



The Soap and Detergent Association



December 23, 2009

OSHA Docket Office
Docket No. OSHA-H022K-2006-0062
Room N-2625
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

RE: 29 CFR Parts 1910, 1915, and 1926 Hazard Communication; Proposed Rule; *Federal Register* (Vol. 74, No. 188, September 30, 2009)

Dear Sir or Madam:

The Soap and Detergent Association (SDA)¹ and the Consumer Specialty Products Association (CSPA)² appreciate the opportunity to comment on the Occupational Health and Safety Administration's (OSHA) Notice of Proposed Rule Making (NPRM) to modify its existing Hazard Communication Standard (HCS) to align with the United Nation's Globally Harmonized System (GHS) of Classification and Labeling of Chemicals.

SDA and CSPA members produce chemicals and formulate finished products that are subject to the existing HCS and, therefore, have a significant interest in proposed revisions to the regulation. As such, SDA and CSPA had earlier commented on the potential benefits of adopting the GHS and its potential impact on the Hazard Communications Standard (HCS) in response to OSHA's Advanced Notice of Proposed Rule Making, which was published in the *Federal Register* on September 12, 2006.

¹ The Soap and Detergent Association (SDA) is the trade association representing the \$30 billion U.S. cleaning products market. SDA members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. SDA and its members are dedicated to improving health and the quality of life through sustainable cleaning products and practices. SDA's mission is to support the sustainability of the cleaning product and oleochemical industries through research, education, outreach and science-based advocacy. For more information, please visit www.sdahq.org.

² The Consumer Specialty Products Association (CSPA) is the premier trade association representing the interests of approximately 240 companies engaged in the manufacture, formulation, distribution and sale of approximately \$80 billion annually in the U.S. of hundreds of familiar consumer products that help household and institutional customers create cleaner and healthier environments. Our products include disinfectants that kill germs in homes, hospitals and restaurants; candles, fragrances and air fresheners that eliminate odors; pest management products for home, garden and pets; cleaning products and polishes for use throughout the home and institutions; products used to protect and improve the performance and appearance of automobiles; aerosol products and a host of other products used every day. Through its product stewardship program Product Care[®] and scientific and business-to-business endeavors, CSPA provides its members a platform to effectively address issues regarding the health, safety, sustainability and environmental impacts of their products. For more information, please visit www.cspa.org.

SDA and CSPA support efficient implementation of the GHS for workplace chemicals and appreciate the agency's process for gathering information relevant to potential changes to the HCS. For regulations as complex and with such great potential impact as the HCS, it is very important to obtain and give serious consideration to feedback from all affected parties.

As background to SDA and CSPA's comments, we support the following key elements when implementing the GHS:

Application of the "Building Block Approach"

Taking into account that different target audiences have differing safety information requirements, the GHS provides the flexibility to meet specific user needs through the Building Block Approach.

Maximum use of existing data without mandated test methods

One of the central objectives of the GHS is to "reduce the need for testing and evaluation of chemicals and mixtures." It does not require additional testing of chemical substances or mixtures, plus it is "based on currently available data." When data from scientifically robust, non-animal test approaches (e.g., human experience, bridging data, *in vitro* tests, SAR/QSAR, *in silico* approaches) are available, this information may be used for classification.

Precedence of human experience over other information

The GHS document says "Generally, data of good quality and reliability in humans will have precedence over other data." This is a key concept for determining appropriate labeling and SDS warnings.

Use of a weight-of-evidence approach in classification decision

It is important to consider the weight and credibility of the evidence, taking into account the reliability and consistency of data and all available information. The GHS document says, "For some hazard classes, classification results directly when the data satisfy the criteria. For others, classification of a substance or a mixture is made on the basis of the total weight of evidence. This means that all available information bearing on the determination of toxicity is 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."

Protection of Confidential Business Information

The GHS document says, "The competent authority should protect the confidentiality of the information in accordance with applicable law and practice." Authorities should continue their practices to protect confidential business information.

Further, SDA and CSPA strongly support harmonized implementation of the GHS among NAFTA partners and, in particular, between Canada and the U.S. since the two countries are major trading partners and have mature hazard communication systems in place. Given that manufacturing and marketing are highly integrated in North America, implementation of the

GHS is an opportunity to harmonize hazard communication in order to facilitate trade and improve worker protection. Therefore, SDA and CSPA urge OSHA to work with the Government of Canada to harmonize U.S. OSHA's HCS and Canada's Workplace Hazardous Materials Information System (WHMIS) during implementation of GHS.

As a general comment, estimates of the burden for complying with proposed revisions to the HCS (e.g., training, label revisions, MSDS revisions) are difficult to generate in the relatively short time available to comment and would be highly variable across industry. However, OSHA can help minimize the burden on industry by adopting only those components of the GHS that match existing HCS provisions. We strongly support OSHA's intent to maintain the scope, application, exemptions, and interpretations of the current HCS. 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. Consistent with this point, Sections (b)(5) and (6) contains a series of exclusions and exemptions. The exclusions and exemptions in these sections are the same as those in the current HCS and maintain appropriate application of the HCS to workplace chemicals. SDA and CSPA support OSHA's proposal to maintain them.

The following are SDA and CSPA's comments addressing questions presented in the NPRM. Only questions to which we are responding are presented.

Need and Support for the Standard

1. 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.

We agree with OSHA's belief that use of the GHS standardized label elements would achieve more effective hazard communication, and that GHS standardized headings and a consistent order of information would improve the usefulness of SDSs for chemical users.

Effects on Small Entities

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?

We recognize that the introduction of a specification-based hazard classification system to replace a performance-oriented standard would require certain changes to systems and processes, placing burdens on industry. Since businesses ranging from small to large in size are integrated into the supply chain for chemicals, we strongly believe that the implementation timeline and requirements should be same regardless of business size.

Specifically, alternatives to the rule as a whole or to specific requirements should not be created for small entities. Businesses of all sizes use each others' products in the workplace and in their own manufacturing. There would be increased confusion about hazards if products were labeled

differently due to different size businesses applying different communication standards. It would also be difficult to carry out a workplace hazard communication training plan if not all products are held to the same standard. Therefore, allowing adequate time for businesses of all sizes to transition to compliance with the revised GHS is critical.

However, it should be noted that one of the factors impacting the time to comply will be the time and resources larger companies will need to invest in training of small contract manufacturers in order to ensure compliance with the standards.

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.

Overall, we strongly urge OSHA to maintain the scope, application, exemptions, and interpretations of the current HCS. We support the current scope of the HCS as sufficiently protective of worker health and safety and do not believe additional GHS Building Blocks are needed beyond the current scope of HCS. In this regard, OSHA should not implement any GHS hazard classes or categories that are not already addressed by the current HCS. Therefore, we support OSHA's proposal to apply the "building block approach" in selecting provisions of the GHS applicable to the HCS.

Below are comments on specific building blocks.

Acute Toxicity Category 5

OSHA notes that the acute toxicity criteria in the GHS are much broader than those currently in the HCS for workplace exposures. Components that provide consumer product authorities with the tools to address the protection of children who might accidentally be exposed (.e.g., Acute Toxicity Category 5 for oral, dermal, or inhalation exposures) are not appropriate for the workplace. Therefore, we support OSHA's proposal to not adopt Category 5 of the GHS acute toxicity endpoints.

Aspiration Hazard Category 2

Since Aspiration Hazard Category 2 relies on animal studies for classification and there are no validated animal methods for testing the effects of aspirated chemicals, we support OSHA's proposal to not adopt this category.

Skin Corrosion/Irritation Category 3

We support OSHA's proposal to exclude Skin Corrosion/Irritation Category 3 from the proposed rule to avoid unwarranted over-classification of chemicals as irritants.

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.

Since OSHA is moving from a performance-based standard to a specification-based standard, the endpoints subject to the regulation should be clearly specified and criteria established for each of them. OSHA should allow employers to add supplemental warnings (that do not detract from the required warnings) to cover other hazards in the workplace. If there are specific hazards that OSHA is concerned about that are not included in the GHS, such as “combustible dusts,” then OSHA should develop its own criteria, subject them to notice and comment rulemaking, and include them in the regulation.

Further, the definition of “unclassified hazard” is ambiguous, potentially making compliance difficult. It is unclear how an employer is supposed to know if he/she is in compliance with the regulation. The phrase "Unclassified Hazards" could also be confusing to workers and employees. OSHA should use clearer terminology to describe hazards not defined in the GHS. A phrase such as “Other Hazards” could be easier to understand than "Unclassified Hazards."

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: 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? Are the label elements suggested appropriate?

Similar to the response to question #7, since OSHA is moving from a performance-based standard to a specification-based standard, the endpoints subject to the regulation should be clearly specified and criteria established for each of them. OSHA should allow employers to add supplemental warnings (that do not detract from the required warnings) to cover other hazards in the workplace. If there are specific hazards that OSHA is concerned about that are not included in the GHS, such as “simple asphyxiants,” then OSHA should develop its own criteria, subject them to notice and comment rulemaking, and include them in the regulation.

9. 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?

We support the OSHA proposal to remove the “floor” of chemicals that are considered hazardous and the across-the-board provision of the one-study rule. Regarding the latter, we support a weight of evidence approach in determining hazard for any health effect. The existence of one toxicity study indicating a possible adverse effect may not be sufficiently conclusive. Therefore, we strongly support OSHA’s proposal to remove the one-study rule.

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 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?

Those components of the GHS that are not agreed parts of the text, such as the decision logics, should not be part of the HCS. However, we support OSHA’s proposal to provide the decision logics as guidance. As part of the guidance, OSHA should very clearly indicate the threshold cut-offs for category-specific labeling requirements for mixtures, while also allowing the flexibility to opt out of the labeling requirement if data are available that indicate the cut-off threshold is not appropriate. This is discussed in Part 1 of the GHS Purple Book and OSHA should implement it accordingly (Section 1.3.3.2; Purple Book).

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. 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.

Classification, labeling, and storage of chemicals based on transport classifications should not change from current practices. If anything, the harmonization of criteria for HCS and transportation should reduce any inconsistencies.

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.

We are unaware of any scientific assessments that support OSHA's proposal to make the GHS-suggested 20% cut-off value mandatory. Therefore, OSHA should not go forward with this proposal without making information available for review and comment on the origins and rationale for the 20% concentration limit with the justification for making it mandatory.

Other Hazard Classification Comments

Key Concepts

We strongly support the range of key concepts that OSHA presents in Appendix A, paragraph A.0.2, including no testing is required by OSHA's proposal (use available data), the proposal is intended to be test method neutral, chemicals that are not bio-available should not be classified, and human experience should be taken into account when classifying a chemical. We also strongly support the concepts in paragraph A.0.3, which notes using a weight of evidence approach and the precedence of human experience over other data. Finally, paragraph A.0.4 notes how to use cut-off values, including using higher or lower cut-offs than specified when scientifically justified. SDA and CSPA fully support OSHA's intention to follow this concept.

Germ cell mutagenicity

With regard to GHS hazard classes that are not currently covered by the HCS, we urge OSHA to remove "germ cell mutagenicity" (GCM) from its definition of "health hazard." OSHA notes that it currently addresses GCM through the reproductive toxicity endpoint (see NPRM, page 50388: "The GHS has a separate definition for germ cell mutagenicity, which is considered part of reproductive toxicity in the current HCS [Hazard Communication Standard].") In the absence of results from higher-tier more sophisticated studies, the results from genotoxicity assays (i.e., mutagenicity tests) are used by most scientists to predict the potential carcinogenicity of a substance. A material that tests positive for mutagenicity either will be predicted to be a carcinogen or additional higher-tier tests may be undertaken to confirm or over-ride the concern. This is a conservative approach because there are mutagenicity screening tests that yield positive results for substances that are confirmed later not to be carcinogenic. Thus, since OSHA proposes covering the Carcinogen and Reproductive toxicity hazard classes in the revised HCS, implementation of GCM hazard would not improve protections.

In addition, implementation of the GCM endpoint would place significant burdens on companies to understand the new classification criteria for this endpoint and investigate relevant information to do the classification. Currently, workers are trained and educated on the meaning and relevance of carcinogenicity and reproductive toxicity hazard warnings. Thus, employers would need to expend resources to train and educate workers on the meaning of the GCM hazard warnings, without any higher level of protection being provided. Further, the use of GCM classification for container labelling for workers would lead to greater distraction from other warnings that may be on a container label.

Since the carcinogenicity and reproductive toxicity hazard classes are proposed for the revised HCS and they cover the adverse effects of GCM, and there would be a greater impact from the rule due to the need to provide classification education and workplace training related to the GCM warnings, the GCM hazard class should not be adopted in the final rule.

However, should OSHA decide to include GCM in the final rule, we recommend that OSHA only include Germ Cell Mutagenicity Category 1A. Categories 1B and 2 should not be included. Inconclusive evidence of germ cell mutagenicity, addressed by Categories 1B and 2, would be better handled through the reproductive toxicity endpoint, which would be consistent with the current HCS.

Acute Toxicity

The definition of “health hazard” notes that it includes “acute toxicity (by any route of exposure)”. However, there are only three routes of exposure for which classification criteria are included in the Appendix – oral, dermal and inhalation. While these are the three most important routes, there are other routes, albeit ones that generally are not evaluated (e.g., mucosal, sublingual, intraperitoneal, etc.). For consistency and clarity, the definition for health hazard should include “acute toxicity (by the three routes of exposure for which there are classification criteria)”.

Mixture Classification

In Appendix A, paragraph A.0.5.1.1(a), the proposal states “the new diluted mixture **shall be** classified as equivalent to the original tested mixture;” [emphasis added]. The GHS for this same topic states “the new mixture **may be** classified as equivalent to the original mixture.” [emphasis added]. While it is difficult in the short time available to develop comments on the NPRM to assess the impact of this modification from the GHS, we are concerned that this wording change could have a large effect on how the regulation impacts employers, since OSHA’s proposal appears to be more prescriptive than the GHS. OSHA should adhere to the GHS language.

Serious Eye Damage/Eye Irritation

In Appendix A, Section A.3, addressing eye effects, OSHA has included criteria for Category 2A, but neglected to include criteria for hazard category 2B. Category 2B allows chemicals to be differentiated between severe (but reversible) eye irritants and mild eye irritants. Classification for Category 2B versus 2A or 2 is important in the workplace environment because risk management requirements (e.g., PPE, first aid) can be very different for severe irritants compared to mild irritants. For example, some states require eye washes to be available when using chemicals classified as severe irritants, but not mild irritants. Therefore, compliance with workplace regulations pertaining to PPE and first aid requirements would be facilitated by the ability to distinguish between mild and severe eye irritants. Appendix C (at C.4.5) does include label hazard communication elements for category 2B. In order to be consistent with Appendix C and provide valuable classification information to workplace chemical users, Appendix A should be modified to include criteria for the eye irritant hazard category 2B.

Effects on or via Lactation

Appendix A, section A.7, addresses reproductive toxicity and proposes to include “effects on or via lactation”. There is no standard assessment method for this effect. Therefore, OSHA should not adopt the “effects on lactation” building block of reproductive toxicity.

Specific Target Organ Toxicity – Single Exposure (STOT-SE)

Appendix A, Section A.8 addresses Specific Target Organ Toxicity – Single Exposure (STOT-SE). The STOT-SE classification addresses two distinctly different health effects, significant target organ or systemic toxicity (covered in category 1 and 2) and transient effects of respiratory irritation and narcotic effects (category 3). Also, categories 1 and 2 address significant structural or functional effects whereas category 3 addresses two specific transient effects that by themselves may not adversely impact human health, but may impact adversely if there are pre-existing conditions (e.g., asthma) or in the case of narcosis may make one susceptible to accidents.

Category 1 requires classification based on “reliable and good quality evidence from human epidemiological studies,” which is consistent with the statement in paragraph 3.8.1.3 of the GHS book that “It is recognized that human data will be the primary source of evidence for this hazard class.” Therefore, it is appropriate for OSHA to adopt Category 1.

However, Category 2 classification relies primarily on “. . . studies in experimental animals, in which significant toxic effects, of relevance to human health, were produced . . .” This category is inconsistent with paragraph 3.8.1.3 of the GHS in that it does not rely primarily on human data. In those cases where there is compelling evidence from animal data that significant effects in humans may occur, the substance/product should be classified in category 1.

There are also significant difficulty and a potential unintended outcome that weigh against applying category 2. Animal studies may be done for a variety of purposes, some of which are not relevant to consumer product uses, and the interpretations of animal data from these types of studies often yield conclusions not relevant to consumer products. Using the outcomes from animal studies for classification into category 2, especially studies at exposures near the point of morbidity, requires an unusual level of expertise that many classifiers would not possess. In addition, classification into category 2 relies on interpretation of the phrase “relevant to human health,” which would involve an additional expertise. Therefore, category 2 should not be adopted.

Category 3 provides appropriate precautions that could be helpful to workers if it is applied judiciously by classifiers and is primarily based on human information. As recognized in the GHS text under paragraph 1.1.3.1.5.4 (NOTE 1)³, Category 3 “transient target organ effects” can be considered a standalone category, separate from categories 1 and 2 for STOT-SE.

³ Under paragraph 1.1.3.1.5.4: “NOTE 1: Some hazard classes contain additional categories that can be considered on a stand alone basis, for example, Category 3 “transient target organ effects” for the hazard class “Specific target organ toxicity” (Chapter 3.8) and hazard category “Effect on or via lactation” for the hazard class reproductive toxicity (Chapter 3.7).”

In summary, Category 1 is appropriate to include in the proposed rule since it is based primarily on human experience. However, Category 2 is problematic and should not be adopted since it could lead to inappropriate classification due to its reliance on animal tests, many of which may not be relevant to the human outcomes. Category 3 can be appropriate if it is applied judiciously, using appropriate expert judgment. Normally, with GHS, one cannot skip over categories (e.g., implement categories 1 & 3 but not categories 2). However, in the case of STOT-SE, category 3, the GHS notes that Category 3 is considered independent of the other categories for this endpoint and can be considered separately.

Respiratory or Skin Sensitization

For Appendix A at A.4 Respiratory or Skin Sensitization, we strongly support OSHA's proposal to adopt the sub-categorization of Category 1.

Skin corrosion/irritation

Section A.2.4.2 states:

“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.” [emphasis added]

Figure A.2.1 presents a sequential evaluation process for skin corrosion and irritation. However, the classification should rely on a weight of evidence evaluation considering all available information. This is recognized in the following text from proposed section A.2.4.1:

“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.”

Therefore, Figure A.2.1 appears to be inconsistent with the classification criteria presented in the text and presents the opportunity for classifiers to be confused. On this basis, we recommend that Figure A.2.1 be removed from the proposal. It could alternately be presented in separate OSHA guidance, with proper explanation of how it relates to the classification criteria.

If OSHA decides to maintain Figure A.2.1 in the HCS, it should be made clear, at a minimum, that it is guidance. In such a case, we suggest the following change in A.2.4.2 to accomplish this:

“A *tiered approach* to the evaluation of initial information **shall could** be considered, where applicable (Figure A.2.1 **is presented as guidance for such an approach**), recognizing that all elements may not be relevant in certain cases **and that all information should be considered in its totality in a weight of evidence evaluation.**” [emphasis added]

Eye corrosion/irritation

Section A.3.3.4 states:

“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).” [emphasis added]

Figure A.3.1 presents a sequential evaluation process for eye corrosion and irritation. However, the classification should rely on a weight of evidence evaluation considering all available information. This is recognized in the following text from proposed section A.3.3.2:

“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 outcome of skin irritation testing and well validated alternative methods.”

Therefore, Figure A.3.1 appears to be inconsistent with the classification criteria presented in the text and presents the opportunity for classifiers to be confused. On this basis, we recommend that Figure A.3.1 be removed from the proposal. It could alternately be presented in separate OSHA guidance, with proper explanation of how it relates to the classification criteria.

If OSHA decides to maintain Figure A.3.1 in the HCS, it should be made clear, at a minimum, that it is guidance. In such a case, we suggest the following change in A.3.3.4 to accomplish this:

“A *tiered approach* to the evaluation of initial information **shall could** be considered, where applicable, recognizing that all elements may not be relevant in certain cases **and that all information should be considered in its totality in a weight of evidence evaluation** (Figure A.3.1 **is presented as guidance for such an approach**).” [emphasis added]

Also, buffering capacity can impact the effects of extreme pH mixtures on the eye. However, in Table A.3.4, there appears to be no accounting for buffering capacity in the assignment of hazard categories. We urge OSHA to amend the criteria in Table A.3.4 to account for the role of buffering capacity in classifying mixtures of extreme low and high pH.

Dilution

OSHA should adhere to the GHS text on the classification criteria and align section A.0.5.1.1 (Dilution) of Appendix A with version 3 of the GHS. For example, OSHA has proposed the following text:

"If a tested mixture is diluted with a diluent of 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 (emphasis added), or
- b) for acute toxicity the additivity formula should be applied

However, version 3 of the GHS states the following for Reproductive Toxicity:

"If a tested mixture is diluted with a diluent which is not expected to affect the reproductive toxicity of other ingredients, then the new diluted mixture **may** be classified as equivalent to the original tested mixture." (emphasis added)

The change in wording is significant and, in the case of the proposed OSHA text, inappropriately reduces classifiers' flexibility.

Batching

Section A.0.5.1.2 on Batching states:

"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." [emphasis added]

The term "commercial product" is not defined in OSHA's proposal and could be interpreted to mean that in the case of using batching as a basis for bridging, batching could not be utilized in the case of non-commercial mixtures (e.g., closed system intermediates). OSHA should define the term "commercial product" and substantiate any restriction on the use of batching as a means of classifying mixtures.

Criteria for pH extremes

In section 1910.1200 A.3.3.2, the OSHA proposal states "pH extremes like ≥ 2 and >11.5 ", which differs from A.2.4.1 which states: "pH extremes like ≤ 2 and >11.5 ". In addition, Figure A.2.1 and Table A.3.4 both refer to: " ≤ 2 or ≥ 11.5 ". All of these criteria should match the GHS standard and be consistent.

Environmental Hazards

Since OSHA does not have the regulatory authority to address environmental concerns, we support OSHA's proposal to not adopt the GHS criteria for aquatic toxicity. However, since other jurisdiction may include this hazard class in their requirements, OSHA should permit such information to be present on labels and in SDS without requiring it or regulating it.

Cut-off values/concentration limits

OSHA has proposed concentration cutoffs in Appendix C that require the most conservative value for classification from among the range of allowable values in the GHS, or disallows use of allowed GHS cutoffs above 1%. We support protective limits for the classification of

mixtures, but in some cases the proposed limits are 10 times more conservative than the existing HCS (e.g., for sensitization, reproductive toxicity), without any scientific rationale.

Further, the selection of cut-off values should result in labels that are relevant to the chemical use situations in which workers find themselves. Exceptionally low cut-off values could lead to labels becoming crowded with irrelevant information that would make it difficult for workers to discern the useful and important information relevant to how they specifically handle and use a chemical, thereby reducing protection.

Of particular concern is that OSHA has proposed cut-off values/concentration limits that are 3 to 30 times more conservative than those adopted by the European Union (EU), one of the U.S.'s largest trading partners. These substantial differences in mixture cut-off values/concentration limits increase the burden and lessen the benefits of GHS implementation for companies who do business internationally.

For the above reasons, we urge OSHA to reconsider its proposed cut-offs on the basis that they are not scientifically-based and likely to lead to over-labeling to the extent that worker protection could be compromised. The following paragraphs provide detailed comments on some of the cut-off values proposed by OSHA.

The current HCS has a 1% cut-off value for reproductive hazards. OSHA is proposing to lower this value to 0.1% for Categories 1A and 1B reproductive toxicity. The GHS offers a cut-off value/concentration limit of 0.3% that is closer to the cut-off values in the current HCS. OSHA has not provided any scientific justification for its proposal that a 0.1% cut-off value/concentration limit is appropriate. Given that 1% has been in use for decades, the 0.3% cut-off value/concentration limit for Categories 1A and 1B reproductive toxicity would align with the EU, and the 0.3% cut-off value/concentration limit would be more practical to implement, we urge OSHA to adopt 0.3% as the cut-off value/concentration limit for Categories 1A and 1B reproductive toxicity. OSHA should provide substantial justification for review and comment before lowering it below 0.3%.

OSHA proposes to use the same 0.1% cut-off value/concentration limit for Category 2 reproductive toxins as for Categories 1A and 1B. Category 2 is provided for substances where human or animal evidence is insufficient for classification into Category 1. The Category 2 criteria do not meet OSHA's "one well conducted animal study" criteria⁴ and including Category 2 reproductive toxicity in the revised HCS would be going beyond OSHA's existing HCS. Also, the proposed 0.1% threshold for Category 2 reproductive toxicity is inconsistent with the approach for germ cell mutagens which distinguishes between Categories 1 and 2 mixtures (0.1 and 1.0%, respectively). Recognizing that the 3rd revised edition of the GHS supports a cut-off value/concentration limit of 3% for Category 2 reproductive toxicity, that a lower weight of evidence is required for classification into Category 2, and that the EU has adopted the 3% value, OSHA should establish a 3% cut-off value for classification of mixtures into Category 2 reproductive toxicity.

⁴ 29 CFR 1910.1200 Appendix B

Similar to the situation for reproductive toxins, OSHA proposes to use the same cut-off value/concentration limit (1%) for Category 2 Specific Target Organ Toxicity (STOT) as for Category 1 without justification. The 3rd edition of the GHS allows 10% as the cut-off value/concentration limit for classifying STOT Category 2 mixtures and the EU has adopted the 10% value. Without justification for the 1% cut-off value to review and comment on, we urge OSHA to adopt the 10% cut-off value/concentration limit for Category 2 Specific Target Organ Toxicity, Single and Repeated Exposure.

Further, there is no definition under (c) for “cut-off values” or “concentration limits”. In *A.0.4.3 Use of Concentration Limits*, only “concentration limits” are discussed. In the corresponding GHS Purple Book discussion (*1.3.3.2 Use of cut-off values/concentration limits*) both terms are used. In Appendix A (*A.2.5.3.3, A.3.4.3.2, A.3.4.3.3, A.3.4.3.5, A.4.3.3, Table A.4.5, Table A.4.5, A.5.3.1.1, A.5.3.1.2, Table A.5.1, A.6.3.1, Table A.6.1, A.7.3.1.1, A.7.3.1.2, Table A.7.1, A.8.3.4.1, Table A.8.2, A.8.3.4.5, A.9.3.4.1, Table A.9.3*), both terms are frequently used together as in the Purple Book. For consistency, understanding and clarity OSHA should follow the Purple Book and use both terms (e.g., use “cut-off values” as well as “concentration limits”).

Labels

13. The proposal would require pictograms to have a red frame. OSHA believes that use of the color red will make warnings more noticeable and will aid in communicating the presence of a hazard. 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?

SDA and CSPA support OSHA’s acceptance of the flexibility in GHS to use either black or red pictogram frames on packages shipped domestically. Having the option of using a black frame could minimize compliance costs by avoiding the need for color printing.

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. 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 suggested language. OSHA expects that other countries may adopt the codified precautionary statements when they put GHS in place. For example the European Union (EU) has required that labels use the GHS codified precautionary statement text in adapting the GHS. OSHA is proposing to use those currently in the GHS as the mandatory requirements, with the option of consolidating statements where appropriate. OSHA is seeking comment on whether any of these statements should be modified, or if other precautionary statements should be included.

In addition, OSHA is seeking feedback on whether it 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.

While precautionary statements are an important element of hazard communication and improvements in the consistency of precautionary text for materials classified the same would be helpful, we urge OSHA to not mandate the use of specific precautionary statements. The precautionary statements appearing in the GHS annexes were not negotiated on the basis that they are part of the GHS. Further, they are still the subject of discussions at the United Nations on the basis that they are guidance. OSHA should not adopt them without the statements being harmonized as a result of negotiations under a work plan specifically targeted to harmonization. Any future consideration of inclusion of mandatory precautionary statements from the GHS in the HCS should be contingent upon UN agreement on harmonized phrases and appropriate notice and comment by U.S. stakeholders.

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.

Proposed Section 1910.1200(f)(12) would require that labels be revised within three months of an employer becoming “newly aware of any significant information regarding the hazards of a chemical.” This is too short a period of time for making a label change. Designing, translating, approving and printing new labels in three months is too short. In addition, for labels on products being shipped internationally, there could also be logistical issues, as well as compliance issues in the receiving country, that would need additional time to be addressed by manufacturers. A minimum of 6 months should be adopted for updating labels based on new information. The timing for re-labeling could be on a different schedule from a shorter time period for requiring updated SDSs reflecting new information (e.g., OSHA’s proposed three month period for updating SDSs).

There are a wide variety of techniques for applying a label to a product. These range from simple ink-jetting text onto a paper bag to the incorporation of printed labels into the blow-molding of plastic bottles, to a great many other techniques. Depending on which technique is employed and its complexity, the timing required to change labeling can take more than three months. Further, manufacturers will often have stocks of printed labels and labels on containers in-house and in the supply chain of three months or more. In order to avoid undue costs, they should not have to discard the old labels or discard pre-preprinted containers immediately. Unless there is a substantial change in the hazard positioning of a product as a result of implementing the revised HCS, which is expected to be a relatively rare event, labelers should be allowed to produce and sell products made before the end of the specified update period using the existing label. And since the times to complete the journey through the chain of commerce can vary across industry and products, the requirement for utilization of the new label should apply at the point of production only, and not apply to product in inventory or in commerce. See our comment on question 27 for more details on this point.

Further, while it would be good to update portable containers in the workplace, OSHA should recognize that once portable containers (small containers less than 5 gallons) are dispersed in the workplace they would be extremely hard to track down and re-label even if the supplier sent new labels. In addition, (M)SDSs are already required to be updated and those (M)SDSs are required to be made available to workers under the existing and the proposed standards.

Other Labelling Issues

Pictograms

The definition of “pictogram” proposed by OSHA is inconsistent with the GHS definition. OSHA proposes to amend the GHS definition by including in its proposed definition the clause “about the hazards of a chemical” without explanation. Although this may not be a big difference, OSHA should justify any change to something as fundamental as a GHS definition and address any potential impacts it could have on consistency of GHS implementation.

Product Identifier

In the definition of “product identifier,” OSHA refers to a “required list of hazardous chemicals”. It is not clear in this definition what is being referred to. It could be surmised that it is the list of all hazardous chemicals maintained on site, mentioned in section (a)(2), and further explained in section (e)(1)(i). If this is the case, we suggest that OSHA include a reference to section (e)(1)(i) in the definition so it is clear what list is being referred to.

Languages

Section (f)(3) specifically states that additional languages beyond the required English may be included in labels and other warning mechanisms. SDA and CSPA support OSHA’s proposal to include this provision.

Specific Precautionary Statements

Appendix D contains the required label elements. As noted before, the proposal in this appendix inappropriately includes the precautionary statements among the required elements. This is inconsistent with the GHS and these statements have not been the subject of international negotiation specifically because they were provided by GHS as guidance, not as mandatory text.

Further, some of these statements are not appropriate. For example, there are a number of hazard categories for which a storage statement says “Store locked up.” For many substances and mixtures that would be classified in this way, keeping them out of the reach of children would be appropriate (and not especially challenging in most workplaces). However, the requirement to keep them under lock and key is excessive and unnecessary. OSHA’s intent is to be consistent with the GHS. Since the GHS treatment of these statements is as guidance only, OSHA should also consider them to be guidance only. A product supplier knows best how to communicate with his/her customers and should be provided the flexibility to choose the verbiage that best meets the needs of that target audience, completely in line with the provisions of the GHS.

Shipped Containers

In section 1910.1200(f)(1), it is proposed that labels on shipped containers require a product identifier, signal word, hazard statement, pictogram(s), precautionary statement(s), and, name, address & telephone number of the responsible party. Even if a hazardous chemical does not require one or more of these, it appears that it is still required (e.g., a chemical that has a flashpoint of 250 degrees F wouldn't require any of the flame pictograms). An addition of the text "(where specified)" after "hazard statement(s)", "pictogram(s)" and "precautionary statement(s)" on the label would reduce confusion.

Unclassified Hazards

In (f) *Labels and other forms of warning*, the name of the chemical is required on the label for unclassified hazards, as follows:

*"(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."*

However, for classified hazards, the product identifier but not the chemical name is required on labels, as stated in Appendix C of OSHA's proposal (from Appendix C to § 1910.1200– Allocation of Label Elements):

*"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."

OSHA should require that the product identifier be on the label for both classified and unclassified hazards, since the logic that applies for using the product identifier for classified hazards should also apply to unclassified hazards. Requiring a chemical name for unclassified hazards, but not classified hazards, is also confusing and inconsistent. This could lead to the conclusion that the chemical responsible for the unclassified hazard is responsible for all the classified hazards. OSHA should revise its proposal to eliminate this inconsistency. Further, OSHA should provide provisions for withholding a chemical name on a label for unclassified hazards as a trade secret.

Hazard statements

Several hazard statements combine hazards. If the material does not have one of the hazards expressed in a combined hazard statement, then the hazard warning should not be required to include that part of the hazard statement. This would improve the accuracy and comprehension of the hazard information for the chemical user. Some examples of combined hazard statements where OSHA should permit separating hazards are as follows:

- Causes severe skin burns and eye damage
- May damage fertility or the unborn child
- Suspected of damaging fertility or the unborn child

For example, in the case of skin corrosives that do not cause severe eye damage, OSHA should specify that the severe eye hazard statement can be omitted from the label when severe eye damage is not a hazard of the material.

Further, as the EU's Classification, Labelling and Packaging (CLP) regulation allows, labelers should be allowed to differentiate between fertility hazards and developmental hazards in specific hazard statements. Examples of individual fertility and developmental hazards statements are:

- *May damage fertility*
- *May damage the unborn child*
- *Suspected of damaging fertility*
- *Suspected of damaging the unborn child.*

Safety Data Sheets

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

SDA and CSPA support OSHA's proposal to require PELs on SDSs and allow manufacturer discretion to include other limits, provided that the other limits are properly identified.

However, the statement "and any other exposure limit" appears to imply that "all" manufacturer-derived OELs are mandatory for listing on the SDS. We recommend that the wording be clarified to state that only OSHA PELs, where available, are mandatory, and where OSHA PELs are not available that the manufacturer, importer, or employer preparing the SDS may evaluate other available exposure limits.

18. OSHA is proposing that Section 15 of the SDS be non-mandatory. 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?

The inclusion of Section 15 is necessary to remain consistent with the standard 16-section format for SDSs. SDA and CSPA support OSHA's proposal for the content of Section 15 to be non-

mandatory. Manufacturers should be allowed flexibility in the type of information provided in this section to sufficiently explain the regulatory considerations for the SDS substance. However, the inclusion of mandatory information in Section 15 in the presence of information or elements that are not mandatory may cause confusion and inconsistent enforcement between mandatory and non-mandatory elements.

Other SDS Comments

Table D.1 in Appendix D addresses the information requirements in the SDS. OSHA has taken inappropriate liberty with the requirements as outlined in the GHS. Specifically, for section 3 of the SDS, the composition information, the OSHA proposal says that for mixtures, the SDS must contain “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.” The GHS is more limited in its information requirements: “For a mixture, provide the chemical identity, identification number ... and concentration or concentration ranges of all hazardous ingredients, which are hazardous to health or the environment within the meaning of the GHS, **and are present above their cut-off levels.**” [emphasis added] OSHA should modify its information requirements accordingly, while increasing its consistency with the GHS, by adopting this phrase.

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 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°F (37.8°C) or less to 95°F (35°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.

If OSHA adopts 140°F as the definition of a flammable liquid, then some unintended consequences would be created.

As background, OSHA 29 CFR 1910.106 (Flammable and Combustible Liquids) and NFPA 30 define a flammable liquid as having a closed-cup flashpoint (ccfp) of less than 100°F. The

proposed adoption of the GHS flammable liquid criteria fundamentally changes this OSHA definition, which is a long-established and effective risk management practice with regard to the design and operation of flammable liquid systems.

Changes to the definition of flammable liquids would cause significant, costly, and unwarranted changes to facility design and operation, such as in the following areas of facility design and operation:

- Facility siting
- Mechanical integrity
- Electrical classification
- Storage quantities
- Unloading and storage location
- Ventilation requirements
- Spill protection
- Grounding and bonding
- Tank and vessel design
- Interlocks and safety devices
- Process hazard analysis

Many facilities in the U.S. handle flammable and combustible liquids which could be impacted by this change. OSHA should avoid changes that have consequential impact on operations, but no demonstrated benefits to risk management.

Considering the unacceptability of OSHA's proposed change in flammable liquids criteria, as described above, SDA and CSPA recommend two alternative courses for the agency to take regarding this building block:

Option 1: Leave the current OSHA definition of flammable liquids unchanged. This is easy, clear, and no-cost to U.S. industry.

Option 2: In principle, GHS is a labeling and hazard communication system, and was not intended to regulate the design and operation of facilities. OSHA 1910.106, by comparison, is a risk management regulation used in such design and operation. If OSHA adopts the GHS building block of 140°F, leave the parallel definition of 100°F intact in 1910.106. This dual system will create some confusion, but will minimize the negative effects listed above.

20. OSHA is proposing to eliminate the term "combustible liquid" in 29 C.F.R. Sections 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. Are there other standards that OSHA should update with the new terminology?

See comments in the response to question #19.

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?

SDA and CSPA supports OSHA’s proposal to require consistency of language on labels and signs.

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 rely primarily on the determinations made by OSHA 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?

We request that OSHA clarify its proposal on this point. It is not clear if the citations are fixed references or if OSHA will continue to rely on these secondary sources over time as their guidance is updated or changed.

24. OSHA is not proposing 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?

Refer to comments in response to question #19.

Effective Dates

25. OSHA has proposed to require that employers train employees regarding the new labels and SDSs 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?

The proposal would require that training be completed within 2 years of the publication of the final rule. Two years for training of all employees would be a challenge for many large companies. Consistent with the response to question #26 below, the time allowed to comply with the revised HCS should be lengthened. We recommend that OSHA specify that training needs to be done a year before the final compliance date to which a chemical producer or formulator is subject.

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 SDSs to reflect the new requirements? Would a shorter time frame be sufficient?

The final compliance date is specified as 3 years after the publication of the final rule. We recommend either sequencing the compliance requirement (e.g., ingredient suppliers first, formulators last) or providing a longer overall timeframe in order to avoid unnecessary expenditures of resources.

A transition period after the effective date of the final regulation is required for chemical and product producers to reclassify, create new labels, deplete existing inventories of labels and product, and sell through existing stock. As commented on the ANPR, SDA and CSPA recommend a multi-tiered approach to implementation to allow time for information to be generated in upstream stages of the supply of chain that could be used by downstream stages to facilitate compliance.

Following the promulgation of a final regulation implementing the GHS, an appropriate transition period is required to enable manufacturers (or importers) of substances (including technical grade raw materials from chemical producers) to reclassify substances, create new labels and SDSs, deplete existing inventories of labels and product, and sell through existing stock.

These substances could be brought to market as intermediates or pre-mixtures, which themselves would require a transition period to reclassify them, create new labels and SDSs, deplete existing inventories of labels and product, and sell through existing stock. For example, the European Union is allowing 4.5 years between the compliance dates for substances and mixtures classification and labeling. This transition period could start during the initial phase for substances, but should continue past the deadline for transitioning substances to the revised HCS.

Finally, since formulators of workplace products may require information about the component materials that they purchase from their suppliers in order to classify their formulated products according to GHS, an additional transition period, beyond that provided to the manufacturers of chemicals and intermediates/pre-mixtures is needed for the producers of formulated products. This transition period could start during the earlier transition periods, but should continue past the deadline for transitioning intermediates and pre-mixtures to the revised HCS.

Since OSHA states in the NPRM that "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." (page 50289, NPRM), OSHA should establish an implementation phase-in or total time period that maximizes the opportunity for workplace product formulators to use information, including any test results and evaluations of chemicals, from upstream suppliers of mixtures and substances so as to avoid the redundant application of resources by formulators to meet those needs. If a phase-in approach or an adequate overall compliance period (e.g., 5 years) is not allowed, OSHA should revise its economic impact assessment to account for some portion of workplace product producers having

to conduct evaluations in the absence of supplier information in order to meet the 3 year deadline.

In a tiered phase-in approach, regardless of their position in the supply chain, (i.e., chemical manufacturers, intermediate/pre-mixture producers, product formulators), a company should be allowed to begin to transition their products to GHS-compliant labels as soon as the final regulation is in effect. They should be required to have completed the transition for their production/importation by the conclusion of their respective transition periods. In this way, all members of the regulated community would be able to make orderly changeovers consistent with reasonable business practices.

Phased-in compliance based on company size is unacceptable. Both small and large businesses use materials of the other in creating end-use products.

Therefore, SDA and CSPA support either a sequenced approach of substance suppliers first and formulators last, or a longer overall timeframe in order to minimize the impact of undertaking this significant effort to reclassify substances and mixtures, develop revised labeling, while allowing time to deplete inventories of labels and products with a current label. Any consideration of business size for a phase-in approach would be unacceptable as businesses large and small use each other's products in their end-use products; each one may rely on the upstream supplier for information in hazard classification.

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

The onus should be on the manufacturer or importer of the materials, not on parties in the distribution chain, to ensure compliance with classification and labeling requirements. Controls should be applied to prevent manufacturing or importing beyond a certain time, but no restrictions should be placed on the sale of legally produced or imported chemicals or products.

By design, implementation of the GHS will provide a similar level of protection compared to existing classification and labeling systems. Therefore, there is no reason to accelerate clearing existing stocks of product from the channels of commerce. Purchasers of chemicals and products are very familiar with current labels and will be learning about GHS-compliant labels as time passes. Thus, chemicals and products that were produced or imported legally under the current classification and labeling regulations should be allowed to pass through the channels of commerce without any requirement for retailers to stop sales after any particular date. Some form of code dating, indicating the date of production or importation would be needed to substantiate compliance.

A possible concern with the lack of a stop sale date is that producers or importers may build extraordinary stockpiles of materials labeled according to the current system. In reality, the cost of maintaining an inventory of any substantial size far outweighs any possible business advantage that could be gained by continuing to sell product with current labeling. Thus, only relatively small volumes of pre-GHS product are likely to remain in the channels of commerce. Given that the level of protection is similar under either labeling system, an effort to remove such product from commerce is not warranted.

SDA and CSPA also urge 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.

SDA and CSPA also encourage OSHA to coordinate implementation of the revised standard with the efforts of Health Canada (WHMIS), which has announced its intentions to implement GHS in their regulations. Harmonization and coordination of implementation timing with Canada could improve effectiveness and efficiency of conversion to GHS standards by the regulated industry in North America.

Compliance Assistance and Outreach

28. OSHA received many comments in response to the questions in the advance notice of proposed rulemaking (ANPR) (September 12, 2006) regarding compliance assistance and outreach, and is seeking additional comment in this proposal. Specifically, OSHA is interested in 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, SDSs), and the best means of distributing these materials.

Materials and products that would be of assistance in complying with the modified HCS include a mixture calculation tool (such as the one Japan uses on its website) and classification and mixture examples on OSHA's website. A quick reference guide and OSHA workshops and webinars would also be helpful. However, the surest approach to facilitate compliance would be for OSHA to have a clear and straightforward hazard communication regulation, rather than one that requires complex guidance.

29. OSHA received a number of comments that suggested that a database 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 database be helpful? Who would be responsible for doing the classifications and maintaining them? How would the database be kept aligned with other countries' classifications?

The principle of self-classification, as articulated in the GHS [(Section 1.1.4.1): "The GHS is designed to permit self-classification"] should be observed by OSHA. Therefore, chemical producers or users should be allowed to self-classify, which is consistent with paragraph 1.3.2.1.2 of the GHS:

"1.3.2.1.2 One objective of the GHS is for it to be simple and transparent with a clear distinction between classes and categories in order to allow for "self classification" as far as possible. For many hazard classes the criteria are semi-quantitative or qualitative and expert judgment is required to interpret the data for classification purposes. Furthermore, for some

hazard classes (e.g. eye irritation, explosives or self-reactive substances) a decision tree approach is provided to enhance ease of use.”

Further, companies with valid data, particularly end product data that may show results that are contrary to the listed classification, should be free to use that result for classification.

SDA and CSPA do not support development of a chemical classification database, which would likely create yet another un-harmonized list of classifications compared to lists in other geographies. However, should OSHA develop such a database, it should not be binding but be restricted to the purpose of providing guidance to those classifiers that need assistance. In order to promote the overarching GHS goal of global harmonization and facilitation of trade, any database should:

- be accepted globally with national/regional lists eliminated;
- be based on a rigorous, evidence-based scientific process;
- provide access to the data used to support the classifications
- provide a clear explanation of the rationale behind the classifications;
- include mechanisms for updating classifications as new scientific evidence and understandings become available; and
- have defined criteria for assessing the quality and reliability of data.

Alternative Approaches

30. OSHA has described alternatives to the scope and application of the proposed rule. 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.

SDA and CSPA support OSHA utilizing the flexibility under the GHS to adopt some of its components, but not others, which is consistent with the Building Block approach. We also urge that OSHA not adopt guidance in the GHS as mandatory (e.g., the precautionary statements in the guidance annexes of the GHS). Conversely, we believe that alternatives like voluntary implementation and variations in the application of HCS based on size of a company are not acceptable if OSHA intends to achieve the stated benefits.

Additional Comments

Revision 3 of the GHS

SDA and CSPA support OSHA’s proposal to adopt the GHS by relying on revision 3 of the GHS.

Physical Hazards

In 1910.106(4)(iv), “Pilot light” sounds like a small flame used to start gas-fired equipment which would not be something to have just outside a room storing flammable materials. Perhaps a better description would be using a term like “indicating light.”

In section 1910.106(j)(5), should “...flammable liquids or liquids with a flashpoint greater than 199.4°F” be changed to “flammable liquids or liquids with a flashpoint at or below 199.4°F” in order to be consistent with the definitions in 1910.106(a)(19)(ii)? Alternately, this section could refer to “flammable liquid” because a definition for this term is provided in 1910.106(a)(19): “Flammable liquid means any liquid having a flashpoint at or below 199.4°F (93°C).” Similarly, the same changes made in 1910.106(j)(5), should also be made in sections 1910.107(e), 1910.107(4), and 1910.124(c)(2).

Regarding section 1910.1200(c), the term “flashpoint” is used in Appendices B.6 and D.9.g. Therefore, the definition of flashpoint should not be removed or should at least be listed in the Appendices.

Process for stakeholder input into GHS revisions at UNSCEGHS at early formative stage

The following text in the preamble to the OSHA proposed rule describes the potential impact of further changes to the GHS:

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.

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.

The text recognizes that the GHS is a living document and that there are mechanisms available to OSHA for updating its Hazard Communication Standard in the future. However, these mechanisms fail to recognize the need for U.S. stakeholder input into the negotiations and technical decisions on potential GHS revisions as they are being made at the UNSCEGHS. The approach described above would only allow an after-the-fact decision on whether to update the HCS to be compatible with the revised GHS. Further, it suggests a truncated notice and comment period for what could be very technical issues.

SDA and CSPA urge OSHA to create a process for U.S. stakeholder input into the discussions and technical issues at the UNSCEGHS and into decisions taken by the U.S. government representatives participating in its meetings. Early input would be more effective in shaping issues and decisions that would have increased acceptability among U.S. stakeholders if OSHA chose to propose adoption of those decisions for the HCS. The absence of a clear and consistent mechanism for U.S. stakeholders to provide comments on the UNSCEGHS papers is in reality

giving short shrift to OSHA's notice and comment process in favor of a process that relies mostly on international negotiations.

The US DOT recognized this as a concern many years ago for U.S. transportation stakeholders in relation to negotiations on the *UN Recommendations on the Transport of Dangerous Goods - Model Regulations*. DOT routinely solicits public comments on positions for the UNSCETDG papers and informs U.S. stakeholders of the outcome of the UNSCETDG meetings through DOT public meetings and outreach activities. This ensures that U.S. stakeholder interests are communicated and considered in the development of international standards. OSHA should develop a similar process to obtain U.S. stakeholder input into the development of U.S. positions for the GHS Purple Book as it undertakes discussions on possible updates in the future. SIPS or DFR after the revisions to the GHS Purple Book have been finalized is bypassing the intent of the USA notice and comment process.

Trade Secrets

The trade secret provisions in OSHA's proposal would apply only to SDSs, as follows:

“(i) Trade secrets.

(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:”

There is no trade secret provision in OSHA's proposal for the chemical identity on a label of a material which has an unclassified hazard. Also there is no trade secret provision for identifying x percentage of a component with unknown acute toxicity in a mixture. OSHA should allow for trade secret protection in both these situations.

Under certain conditions both the SDS and label can require text such as: *x percent of the mixture consists of ingredient(s) of unknown toxicity*⁵. This statement may apply to an ingredient of a mixture whose percentage of composition is a trade secret. In such a case the trade secret provisions only apply when this statement is on the SDS. The current trade secret provisions do not apply to labels. Since the percentage composition of an ingredient can be required on labels as well as SDSs, the trade secret provisions should also apply to labels.

Since the NPRM includes both the name of the chemical and *x percent of the mixture consists of ingredient(s) of unknown toxicity* as potentially required label elements, trade secret claims should apply to labels as well as to SDSs. We suggest the following revision to section (i)(1) of the NPRM:

(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

⁵ 74 FR 50447, 50483, 50540

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Test Methods

OSHA has proposed incorporation by reference a list of ASTM standards, including test methods, into section 1910.6 (see page 50420 of the September 30, 2009 Federal Register). Many companies use a mini-flash apparatus manufactured by Petrolab for determining flash points of liquids. This apparatus adheres to ASTM D6450, which is not one of the standards listed in OSHA's proposal for this section. ASTM D6450 is approved by the DOT for determination of flashpoint for the shipping of flammable liquids. In order for the proposed changes to the HCS to be implemented most efficiently, as well as provide alignment with a DOT method, OSHA should include ASTM D6450 in the list of methods that it intends to incorporate into section 1910.6 by reference.

SDA and CSPA are committed to the process for harmonizing chemical hazard classification and labeling and the development of quality systems. Please let us know if you would like to discuss our views and concerns or have any questions.

Sincerely,



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