following 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; target organ specific systemic toxicity (single or repeated dose); or aspiration toxicity.

* * * * *

Subpart F—[Amended]

41. Revise the authority citation for subpart F to read as follows:

Authority: Section 3704 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3701 *et seq.*); Sections 4, 6, and 8, 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), or 5–2007 (72 FR 31159), as applicable; and 29 CFR part 1911.

42. Amend § 1926.152 as follows:

A. Revise the section heading;

B. Remove the words ''and combustible'' from the first sentence in paragraphs (a)(1), (b) introductory text, (b)(2) introductory text, and (b)(4)(viii);

C. Remove the words ''or combustible'' in paragraphs (a)(2), (b)(1), (b)(4)(iii), (b)(5), (c)(3), (d) introductory

text, (d)(1), (d)(4), (e)(1), (e)(3), (f)(2), (g)(1), (g)(8), (i)(1)(i)(D), (i)(1)(i)(F), (i)(1)(iii)(D), (i)(2)(ii)(A), (i)(2)(ii) (D), (i)(2)(ii)(F), (i)(2)(vii)(B)(*2*), (i)(4)(iv)(C), (i)(5)(vi)(A),(i)(5(vi)(D), (i)(5)(vi)(G), (i)(5)(vi)(V) introductory text, (i)(5)(vi)(V)(*1*); (j)(1)(i), (j)(2)(ii), (j)(5), and (k)(4);

D. Amend the fifth sentence of paragraph (b)(4)(vi) by inserting the words ''Category 1, 2, or 3'' in front of the words ''flammable liquids;''

E. Amend the first sentence of paragraphs (e)(2); (e)(5); (g)(7)(i); (g)(7)(ii); by inserting the words ''Category 1, 2, or 3'' in front of the words ''flammable liquids;''

F. Amend the first sentence of paragraphs (f)(1) and (f)(3) by removing ''Flammable liquids'' and inserting ''Category 1, 2, or 3 flammable liquids'' in its place;

G. Revise paragraphs (b)(2)(iii), (b)(3), (h) introductory text, (i)(2)(iv)(F), (i)(2)(iv)(G), (i)(2)(vi)(B), (i)(2)(viii)(E), (i)(3)(i), (i)(3)(iv)(A) and (C), (i)(3)(v)(D), (i)(4)(iv)(E), and (k)(3)(iv).; and

(H) Amend paragraph (k)(3)(i) by revising Table F–19.

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 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 to paragraph (i)(2)(iv)(F):'' Tanks of 3,000 bbls (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 to 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.

(B) * * *

(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 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) * * *

(i) * * *

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		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, 2 flammable liquids or 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).		
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.

Footnote(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.

* * * * *

43. 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 and having a flashpoint at or below 199.4 °F (93 °C). Flammable liquids are divided into four categories as follows:

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).

Category 2 shall include liquids having flashpoints below 73.4 °F (23 °C) and having a boiling point above 95 °F (35 °C).

Category 3 shall include liquids having flashpoints at or above 73.4 °F (23 °C) and at or below 140 °F (60 °C).

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 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 or an equivalent method as defined by 1910.1200 appendix B.

* * * * *

Subpart Z—[Amended]

44. Revise the authority citation for subpart Z to read as follows:

Authority: Section 3704 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3701 *et seq.*); 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), or 5–2007

(72 FR 31159), as applicable; and 29 CFR part 1911.

Sections 1926.1101 and 1926.1127 also issued under 5 U.S.C. 553.

Section 1926.1102 of 29 CFR not issued under 29 U.S.C. 655 or 29 CFR part 1911; also issued under 5 U.S.C. 553.

45. 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 paragraph (k)(1)(ii);

C. Amend paragraphs (k)(2)(i) and (k)(3)(i) by changing the reference in the last line from ''(k)(1)'' to ''(k)(1)(i);''

D. Revise paragraphs (k)(7)(ii)(A) and (B), and (k)(8)(ii) and (iii).

The additions and 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) (29 CFR 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

* * * * *

(8) * * *

(ii) The employer shall ensure that such labels comply with paragraphs (k).

(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 BREATH DUST

* * * * *

46. Amend § 1926.1126 to revise paragraphs (g)(2)(iv) and (j)(1) to read as follows:

§ 1926.1126 Chromium.

* * * * *

(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, 29 CFR 1910.1200. The employer shall ensure that the labels state the following hazards: Cancer, eye irritation, and skin sensitization.

* * * * *

(j) * * *

(1) *Hazard communication.* The employer shall include chromium (VI) in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 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 29 CFR 1910.1200 and paragraph (j)(2) of this section. The employer shall provide information on at least the following hazards: Cancer; skin sensitization; and eye irritation.

* * * * *

47. Amend § 1926.1127 to revise paragraphs (i)(2)(iv), (k)(7), and (m)(1), (m)(2)(ii), and (m)(3)(i) and (ii).

The revisions read as follows:

§ 1926.1127 Cadmium.

* * * * *

(i) * * *

(2) * * *

(iv) The employer shall ensure that containers of contaminated personal 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) of this section. As a minimum, labels on containers of contaminated protective clothing and equipment must state MAY CAUSE CANCER, CAUSES DAMAGE TO LUNGS AND KIDNEYS. AVOID CREATING DUST.

* * * * *

(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 (i)(2)(iv) of this section.

* * * * *

(m) * * *

(1) *Hazard communication.* The employer shall include cadmium in the program established to comply with the Hazard Communication Standard (HCS) (29 CFR 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) * * *

(ii) Warning signs required by paragraph (m)(2)(i) of this section shall bear the following information:

DANGER

CADMIUM

MAY CAUSE CANCER

CAUSES DAMAGE TO LUNGS AND KIDNEYS

WEAR RESPIRATORY PROTECTION IN THIS AREA

AUTHORIZED PERSONNEL ONLY

(iii) * * *

(3) * * *

(i) Shipping and storage containers containing cadmium and cadmium compounds shall bear appropriate warning labels, as specified in paragraph (m)(1) of this section.

(ii) The warning labels for waste, scrap, or debris shall include at least the following information:

DANGER

CONTAINS CADMIUM

MAY CAUSE CANCER

CAUSES DAMAGE TO LUNGS AND KIDNEYS

CAN CAUSE LUNG AND KIDNEY DISEASE

AVOID CREATING DUST

* * * * *

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