American Petroleum Institute (API) High Level Comments on OSHA GHS Proposal

- To achieve the goal of harmonization and reap the associated benefits, OSHA should align the HCS with the GHS as negotiated and seek to implement it in a manner that minimizes differences among countries. API urges OSHA to be as consistent as possible with European Union (EU) GHS implementation and the GHS as negotiated at the UN, especially for hazard classes/categories, for mixture cut-off values/concentration limits, and for the effective dates and transition periods. API supports U.S. efforts to globally promote the adoption of the GHS as negotiated at the UN ("3rd revised edition").
    - In several instances, OSHA proposes not to use the text of the 3rd edition of the GHS verbatim. API urges OSHA to adhere to the text of 3rd edition of the GHS as much as possible.

- OSHA has proposed the most conservative cut-off values/concentration limits for sensitization, reproductive toxicity, and Specific Target Organ Toxicity (STOT) without providing any scientific justification, which API opposes. API urges OSHA to adopt the same mixture cut-off values/concentration limits as those used by the EU.

- API recommends that OSHA ensure and set forth a process for U.S. stakeholder input into future GHS technical decisions to be made through negotiations at the UN Sub-Committee of Experts on the GHS (UNSCEGHS).

  OSHA needs to develop a process similar to that of DOT to obtain U.S. stakeholder input into the development of U.S positions for the GHS Purple Book during the UNSCEGHS discussion stage. It would be bypassing the rulemaking process required by the APA to issue Standards' Improvement Process (SIPs) or a Direct Final Rule (DFR) after the revisions to the GHS Purple Book have been finalized. This proposed approach does not allow notice and comment on the technical issues.

- API does not support a database of chemical classifications developed and maintained by OSHA. The proliferation of national/regional lists is contrary to harmonization. Such a database or list of chemicals classified in terms of the GHS has the most value when it is accepted by all countries implementing the GHS. In order to promote the overarching GHS goal of global harmonization and facilitation of trade, any list/database would need to:
    - be accepted globally with national/regional lists eliminated;
    - be based on a rigorous, evidence-based scientific process to be defined in advance and applied globally;
    - contain the data to support the classifications or a section explaining the rationale behind the classifications;
    - ensure accuracy by including impurities and CAS numbers for the chemicals;
    - provide a conflict resolution mechanism;
    - have provisions for stakeholder input/data;
    - include mechanisms for updating as new evidence-based science becomes available; and
    - have defined criteria for source data.

- API recommends that OSHA support sector-specific guidance, including providing links on its web page to relevant documents.

- API recommends that OSHA work closely with other government agencies to ensure consistent and timely implementation of the GHS and alignment to the UN endorsed version of the GHS.

- Companies need flexibility for the specific language to describe a trade secret. API recommends that OSHA allow trade secret claims for labels to address the chemical identity for unclassified hazards and the percentage unknown for acute toxicity.

- Some of API's key points concerning the proposed rule are as follows:
  - The time allowed for updating labels on shipped containers to include new information should be 12 months. For the requirement to update labels, OSHA needs to clarify the meaning of "new and significant information."
  - Updating workplace signs for the substance-specific standards should be done according to the normal facility signage replacement schedule. Workplace signage requirements should be phased-in, along with the other components of the revised HCS.
  - Manufacturers should be allowed to use their own precautionary statements in addition to the precautionary statements in proposed Appendix C, which should be non-binding suggestions.
  - Companies need flexibility in SDS format and wording in order to comply globally even though there may be national/regional differences.
  - The hazard statement and precautionary statement that OSHA discusses for asphyxiants are not appropriate.
  - API supports requiring the Permissible Exposure Limits (PELs) on the SDS and also allowing (but not requiring) the inclusion of other occupational exposure limits.
  - API recommends that OSHA use the phrase "Other Hazards" instead of "Unclassified Hazards" and work with the appropriate functions at the UN to develop the criteria for these other hazards.
  - API recommends that SDS Section 15 remain non-mandatory.

Derek D. Swick
Policy Advisor

Regulatory and Scientific Affairs

1220 L Street, NW
Washington, DC 20005-4070
USA
Telephone 202-682-8341
Email swickd@api.org
www.api.org

VIA REGULATIONS.GOV

December 29, 2009

OSHA Docket Office
Docket No. OSHA–H022K–2006–0062
U.S. Department of Labor, Room N2625
200 Constitution Avenue, N.W.
Washington, DC 20210

Attn: **Docket No. OSHA–H022K–2006–0062**

Re: Hazard Communication; Proposed Rule; 74 *Federal Register* 50280-50549, September 30, 2009

Dear Sir or Madam:

The American Petroleum Institute (API) is pleased to submit the attached comments to the Occupational Safety and Health Administration (OSHA or Administration), Department of Labor, on its Notice of Proposed Rulemaking (NPRM, proposal, or proposed rule) 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) [74 *Federal Register* 50280 - 50549, September 30, 2009]. API is the primary trade association of America's oil and natural gas industry and represents nearly 400 member companies involved in all aspects of the industry. API members are regulated under the existing HCS, and any change to it will directly affect them.

API's main comments on OSHA's proposed rule include but are not limited to the following:

- API supports thorough and consistent adoption of the GHS. To achieve the goal of harmonization and reap the associated benefits, OSHA should align the HCS with the GHS as negotiated at the UN and seek to implement it in a manner that minimizes differences among countries. API urges OSHA to be as consistent as possible with European Union (EU) GHS implementation, especially for hazard classes/categories, for mixture cut-off values/concentration limits, and for the effective dates and transition periods. API supports U.S. efforts to globally promote the adoption of the GHS as negotiated at the UN ("3rd revised edition").[1]

[1] *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, Third Revised Edition, United Nations, 2009.

- OSHA has proposed the most conservative cut-off values/concentration limits for sensitization, reproductive toxicity and Specific Target Organ Toxicity (STOT) without providing any scientific justification, which API opposes. API urges OSHA to adopt the same mixture cut-off values/concentration limits as those adopted by the EU. Our comments discuss and recommend specific cut-offs.

- API recommends that OSHA ensure and set forth a process for U.S. stakeholder input into future GHS technical decisions to be made through negotiations at the UN Sub-Committee of Experts on the GHS (UNSCEGHS).

- API recommends that OSHA support sector-specific guidance, including providing links on its web page to sector-specific guidance.

- API recommends that OSHA work closely with other government agencies to ensure consistent and timely implementation of the GHS and alignment to the UN endorsed version of the GHS.

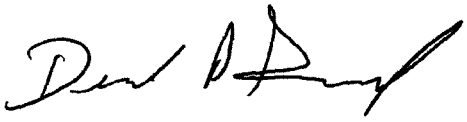
- Companies need flexibility for the specific language to describe a trade secret.

- API recommends that OSHA allow trade secret claims for labels to address the chemical identity for unclassified hazards and the percentage unknown for acute toxicity.

API also offers comments on most of the questions posed by OSHA in the NPRM.

API appreciates the opportunity to comment on this NPRM. We look forward to continued dialogue with OSHA as the effort to implement GHS in the U.S. progresses. Please contact me if you have any questions about our comments or would like additional information from API.

Sincerely,



cc: Maureen Ruskin, U.S. OSHA
Kathy Landkrohn, U.S. OSHA
Deana Holmes, U.S. OSHA
GHS Task Force, API

Attachment

COMMENTS
OF THE

AMERICAN PETROLEUM INSTITUTE

ON

**Occupational Safety and Health Administration (OSHA)
Proposed Rule to Modify
the Hazard Communication Standard (HCS)
to Conform with the
United Nation's (UN) Globally Harmonized System
of Classification and Labelling of Chemicals (GHS)**

[OSHA–H022K–2006–0062]

74 FR 50280 – 50549, September 30, 2009

December 29, 2009

American Petroleum Institute
1220 L Street, Northwest
Washington, DC 20005
202-682-8000

COMMENTS OF THE AMERICAN PETROLEUM INSTITUTE

Occupational Safety and Health Administration (OSHA)
Proposed Rule to Modify the Hazard Communication Standard (HCS) to Conform with the United Nations' (UN) Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

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Comments of the American Petroleum Institute
Occupational Safety and Health Administration (OSHA)
Proposed Rule to Modify the Hazard Communication Standard (HCS) to Conform with the United Nations' (UN) Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

I. Introduction and Executive Summary

The American Petroleum Institute (API) is pleased to submit these comments to the Occupational Safety and Health Administration (OSHA or Administration), Department of Labor, on its Notice of Proposed Rulemaking (NPRM, proposal, or proposed rule) 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) [74 *Federal Register* 50280 - 50549, September 30, 2009]. API is the primary trade association of America's oil and natural gas industry and represents nearly 400 member companies involved in all aspects of the industry.

API member companies comply with many OSHA standards including the HCS and support OSHA's efforts to ensure that workers are provided with information about hazards of chemicals they may be exposed to in the workplace. Through HCS compliance programs and broader safety and product stewardship programs, API's members evaluate the hazards of the chemicals they produce or import and provide information about them through container labels and detailed chemical information sheets (i.e., the Material Safety Data Sheet (MSDS or SDS)). Each member company prepares and implements a written hazard communication program, ensures that chemical containers are labeled, provides employees with access to SDSs, and conducts training for potentially exposed employees. API members are regulated under the existing HCS, and any change to it will directly affect them.

In this document, API offers comments pertaining to OSHA's proposal to modify its existing HCS to conform with the GHS. In Section II below, API provides responses on the specific questions posed by OSHA in the NPRM. In Sections III through VIII, API discusses additional issues concerning the Administration's adoption of the GHS. API's main comments on OSHA's proposed rule include the following:

- API supports thorough and consistent adoption of the GHS. To achieve the goal of harmonization and reap the associated benefits, OSHA should align the HCS with the GHS as negotiated at the UN and seek to implement it in a manner that minimizes differences among countries. API urges OSHA to be as consistent as possible with European Union (EU) GHS implementation, especially for hazard classes/categories, for mixture cut-off values/concentration limits, and for the effective dates and transition periods.

API supports U.S. efforts to globally promote the adoption of the GHS as negotiated at the UN ("3rd revised edition").[1]

- OSHA has proposed the most conservative cut-off values/concentration limits for sensitization, reproductive toxicity, and Specific Target Organ Toxicity (STOT) without providing any scientific justification, which API opposes. API urges OSHA to adopt the same mixture cut-off values/concentration limits as those used by the EU. Our comments discuss and recommend specific cut-offs.

- API recommends that OSHA ensure and set forth a process for U.S. stakeholder input into negotiations when future GHS technical decisions are being made at the UN Sub-Committee of Experts on the GHS (UNSCEGHS).

- API recommends that OSHA support sector-specific guidance, including providing links on its web page to sector-specific guidance.

- API recommends that OSHA work closely with other government agencies to ensure consistent and timely implementation of the GHS and alignment to the UN endorsed version of the GHS.

- Companies need flexibility for the specific language to describe a trade secret.

- API recommends that OSHA allow trade secret claims for labels to address the chemical identity for unclassified hazards and the percentage unknown for acute toxicity.

- Some of API's key points in response to OSHA's specific questions in the proposed rule are as follows:
  - API strongly urges OSHA to implement GHS uniformly for all sizes of businesses, and not to pursue alternative approaches that include exemptions or other non-uniform application of the GHS.
  - API is supportive of OSHA's proposal to adopt all the GHS health and physical hazard classes in the 3rd revised edition of the GHS.
  - API recommends that OSHA use the phrase "Other Hazards" instead of "Unclassified Hazards" and work with the UNSCEGHS to develop the criteria for these other hazards.
  - The hazard statement and precautionary statement that OSHA discusses for asphyxiants are not appropriate.
  - API supports OSHA's proposal to eliminate the "floor" of hazardous chemicals as well as the "one study" requirement.

[1] *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, Third Revised Edition, United Nations, 2009.

- API recommends that the OSHA and U.S. Department of Transportation (DOT) classification criteria be consistent for self-reactive chemicals, organic peroxides, self-heating chemicals, and explosives.
- It is not appropriate to mandate the suggested 20 percent concentration limit for STOT Category 3. API urges OSHA to adhere to the text of 3rd edition of the GHS as much as possible.
- The use of the black pictogram frame for packages that are not exported should be allowed.
- Manufacturers should be allowed to use their own precautionary statements in addition to the precautionary statements in proposed Appendix C, which should be non-binding suggestions.
- The time allowed for updating labels on shipped containers to include new information should be 12 months. For the requirement to update labels, OSHA needs to clarify the meaning of "new and significant information."
- API supports requiring the Permissible Exposure Limits (PELs) on the SDS and also allowing (but not requiring) the inclusion of other occupational exposure limits.
- API recommends that SDS Section 15 remains non-mandatory.
- API supports OSHA being consistent across all OSHA standards.
- Updating workplace signs for the substance specific standards should be done according to the normal facility signage replacement schedule.
- API agrees with the proposed two-year implementation timeframe for training.
- API supports OSHA's proposed three-year implementation time frame and allowing either the current rule or new final rule to be followed during the three-year transition period.
- API requests that OSHA provide assistance materials including electronic learning tools, posters, and reference tables.
- API does not support OSHA's development of a chemical classification database.

- API also provides comments on several additional issues:
  - Several hazard statements include two hazards, and no option for separating the hazard statements is provided. Where data are available, individual hazard statements for skin corrosives, for fertility hazards, and for developmental hazards should be allowed.
  - API recommends that OSHA revise the proposed skull and crossbones pictogram precedence to align with the GHS. API urges OSHA to adhere to the text of 3rd edition of the GHS as much as possible.
  - Electronic distribution of SDSs should be an acceptable alternative method of distribution.
  - Companies need flexibility in SDS format and wording in order to comply globally even though there may be national/regional differences.

These points and others are discussed in detail in the remainder of this document.

II. API Responses to NPRM Questions

In the proposed rule, OSHA presents a list of questions for which it is specifically interested in receiving answers. API responses to selected questions are presented below, with the OSHA question presented in italics.

A. 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.*

   API supports OSHA's adoption of the 3rd revised edition of the GHS. API supports consistency with the GHS as negotiated at the UN and with minimum country-specific deviations. Internationally harmonized hazard classification and communication should lead to increased worker protection, especially as the new hazard pictograms become recognized. Standardization will improve training and understanding of U.S. SDSs. Furthermore, consistent information on SDSs will improve downstream hazard assessment activities.

B. Economic Impacts and Economic Feasibility

2. *The preliminary economic analysis (PEA) raises a variety of specific questions and issues: a. Industrial profiles: This covers issues concerning how many employees, establishments, and products would be affected by the proposed standard. OSHA is particularly interested in comments on the number of affected employees, and the number of SDSs that would need revision, by industry.*

   As OSHA is aware, the OSHA HCS is widely implemented throughout American industry, and SDSs are produced for the vast majority of chemicals and chemical mixtures in commerce in the U.S. Changes in SDSs will affect virtually all workers in the U.S. who are employed in workplaces where chemicals are used. These workers will need updated training and will need to become familiar with the new label and SDS format.

   API member companies issue tens of thousands of SDSs that would need revision to meet the revised standard. For example, one API member company currently has approximately 4,500 SDSs for the U.S. market, all of which would require revision under the NPRM. For this one company, approximately 10,000 U.S. employees would be affected, e.g., require updated training.

2b. Issues with respect to estimated benefits of the proposed standard: OSHA considers three kinds of benefits in this preliminary analysis:

(1) benefits associated with preventing injuries, illnesses, and fatalities through clearer and more accessible information;
(2) 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
(3) 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.

API member companies have in place effective processes to comply with existing regulatory requirements, including the OSHA HCS, and to meet their own corporate standards and practices for product stewardship. Many API members are leaders in industry performance in worker health and safety. For these companies, implementation of the GHS will not have significant impact on the occurrence of injuries, illnesses, or fatalities—because such incidents already are minimized. Furthermore, in multinational companies, GHS activities have already commenced.

However, in general, API does believe that the benefits OSHA discusses will accrue if GHS is implemented comprehensively and consistently across industries on a global basis. In order to achieve harmonization and the principal benefits of the GHS, it is necessary for the GHS to be adopted in a consistent manner worldwide. It is important that the revised HCS reflect as closely as possible the criteria, methodologies, and approaches to classification of substances and mixtures in the GHS as adopted and negotiated at the UN.

2c. 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 SDSs, and redoing labels; and to chemical users for familiarization and program changes for managers and for training exposed employees. OSHA 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.

Significant costs are anticipated for SDS revisions, re-labeling, re-distributing revised SDSs to customers, and employee training. Information Technology (IT) solutions (i.e., software) are already available through major vendors offering SDS authoring systems supporting GHS. Although in many cases the bulk of the software (i.e., algorithm) work is complete, country or regional differences in regulatory provisions may require upgrades.

C. 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?

API strongly urges OSHA to implement GHS uniformly for all sizes of businesses. Reducing or otherwise changing the requirements for small entities

would hinder the hazard communication programs of larger companies, who often work with smaller entities and need to comply with all aspects of the HCS. In order to achieve the stated benefits of GHS implementation, the complete adoption of GHS is necessary. Not implementing the GHS completely and uniformly would cause confusion, thereby negating the benefits of the GHS.

D. 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.

API concurs with OSHA's determination.

E. 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.

API is supportive of OSHA's proposal to adopt all the GHS health and physical hazard classes in the 3rd revised edition of the GHS. API agrees that these hazard categories are generally consistent with the scope of the current HCS. Although the Acute Toxicity Category 4 will increase coverage over the current HCS, we agree with the exclusion of the indicated categories and are particularly pleased that the categories proposed are mainly aligned with those adopted by the European Union (EU), one of the U.S.'s largest trading partners.

In Table A.3.2: Reversible Eye Effects, OSHA needs to clarify which Eye Irritant Category is adopted (i.e., fully reversible in 21 days or fully reversible in 7 days).

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?

OSHA should use simple and clear terminology to describe hazards not defined in the GHS. Phrases such as "Other Hazards" or "Additional Hazards" would be easier to understand than "Unclassified Hazards." The phrase "Unclassified Hazards" could be confusing to workers and employees.

API recognizes OSHA's desire to ensure that all hazards currently covered by the HCS and new hazards identified in the future are included in the scope of the revised standard. However, the "unclassified hazards" approach has the

potential to result in lack of harmonization. API strongly encourages OSHA to work to develop these criteria at the UNSCEGHS. In instances where OSHA believes the UNSCEGHS process will be too lengthy, OSHA should define and communicate the hazard criteria until UNSCEGHS adopts appropriate guidance and then adopt the UNSCEGHS approach through notice and comment rulemaking, once agreed to at the UN.

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? Are the label elements suggested appropriate?

API recommends that harmonization of unclassified hazards be achieved through the current GHS update process, as described above in our response to question number 7.

The hazard statement "*may be harmful if inhaled*" is inappropriate for a simple asphyxiant. A statement like "May be harmful in enclosed spaces" or "Asphyxiation hazard" should be used so that there is no confusion about the acute toxicity. The proposed precautionary statement "m*ay displace oxygen in breathing air and lead to suffocation and death, particularly in confined spaces"* is not a precautionary statement but a statement of hazard. As in the GHS, any HCS precautionary statements should focus on preventions to avoid the hazard. The precautionary statement for asphyxiants should include a preventive measure such as "Avoid exposure in confined spaces."

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?

API supports OSHA's proposal to eliminate the "floor" of hazardous chemicals as well as the "one study" requirement. The detailed GHS criteria provide specific, consistent guidance for hazard classification and allow a more comprehensive approach to be used for the evaluation of health hazards.

Since the GHS offers specific guidance on evaluating each health hazard, the information used to establish the referenced "floor" would be evaluated by companies along with any new information/data that has been identified in the evaluation process. For example the same underlying data used by the International Agency for Research on Cancer (IARC), OSHA, or the National Toxicology Program (NTP) to classify individual chemicals as carcinogenic would be examined by companies as part of the GHS classification process. Further, Appendix F to the GHS provides additional guidance on cancer classification; this has been excerpted from the IARC Monographs program on the evaluation of the strength and evidence of carcinogenic risks to humans (see proposed Appendix A, footnote 23[2]).

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?

OSHA should provide examples and the decision logic in a simple and user-friendly manner to facilitate understanding of these new criteria. OSHA should make such guidance available at the same time as the final regulation is published, not after the publishing of the final rulemaking.

In several instances, OSHA decided not to use the text of the 3rd edition of the GHS verbatim. API urges OSHA to adhere to and align with the text of the 3rd edition of the GHS as much as possible. For example, in Part 3 of the 3rd edition, the Dilution Bridging Principle always uses the wording "**may be.**" In Appendix A, the NPRM uses "shall be." These phrases do not have the same meaning. We strongly believe that OSHA should use the wording in the 3rd edition of the GHS, in part to encourage country-consistent application of the GHS. ***OSHA should review the text in the NPRM and ensure the text of the 3rd edition of the GHS is used verbatim.*** Where OSHA deviates from the GHS text, OSHA should provide an explanation in the final rulemaking with the rationale behind the deviation.

A.0.5.1.1 Dilution

[2] 74 FR 50461.

> *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* (emphasis added)[3]

OSHA's NPRM lacks the guidance language below found in both the GHS and the EU regulation for Classification, Labelling, and Packaging (CLP). To promote consistency and harmonization of classification, particularly for complex substances, OSHA should consider including this guidance:

> *1.3.3.1.3 These definitions should be used to maintain consistency when classifying substances and mixtures in the GHS. Note also that where impurities, additives or individual constituents of a substance or mixture have been identified and are themselves classified, they should be taken into account during classification if they exceed the cut-off value/concentration limit for a given hazard class.* [4]

In Appendix A at A.0.4.2[5], OSHA discusses the tiered mixture classification approach as applied to Carcinogenicity, Germ Cell Mutagenicity, and Reproductive Toxicity. Although the NPRM language is not exactly the text from the 3rd edition of the GHS, the intent is the same. API supports the use of test data on the mixture as a whole on a case-by-case basis where justification can be provided.

For Appendix A at A.4 Respiratory or Skin Sensitization[6], OSHA should not adopt the sub-categorization. The GHS allows competent authorities discretion in adopting sub-categories 1A and 1B for respiratory and skin sensitization. To align with the EU CLP, OSHA should only adopt Category 1 for respiratory and skin sensitization.

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.*

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[3] 74 FR 50444.
[4] *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, Third Revised Edition, United Nations, 2009, 1.3.3.1.3.
[5] 74 FR 50443.
[6] 74 FR 50457.

API recommends that the OSHA and U.S. DOT classification criteria be consistent for self-reactive chemicals, organic peroxides, self-heating chemicals, and explosives. These classification criteria are appropriate for the workplace. Using the GHS/DOT criteria for these hazards provides a consistent hazard warning in the workplace. It alerts the user to the type of hazard and provides qualitative information. OSHA should adhere to the GHS as negotiated at the UN and adopt minimum country–specific deviations.

12. The GHS gives countries guidance on a cut-off or concentration limit for chemical mixtures containing target organ toxicity hazards. OSHA is proposing to make the suggested 20 percent 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.

For completeness, the cut-off value/concentration limit for STOT Category 3 should be included in Table A.8.2.[7] OSHA should adhere to the 3rd edition of the GHS, which does not mandate the 20 percent cut-off value/concentration limit for STOT Category 3. The classification of mixtures containing STOT Category 3 ingredients should be based upon science and hazard determination rather than an arbitrary 20 percent concentration threshold.

F. 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, however. 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?

To be consistent with the 3rd edition of the GHS, OSHA should allow the use of the black pictogram frame for packages that are not exported. However, OSHA should not require the use of the black pictogram frame domestically. The black pictogram frame may have cost advantages as it would not require color printing, but use of the black pictogram frame can add operational costs and complexity due to different label requirements for domestic versus export destination. Allowing the black pictogram frame for domestic labels would require additional training for employees to understand that, although the color is different, the meaning is the same.

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, however; 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,

[7] 74 FR 50470.

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.

Manufacturers should be allowed to use their own precautionary statements in addition to the precautionary statements in Appendix C.

To be consistent with the 3rd edition of the GHS, OSHA should require that labels include precautionary statements, but the precautionary statements in Appendix C should only be suggested language. The precautionary statements provided in Appendix C should not be mandatory and should be nonbinding examples, as in the GHS.

A number of the precautionary statements are very general, and for certain hazards may clutter the label with information that is not very useful, thereby distracting from effective hazard communication. OSHA should work through the UNSCEGHS to develop additional guidance on how to combine and choose precautionary phrases for each hazard to provide succinct and legible labels, and then incorporate the guidance into the HCS through notice and comment rulemaking. OSHA should adhere to the GHS and adopt minimal country–specific deviations for precautionary statements.

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?*

Although this hazard is not directly applicable to API members, we have no objection to this proposal.

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. OSHA 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)?*

OSHA needs to clarify what is meant by "new and significant information." New significant information must be communicated globally to minimize liability for affected companies. Since most companies do business internationally, time is needed to revise labels globally and comply with the various country specific requirements, including translation. Three months is not enough time to revise and print labels. It would be difficult if not impossible for companies to update labels on shipped containers and workplace signs in three months. We recommend that OSHA extend the time

interval to 12 months for updating labels on shipped containers and for in-plant labeling.

Other authorities have allowed more than three months for regulatory implementation, to minimize costs and to ensure that existing preprinted labels/containers and packages may be used. In implementing its CLP, the EU has provided a two-year transitional provision concerning the labeling of substances/mixtures already placed on the market (12/1/2012 and 6/1/2017). While implementing the GHS (e.g., changes for the revision of the ORGANIC PEROXIDE label and placard, revision of the classification criteria for PG III flammable liquids, and revision of the classification criteria and packing group assignments for Division 6.1 materials), DOT is allowing a five-year transition period. As stated in its final rule implementing GHS[8], DOT supports a five-year transition to changeover to the new classification criteria and to ensure that packages marked based on existing regulations are out of the transportation stream.

G. 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.

API is highly supportive of OSHA requiring the PELs on the SDS and also allowing the inclusion of other occupational exposure limits. For communicating exposure limits on the SDS, no exposure limits, other than OSHA PELs, should be required. Manufacturers should be permitted to include other information at their discretion, such as American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), American Industrial Hygiene Association (AIHA) Workplace Environmental Exposure Levels (WEELs), and/or other exposure limit guidelines.

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?

API recommends that SDS Section 15 remains non-mandatory. OSHA could list under non-mandatory Section 15 the applicable substance specific standards, like the sub-headings in non-mandatory SDS Sections 12-14.

H. 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,

[8] 71 FR 78596, December 29, 2006.

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. 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, however.

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?

As stated in API's ANPRM comments[9], API urges OSHA to be consistent across all standards. API recommends that OSHA apply the GHS criteria to all other OSHA standards.

API is supportive of the change to align the definitions of flammable liquids with the GHS categories. This change will streamline labeling of tanks and chemicals in the field, without resulting in substantive changes in work practice.

The DOT flammable liquid ranges and the GHS flammable liquid ranges are already the same. The NPRM includes a crosswalk between the 29 CFR 1910.106 flammable/combustible liquid classes, which are similar to the National Fire Protection (NFPA) classes, and the GHS. The NFPA has not yet changed their flammable and combustible liquids definitions.

One API member company utilizes NPFA 704 for hazard placards on in-plant tanks and, assuming that NFPA will align with the OSHA GHS NPRM, it will prompt a huge effort and significant cost to revise labeling.

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?*

Consistency among OSHA's flammability requirements will advance effective hazard communication. Under the proposal outlined in question 20, the storage requirement for flammable liquids would still be valid based on flash points and volumes. Whether the material is called flammable or combustible is not

[9] OSHA-H022K-2006-0062-0171.

important because physical values such as vapor pressure, boiling point, and flash point are more significant in hazard determination for use and storage requirements.

In OSHA's NPRM, the elimination of the term "combustible liquid" in the 1910.107 Spray Finishing using Flammable and Combustible Materials Standard does not significantly change the requirements of the standard and will not adversely affect industry's ability to comply with the standard.

21. OSHA is proposing to modify the language required on signs in substance-specific health standards. OSHA 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?

API agrees with the proposed modifications to signs for the substance specific health standards. Aligning with the GHS will bring consistency between SDS, labels, and in-plant warning signs and will aid in employee understanding.

Updating workplace signs for the substance specific standards should be done according to the normal facility signage replacement schedule. One API member company recently updated signs at a small refinery at a cost of $200,000 and believes that minor wording changes in the substance specific standards (Table XV-1 Proposed Regulated Area Signs) does not justify the associated cost and time.

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?

Changing the current language for labels in the substance-specific standards would have minimal impact on hazard communication in the work place. The proposed change to the signal word, hazard statement(s), and precautionary statement(s) for the substance specific standards will adequately warn employees. Aligning with the GHS will bring consistency among SDS, label, and in-plant warning signs and will aid in employee understanding. Updating

workplace signs for the substance specific standards should be done according to the normal facility signage replacement schedule.

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?*

The sources/organizations listed by OSHA in the NPRM are not primary sources and should not be used and included in the substance specific standards as references. It is more appropriate for OSHA to reference the GHS criteria as the source for health hazards that need to be considered. The GHS includes the applicable health hazards as well as criteria for their classification.

I. 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?*

API agrees with the proposed two-year timeframe for training. Two years would be adequate for most workplaces to complete the necessary training. Standardized labels and SDS formats would make locating and understanding hazard communication information easier.

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? Would a shorter time frame be sufficient?*

Three years is a reasonable time frame. Three years will allow sufficient time for information to flow through the supply chain and minimize the confusion that could result from a prolonged period of dual regulations.

API also supports the proposal that either the current rule or new final rule can be followed during this three-year transition period.

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

OSHA's NPRM states: "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 three-year transition period."

OSHA needs to clarify the meaning of this statement to indicate that the transition period does not start until the final rule becomes effective and that companies may comply with the existing HCS during the transition period.

J. Compliance Assistance and Outreach

28. OSHA received many comments in response to the questions in the September 12, 2006, advance notice of proposed rulemaking (ANPR) 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.

As mentioned in API's ANPRM comments[10], API suggests that OSHA consider providing at least the following assistance materials:

- electronic guided learning tools with modules for awareness training, classification of chemicals, and training on pictograms;
- for plants, posters with pictograms and explanations (in multiple languages); and
- a reference table with the differing requirements around the globe.

Electronic tools (e.g., slides, web links, etc.) would be useful for large companies and health and safety personnel because of immediate access to computers. Access to computers may be limited in small businesses and for field employees; therefore, paper publications such as posters would be beneficial to employees because they could be posted at multiple worksites. Long detailed documents typically would not be read in entirety, therefore brief and to the point information that provides work-related hazard information is crucial.

API recommends that OSHA provide guidance for both the general user of GHS information and for those involved in SDS and label preparation. Detailed technical guidance should be provided on cut-off interpretations, classification criteria for substances and mixtures, and opportunities and flexibility to replace testing determination of product/substance hazards with predictive assessments (e.g., alternatives to GHS component based limitations for carcinogenicity, mutagenicity, etc.). OSHA should provide easy to understand guidance on calculations of acute toxicity estimates, including example calculations.

API suggests that OSHA consider all relevant distribution approaches to disseminate compliance and other informational tools depending on the target audience. The best method of distribution is a function of employee work location and access to computers. For speed of delivery and efficiency, electronic is the best method for material distribution.

[10] OSHA-H022K-2006-0062-0171.

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?

API does not support a database of chemical classifications developed and maintained by OSHA. The proliferation of national/regional lists is contrary to harmonization. Such a database has the most value when it is accepted by all countries implementing the GHS. In order to promote the overarching GHS goal of global harmonization and facilitation of trade, any database would need to:

- be accepted globally with national/regional lists eliminated;
- be based on a rigorous, evidence-based scientific process to be defined in advance and applied globally;
- contain the data to support the classifications or a section explaining the rationale behind the classifications;
- include mechanisms for updating as new evidence based science becomes available; and
- have defined criteria for data source.

K. 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. OSHA requests comments on these alternatives, with data to support the views expressed. Suggestions and support for other alternatives are requested as well.

The U.S. needs to take an all or nothing approach to succeed in implementing GHS. Voluntary implementation of the GHS would result in many companies using the existing performance-oriented HCS. Allowing two different classification schemes after the transition period expires would result in confusion, different classifications for the same material, and difficulty for multinational companies to perform GHS classification for exports.

Allowing exemptions based on size of the business or on a company's position in the supply chain would result in difficulties for manufacturers and producers of mixtures. For mixtures, some companies may rely upon SDSs from suppliers of the ingredients to determine the overall mixture classification. Any exemptions will impede effective hazard communication, ultimately resulting in a negative impact on the worker.

The goal of harmonization is best served, and benefits will be maximized, by aligning with the 3rd edition of the GHS as negotiated.

III. Cut-off Values/Concentration Limits of Ingredients for the Classification of Mixtures

OSHA has proposed the most conservative cut-off values/concentration limits for the chronic toxicity hazard categories without providing any scientific justification. API supports protective limits for the classification of mixtures, but in some cases the proposed limits are 10 times more conservative than the existing HCS (i.e., for sensitizers, reproductive toxins, mutagens), without any scientific rationale.

A 1 percent mixtures cut-off value for all hazards except carcinogens has been used for the last 24 years under the HCS. It is difficult to understand OSHA's justification for proposing a 0.1 percent cut-off value/concentration limit for sensitizers and reproductive toxins when there are other cut-off values/concentration limits allowable under the GHS and that would align with the EU GHS implementation scheme.

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 EU, one of the U.S.'s largest trading partners. Many U.S. oil and chemical companies have operations in the EU and must provide SDSs for both the U.S. and the EU. 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. API urges OSHA to adopt the same mixture cut-off values/concentration limits for mixtures as the EU, as outlined in the table below.

API Recommended Changes for Cut-Off Values / Concentration Limits			
	NPRM Cut-Off Value / Concentration Limit	**API Recommended Cut-Off Value / Concentration Limit**	Reason for API Recommendation
Respiratory Sensitization	Category 1 ≥ 0.1% Category 1A ≥ 0.1% Category 1B ≥ 1.0% [≥ 0.2% for gases]	**Category 1 Between ≥ 0.1% and < 1% on SDS and label as sensitizing component** **≥ 1% [≥ 0.2% for gases] on SDS/label**	Adopt the same values as the EU CLP which has not adopted subcategories for sensitization.
Skin Sensitization	Category 1 ≥ 0.1% Category 1A ≥ 0.1% Category 1B ≥ 1.0%	**Category 1 Between ≥ 0.1% and < 1% on**	Adopt the same values as the EU CLP which has not adopted the subcategories for

		SDS and label as sensitizing component **≥ 1% on SDS/label**	sensitization.
Reproductive Category 1 (A and B)	0.1%	**0.3%**	If a 1% cut-off value has been protective for 24 years, under the HCS, then certainly 0.3% should also be protective. OSHA has offered no scientific justification why the 0.1% cut-off value/concentration limit is needed. The 0.3% cut-off value/concentration limit for Reproductive Toxins Category 1(A and B) also aligns with the EU.
Reproductive Category 2	0.1%	**3%**	Although the NPRM distinguishes between the Category 1 and Category 2 cut-off values/concentration limits for Germ Cell Mutagenicity and Carcinogenicity, it does not distinguish between the Reproductive Category 1 and 2 cut-off values/concentration limits. This approach is inconsistent. The lower weight of evidence Reproductive Category 2 is provided for substances where there is not sufficient human or animal evidence for classification in Category 1. Reproductive Category 2 criteria do not meet the OSHA HCS "one well conducted animal study" criteria, and including Category 2 reproductive toxins in the revised HCS is already more protective than the existing HCS. The 3% cut-off value/concentration limit for

			Reproductive Category 2 also aligns with the EU.
STOT Category 2	1%	**10%**	Although the NPRM distinguishes between the Category 1 and Category 2 cut-off values/concentration limits for Germ Cell Mutagenicity and Carcinogenicity, it does not distinguish between the STOT Category 1 and 2 cut-off values/concentration limits. This approach is inconsistent. The 10% cut-off value/concentration limit for STOT Category 2 aligns with the EU.

The current HCS has a 1 percent cut-off value for reproductive hazards. OSHA is proposing to lower this value to 0.1 percent for Categories 1A and 1B reproductive toxins. The GHS offers a cut-off value/concentration limit of 0.3 percent that is closer to the current scope of the HCS. OSHA has offered no scientific justification why the 0.1 percent cut-off value/concentration limit is needed. Given that 1 percent has been in use for 24 years, OSHA would need very good reason to lower it by an order of magnitude, and has not provided sound justification. The 0.3 percent cut-off value/concentration limit for Categories 1A and 1B reproductive toxins also aligns with the EU, is protective, and will be more practical to implement. API urges OSHA to adopt 0.3 percent as the cut-off value/concentration limit for Categories 1A and 1B reproductive toxins. If OSHA mandates the lower 0.1 percent cut-off value/concentration limit for Category 1(A and B) reproductive toxins, then the Administration should show cause and data to support the rationale rather than arbitrarily adopting the lower value.

OSHA proposes to use the same 0.1 percent cut-off value/concentration limit for Category 2 reproductive toxins as for Categories 1A and 1B. Category 2 is provided for substances where there is not sufficient human or animal evidence for classification in Category 1. The Category 2 criteria do not meet OSHA's "one well conducted animal study" criteria[11] and including Category 2 reproductive toxins in the revised HCS is already more protective than the existing HCS. This lower weight of evidence in Category 2 should have a 3 percent cut off for classification. Also, the proposed 0.1 percent threshold for all reproductive toxins is inconsistent with the approach for mutagens which distinguishes between Categories 1 and 2 (0.1 and 1.0 percent, respectively). The 3rd revised edition of the GHS supports a cut-off value/concentration limit of 3

[11] 29 CFR 1910.1200 Appendix B.

percent for Category 2 reproductive toxins and the EU has adopted this value. API believes OSHA should adopt 3 percent as the cut-off value/concentration limit for Category 2 reproductive toxins.

Similar to the situation for reproductive toxins, OSHA proposes to use the same cut-off value/concentration limit (1 percent) for Category 2 target organ toxins as for Category 1. The 3rd edition of the GHS allows 10 percent as the cut-off value/concentration limit for classifying STOT Category 2 mixtures and the EU has adopted the 10 percent value. API believes OSHA should adopt the 10 percent cut-off value/concentration limit for Category 2 Specific Target Organ Toxicity, Single and Repeated Exposure. OSHA should adhere to the GHS as negotiated at the UN.

IV. Process for USA Stakeholder Input into GHS Revisions

In the preamble to the proposed rule, OSHA states:[12]

> *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.*

This preamble discussion addresses U.S. mechanisms available to update OSHA's HCS in the future. However, the approach that OSHA enumerates appears to allow no U.S. stakeholder input into the negotiations and discussion while the GHS technical decisions are being made at the UNSCEGHS. Rather, it offers only an after-the-fact decision on whether to update the U.S. GHS instruments to be compatible with the global GHS framework. This approach does not allow notice and comment on the technical issues.

[12] 74 FR 50385.

A transparent process would provide for U.S. stakeholder input into the discussions and technical issues at the UNSCEGHS and into decisions taken by the U.S. delegation to UNSCEGHS. Comments at an early stage are more effective in shaping issues/decisions than after-the-fact comments. The absence of a mechanism for U.S. stakeholders to comment on the UNSCEGHS papers is in effect bypassing the U.S. notice and comment rulemaking process as required by the Administrative Procedures Act (APA).

The U.S. DOT recognized this situation as a concern many years ago for U.S. transportation stakeholders and the UN Recommendations on the Transport of Dangerous Goods - Model Regulations. U.S. DOT routinely solicits public comments on positions for the United Nations Sub-Committee of Experts on the transport of Dangerous Goods (UNSCETDG) papers and on the outcome of the UNSCETDG meetings through DOT public meetings and outreach activities. The DOT process ensures that U.S. stakeholder interests are communicated and considered in the development of international standards.

OSHA needs to develop a process similar to that of DOT to obtain U.S. stakeholder input into the development of U.S positions for the GHS Purple Book during the UNSCEGHS discussion stage. It would be bypassing the rulemaking process required by the APA to issue Standards' Improvement Process (SIPs) or a Direct Final Rule (DFR) after the revisions to the GHS Purple Book have been finalized.

As emphasized throughout these comments, API believes that complete and consistent implementation is necessary for the success of the GHS. Achieving this will require U.S. implementation of future changes to the GHS. The ability of the U.S. to implement future changes may be compromised if stakeholder input is not considered when the UNSCEGHS addresses technical issues and formulates changes to the GHS.

V. Sector-Specific Guidance

API strongly encourages OSHA to support and promote sector-specific guidance. OSHA should provide links on the Administration's website to sector-specific guidance.

The GHS lacks a broadly recognized approach for ensuring that the best information is consistently applied to GHS implementation for certain sectors. Industry is helping to fill the gap by developing sector-specific guidance on GHS application.

It has been API's experience that, while the GHS principles are robust, there are complexities and idiosyncrasies associated with their application to specific materials such as petroleum substances. The International Petroleum Industry

Environmental Conservation Association (IPIECA) GHS guidance (see UNSCEGHS Document ST/SG/AC.10/C.4/2009/7) suggests arranging petroleum substances logically in groups of "similar" substances (product groups), which facilitates read-across for purposes of consistent classification and minimizes unnecessary testing. The IPIECA guidance also informs the user that there are certain hazardous constituents, which should be considered in classification decisions when there is limited data on the complete substance. Without this relevant information, the uninformed might view all petroleum substances as conventional mixtures and base all classification decisions solely on component information.

The concept of sector guidance is consistent with the aims of the UN Strategic Approach to International Chemicals Management (SAICM). SAICM goals include promoting industry participation and responsibility; establishing a clearing house for information on chemical safety to optimize the use of resources; strengthening the exchange of technical information among the academic, industrial, governmental, and intergovernmental sectors; and other goals related to chemicals management.

To promote sector-specific guidance, API urges OSHA to provide links on the Administration's website to sector-specific guidance. Coordinating a location to house sector-specific guidance on the OSHA website will accelerate GHS implementation domestically and promote consistency in the application of GHS to sectors where guidance is needed. The result will be more robust and consistent hazard communication, ultimately benefiting the worker.

VI. U.S. Coordinated GHS implementation

API believes that GHS implementation in the U.S. must be synchronized among all responsible agencies. API recommends that OSHA work closely with other government agencies to ensure consistent and timely implementation of the GHS and alignment to the UN endorsed version of the GHS.

In practice, collaboration is needed among Coast Guard, Environmental Protection Agency (EPA), Consumer Product Safety Commission (CPSC), OSHA, and DOT. DOT has essentially implemented the necessary changes to align with the GHS, and OSHA has published the NPRM. However, EPA and CPSC are not making progress in implementing the GHS. CPSC has stated that GHS implementation is on hold due to other priorities. The recent International Maritime Organization (IMO)/Coast Guard activities related to SDSs do not promote global harmonization and a consistent SDS format. A coordinated effort on hazard communication activities in the U.S. is needed.

VII. Trade Secrets

In the proposed rule, OSHA states:[13]

> *(i)(1)(iii) The safety data sheet indicates that the specific chemical identity and/or percentage of composition is being withheld as a trade secret,*

In order to achieve globally harmonized and consistent SDSs, companies need flexibility for the specific language used to describe a trade secret. Terms such as "confidential," "trade secret," and "proprietary" should all be allowed to indicate that the specific chemical identity and/or percentage of composition are being withheld. API encourages OSHA to allow flexibility for indicating trade secrets on the SDS. OSHA could include in the NPRM a statement such as:

> "Confidential," "confidential business information (CBI) ," "trade secret," and "proprietary" are acceptable ways of indicating a trade secret.

In the NPRM, OSHA only allows chemical identity trade secret claims for SDSs and not for labels. There appears to be an inconsistency between the label elements for classified hazards and unclassified hazards. As opposed to classified hazards, for unclassified hazards OSHA is proposing to require the name of the chemical on the label. Since the name of the chemical is required for unclassified hazards, the trade secret provisions for chemical identity should also apply to labels.

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*[14]. 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. API 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 percentage of the substance in a mixture, from the safety data sheet ***and label***, provided that:

[13] 74 FR 50442.
[14] 74 FR 50447, 50483, 50540.

VIII. Other Issues

A. Hazard Statements

In Appendix C several hazard statements list two hazards and no choice is provided if only a single hazard is present. Examples follow:

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

If the material does not have the second hazard, then that specific hazard should be omitted from the hazard statement in order to provide accurate hazard information. It is not accurate and would be incorrect with potential liability consequences to warn for a hazard that the material does not pose.

In the case of skin corrosives that do not cause severe eye damage, OSHA needs to specify that the severe eye hazard statement can be omitted from the label when severe eye damage is not a hazard of the material. The UNSCEGHS December 2009 informal paper [UNSCEGHS Document UN/SCEGHS/18/INF.3] on the revision of GHS Skin Chapter 3.2 and Eye Chapter 3.3 makes no provision for skin corrosives to not also be classified and labeled as eye corrosives. OSHA should work at the UNSCEGHS to have this guidance included in the revisions to GHS Skin Chapter 3.2 and Eye Chapter 3.3.

The EU CLP allows differentiation between fertility hazards and developmental hazards in EU specific hazard statements. OSHA should allow individual hazard statements for fertility hazards and developmental hazards and work at the UNSCEGHS to provide guidance on allowing the use of individual reproductive 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.*

B. Precedence of Pictograms

It is important for labels to be harmonized globally. OSHA states in the NPRM preamble that the proposed modifications are consistent with the negotiated provisions of the GHS and aligned with the EU CLP where possible. In Appendix C the NPRM provides a precedence of pictograms for multiple hazards. In one case the NPRM precedence deviates from the GHS. API recommends that OSHA revise the pictogram precedence to align with the GHS and the EU CLP. The recommended modification is as follows:

If the skull and crossbones pictogram is included, the exclamation mark pictogram shall not appear ~~where it is used for acute toxicity~~; [15]

The phrase "*where it is used for acute toxicity*" should be deleted.

OSHA should adhere to the GHS as negotiated at the UN. OSHA should review the text in the NPRM and ensure the text of the 3rd edition of the GHS is used verbatim.

C. Distribution of SDSs

In addition to mailing hard copies of SDSs to customers, OSHA should state in the final rulemaking that electronic distribution of SDSs is an alternative acceptable method of distribution.

D. SDS Sub-headings Clarification

In section (g) and Appendix D, the NPRM says that SDS sub-headings are mandatory.

*(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.*[16]

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.*[17] (emphasis added)

No definition of sub-heading is provided in the GHS or the NPRM. It would be useful to have clarification or a definition of SDS sub-headings. Is a sub-heading information or a sub-section? Are the sub-heading letters required, e.g.,

SDS Section 1. Identification,
(a) Product identifier used on the label;
(b) Other means of identification; (emphasis added)

It is important to understand the requirements and flexibility concerning SDS sub-headings in OSHA's proposal. One goal of the GHS is to have a globally harmonized SDS. The draft EU SDS requirements include numbered and mandatory sub-headings.

[15] 74 FR 50481.
[16] Proposed regulatory text at 74 FR 50442.
[17] Proposed regulatory text at 74 FR 50540.

OSHA should allow enough flexibility in both SDS format and wording to allow companies to globally provide appropriate hazard information, advice, and warnings even though there may be regional differences. It is more difficult to provide pertinent health information if the statements must be separated into distinct sub-sections. Companies need to be able to provide consistent safety and health advice on SDSs globally. API encourages OSHA to allow this needed flexibility in SDS formatting.

E. Table A.1.2 Correction

The November 5, 2009, *Federal Register* correction for the NPRM[18] aligns Table A.1.2 to the 3rd edition GHS Table 3.1.2. However, in the 3rd revised edition of the GHS, Table 3.1.2 has an error for the dust/mist exposure route. The dust/mist exposure route needs to be corrected in both NPRM Table A.1.2 and GHS Table 3.1.2.

The *Classification category or experimentally obtained acute toxicity range estimate values* in NPRM Table A.1.2 and GHS Table 3.1.2 for the dust/mist exposure route should read:

0	< Category 1 ≤	0.05
0.05	< Category 2 ≤	0.5
0.5	< Category 3 ≤	1.0
1.0	< Category 4 ≤	5.0

[18] 74 FR 57278–57280.