Miller, Diane M. (CDC/NIOSH/EID)

From: Wise, Kimberly <Kimberly_Wise@americanchemistry.com>
Sent: Thursday, December 29, 2011 1:59 PM
To: NIOSH Docket Office (CDC)
Subject: Comments on Docket # NIOSH-240; 76 Federal Register 52664; August 23, 2011
Attachments: ARASP Comments on the NIOSH Proposed Revisions to Cancer-REL Policies - 12 28 11.pdf; Attachment 1 - ACC OSHA GHS Comments December 2009.pdf

Dear Dr. Schulte:

The American Chemistry Council's (ACC) Center for Advancing Risk Assessment Science and Policy (ARASP) is pleased to provide the attached comments in response to the National Institute for Occupational Safety and Health (NIOSH) request for information on its approach to classifying carcinogens and establishing recommended exposure limits (RELs) for occupational exposures to hazards associated with cancer. Docket # NIOSH-240; 76 Federal Register 52664; August 23, 2011. Feel free to contact me if you have any questions or would like additional information.

Regards,

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Paul Schulte, PhD, Director
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Robert A. Taft Laboratories, MS-34
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SUBMITTED VIA EMAIL: nioshdocket@cdc.gov

December 28, 2011

RE: Request for Information on the Approach to Classifying Carcinogens and Establishing Recommended Exposure Limits (RELs) for Occupational Exposures to Hazards Associated with Cancer (Docket #: NIOSH-240); 76 Federal Register 52664; August 23, 2011

Dear Dr. Schulte:

The American Chemistry Council's (ACC) Center for Advancing Risk Assessment Science and Policy (ARASP) is pleased to provide the following comments in response to the National Institute for Occupational Safety and Health (NIOSH) request for information on NIOSH's approach to classifying carcinogens and establishing recommended exposure limits (RELs) for occupational exposures to hazards associated with cancer. ARASP[1] is a coalition of independent groups and associations that promotes the development and application of up-to-date, scientifically sound methods for conducting safety assessments. ARASP fosters activities to promote adoption of policies and practices, both within and outside government, that assure that the best available science underlies chemical safety determinations. As well, ACC has created the Responsible Care® Program through which ACC member companies commit to the safe, responsible and sustainable management of chemicals through their entire life cycle, and for their intended end use. Responsible Care® is the chemical industry's world-class performance initiative and its companies are industry leaders.

Many of the companies that participate in ARASP are very familiar with the management of possible carcinogens in the workplace and the establishment of exposure limits for these substances. As such, ARASP can provide NIOSH with useful information in response to their request. ARASP has reviewed the background information provided by NIOSH and has organized this submission based on the five questions posed in the August 23, 2011, Federal Register notice (76 FR 52664). In general, NIOSH has an important role in providing leadership and guidance on issues related to workplace hazards and occupational exposure limits. In this role, it is important that NIOSH policies on cancer classification and exposure limits have a common basis and alignment with those of the Occupational Safety and Health Administration (OSHA). Such alignment is critical to avoiding differences in classification and exposure limits between NIOSH and OSHA that would lead to confusion in the workplace. Alignment of NIOSH and OSHA policies also provides a framework for efficient identification, management and regulation of developing workplace risk issues.

[1] ARASP is comprised of the following member organizations: ACC Chlorine Chemistry Division, ACC Ethylene Oxide Panel, ACC Olefins Panel, ACC Propylene Oxide/Propylene Glycol Panel, ACC Regulatory and Technical Affairs Department, The Acrylonitrile Group, American Cleaning Institute, American Petroleum Institute (API), CropLife America, Silicones Environmental, Health and Safety Council of North America, and the Styrene Information and Research Center (SIRC)

With regard to hazard classification of chemicals, there is already an enormous effort underway to develop a common basis for classifying chemical workplace hazards using the globally harmonized system (GHS) for hazard classification and labeling. OSHA is in the process of implementing GHS in the Hazard Communication Standard and, as such, this system should be the common basis for NIOSH classification of substances, including cancer hazards, in the workplace. Use of GHS promotes common classifications for substances not only within the U.S., but also internationally.

Likewise, NIOSH's approach to developing guidance on occupational exposures, including RELs, should be designed with the objective of being of the greatest use in the management and regulation of workplace exposures. This approach needs to fully consider not only chemical hazards and risks, but also the issue of feasibility in both measuring exposure and implementing exposure controls. ARASP fully supports NIOSH's effort to expand its consideration of feasibility as it updates its approach to RELs. Given NIOSH's experience and background in research on workplace chemical exposure, there likely also is a role for NIOSH in conducting research on feasibility to evaluate measurement and control technologies.

I. Input on NIOSH Questions 1 and 2

(1) Should there explicitly be a carcinogen policy as opposed to a broader policy on toxicant identification and classification (e.g. carcinogens, reproductive hazards, neurotoxic agents)?

(2) What evidence should form the basis for determining that substances are carcinogens? How should these criteria correspond to nomenclature and categorizations (e.g., known, reasonably anticipated, etc.)?

As the topics covered in these two questions are related, ARASP is providing a combined response to them.

A. Future Classifications Are Best Addressed by the GHS

The implementation of the United Nations' Globally Harmonized System of Classification and Labeling (GHS) in U.S. workplaces will fully address both of the issues that NIOSH raises in Questions #1 and #2. The GHS program has a clear set of criteria for cancer as well as other hazards that a chemical substance may present in the workplace, including health endpoints such as acute toxicity, local effects on the skin and eyes, mutagenicity and reproductive toxicity, and safety endpoints such as flammability and chemical reactivity. GHS was developed by international representatives of government, industry, and labor and is already being implemented by a number of countries, including the U.S.

In the August 23, 2011, Federal Register notice announcing this request for information, NIOSH mentioned that there have been "expressed concerns recently about limitations in the NIOSH Carcinogen Policy" and that the major limitation in this policy is the use of the term "potential occupational carcinogen" as presented in 29 CFR Part 1990 - Identification, Classification, and Regulation of Potential Occupational Carcinogens (the "OSHA Cancer Policy")[2]. In particular, NIOSH mentions its concern that the adjective "potential" as specified in §1990.103 - Definitions - conveys an uncertainty and that "a major limitation of this definition is that the policy allows for only one cancer category, which is

[2] See OSHA Cancer Policy: 29 CFR Part 1990 Identification, Classification, and Regulation of Potential Occupational Carcinogens.
http://www.osha.gov/pls/oshaweb/owastand.display_standard_group?p_toc_level=1&p_part_number=1990

'potential occupational carcinogen.[3]'" While this statement is correct as it applies to the definition provided in §1990.103; there are other aspects of the cancer policy under 29 CFR Part 1990 that clearly differentiate/classify carcinogens by placing them into different "categories" (see §1990.112) and applying different approaches to the management and regulation of a substance based on its category (see §1990.111). As such, 29 CFR Part 1990 provides that substances which pose carcinogenic hazards in the workplace are not all treated the same. Given NIOSH's stated concerns with limitations of the definition under §1990.103 and the fact that §1990.112 clearly demonstrates a need to categorize carcinogens, the adoption of a cancer policy that is fully aligned with GHS is the most appropriate path forward.

GHS has three levels of cancer classification:

1A – Known to have carcinogenic potential for humans
1B – Presumed to have carcinogenic potential for humans
2 – Suspected human carcinogens

The criteria for these classifications are presented both in the GHS documentation and in supporting guidance documents from the International Program for Chemical Safety (IPCS), the International Life Sciences Institute (ILSI) and the International Agency for Research on Cancer (IARC).

It seems most appropriate for NIOSH to also utilize the GHS scheme given that it: 1) has been developed in collaboration with several international organizations with expertise in cancer evaluation and classification, 2) addresses NIOSH's stated concerns about the vagueness of the term "potential occupational carcinogen," and, most importantly, 3) is a classification scheme that the U.S. government is already in the process of implementing in the workplace via proposed modifications to the Hazard Communication Standard.[4]

ARASP members have been active participants in the development and implementation of GHS and have extensive product stewardship programs for the development of hazard data to support GHS assessments. Internationally, ARASP members supported uniform implementation of the GHS standard as a means of developing common positions on chemical hazards, including carcinogenic hazards. Several ARASP members provided detailed comments to OSHA on their proposed modification of the Hazard Communication Standard to conform to the GHS. A full copy of the ACC comments is provided as Attachment 1.

B. Cancer Classification Considerations

It is somewhat unclear from the recent notice whether NIOSH intends to develop lists of classified substances or whether it intends to provide guidance on how it believes substances should be classified for the workplace. The classification of chemical substances can involve a number of considerations and may change over time as new data become available. The GHS system as it is applied to hazard communication is primarily a self-classification scheme to be completed by the manufacturer. As such, any chemical classification lists developed by NIOSH should provide guidance rather than establish mandatory classifications. This principle is clearly articulated in the GHS framework (Section 1.1.4.1): "The GHS is designed to permit self-classification. In order to provide the flexibility needed for self-

[3] 29 CFR §1990.103, OSHA Cancer Policy.
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=11368
[4] OSHA's Proposed Rule to Modify the Existing Hazard Communication Standard to Conform with the United Nations' Globally Harmonized System of Classification and Labeling – 29 CFR Parts 1910, 1915, and 1926 Hazard Communication Proposed Rule (74 Fed. Reg. 50280, September 30, 2009).

classification, a classification list should acknowledge that products may be classified differently when data exists to support that new classification." In addition, if NIOSH develops classification lists, they should provide a clear explanation of the data used for each classification, provide an effective mechanism for stakeholder input that includes a formal federal register notice and public comment period, and develop a mechanism to quickly change classifications as new data become available.

Hazard classification of chemicals should reflect the following principles:

- Professional judgment is a key component;
- Classification decisions should be based on a weight-of-evidence approach;
- Route of exposure should be considered, especially when determining hazard labeling for chronic endpoints;
- Greater weight should be given to human data than animal data; and
- Transparency of how judgments are made is critically important.

II. Input on NIOSH Question 3

(3) Should 1 in 1,000 working lifetime risk (for persons occupationally exposed) be the target level for a recommended exposure limit (REL) for carcinogens or should lower targets be considered?

The approaches used by NIOSH to develop RELs for carcinogens should be fully aligned with the current practices of OSHA. As NIOSH notes on its website,[5] the 1 in 1,000 risk standard originated in the U.S. Supreme Court's Benzene decision and is the basis used by OSHA for carcinogen workplace exposure limits. The establishment of a new standard for workplace cancer risk, be it higher or lower, would require extensive policy and legal action that could prove difficult to implement.

It is equally important that NIOSH's overall analytic approach to setting RELs for particular substances be consistent with approaches used by OSHA and be reflective of court interpretations of the Occupational Safety and Health (OSH) Act of 1970, such as the Benzene decision, as well as rational, objective policy formulation. It is not useful to have RELs that cannot be used as guidance for OSHA under current legal and regulatory policy.

The science of risk assessment for carcinogens continues to advance and information is increasingly available to evaluate the potential for carcinogenic modes of action and appropriate dose-response models, including threshold models, for cancer. As the science of carcinogenic risk assessment improves beyond the use of default linear regression models, this should be reflected in the policy and practices of both NIOSH and OSHA.

III. Input on NIOSH Question 4

(4) In establishing NIOSH RELs, how should the phrase "to the extent feasible" (defined in the 1995 NIOSH Recommended Exposure Limit Policy) be interpreted and applied?

Feasibility is a specific consideration that was mandated by Congress in Section 6(b)(5) of the OSH Act[6] [feasibility phrases underlined for review]:

[5] http://www.cdc.gov/niosh/enews/enewsV8N12.html
[6] 29 USC Chapter 15, Section 655 (b)(5)

> (5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

NIOSH recognized this mandate in its 1995 guidance document[7] with its stated goal of adopting a "more inclusive policy" that develops RELs "based on risk evaluations using human or animal health effects data, and on an assessment of what levels can be feasibly achieved by engineering controls and measured by analytical techniques." ARASP fully supports NIOSH's efforts to evaluate technological feasibility and consider it in the development of RELs, both in terms of developing sampling and analytical techniques that can effectively measure exposure and control technologies that allow for exposure limits to be achieved. As feasibility is integral to the OSH Act, it is in the best interest of workers, employers, OSHA, and other parties to have exposure limit guidance that is both measurable and reasonably achievable. Neither employers nor OSHA are assisted if NIOSH develops RELs that cannot be accurately or reliably measured with existing sampling and analytical methods. As well, little benefit exists if NIOSH sets exposure limits that cannot be achieved with existing control technology.

Determining what is technologically feasible is often specific to a given substance or operation and therefore is something that will have to be determined on a case by case basis. Given that research is part of its mandate, NIOSH can serve an important role in conducting research on exposure measurement and control techniques and technology. Developing and publishing guidance on technological feasibility, along with exposure limits, maximizes the ability of both NIOSH and OSHA to provide more effective and achievable exposure controls.

IV. Input on NIOSH Question 5

> *(5) In the absence of data, what uncertainties or assumptions are appropriate for use in the development of RELs? What is the utility of a standard "action level" (i.e., an exposure limit set below the REL typically used to trigger risk management actions) and how should it be set? How should NIOSH address worker exposure to complex mixtures?*

A. Approaches to Setting RELs with Data Limitations

1. NIOSH Should Continue to Promote Hazard Banding

ARASP supports the use of scientific data for determining RELs whenever possible; however, ARASP recognizes that in some cases adequate information is not always available. NIOSH mentions in the August 23 notice that it has been considering "qualitative and semi-quantitative approaches such as hazard banding" to address substances for which inadequate information is available. Hazard banding as

[7] NIOSH 1995 REL Policy Statement. http://www.cdc.gov/niosh/topics/cancer/pdfs/1995_NIOSHRELpolicy.pdf

described below can be an effective tool for protecting workers from chemical substances that do not have established occupational exposure limits.

Briefly, hazard banding means grouping chemicals into discrete categories or bands based on the estimated severity of the hazards they present, as determined by an expert evaluation of the dose/response relationships derived from toxicological data. Each band is associated with an acceptable exposure level. Hazard banding is conventionally viewed as the first step in the process of control banding, where specific workplace controls or requirements are associated with each band. Hazard banding has independent value however, for example, it is also useful for determining the risk phrases or other hazard communications to associate with particular chemicals. Hazard and control banding need not – and should not – be coupled in a regulatory context. For example, regulators could specify a number of hazard bands and the hazard cutoffs between them, but leave employers with flexibility regarding the controls to be employed for each band. This flexibility is essential to enabling employers to tailor controls to their specific exposure scenarios rather than having to force-fit controls that may or may not address risk.

There are several well-established hazard banding schemes, perhaps the most prominent of which is the UK's Control of Substances Hazardous to Health (COSHH) regulation table.[8] Members of the American Industrial Hygiene Association (AIHA) Workplace Environmental Exposure Levels™ (WEEL) Committee have also developed a "WEEL Banding Matrix.[9]" Both of these employ 5 bands. A simpler, 4 band system could also be developed, keyed for example to safety datasheet labels such as "hazardous," "caution," "warning," and "dangerous." A NIOSH working group of hazard banding experts is currently integrating the WEEL Banding Matrix and the COSHH bands based on risk phrases with the Globally Harmonized System Health Phrases Hazard Banding Matrix.

Assigning a chemical to a hazard band should require less toxicology data for that chemical than setting a specific exposure limit. A hazard band may include data from a family of chemicals exhibiting a range of hazard endpoints that may span several health categories. Hazard banding allows a useful hazard assessment to be completed by combining all the data into a band even though there is insufficient data to set exposure limits for the individual chemicals.

Because there are multiple examples of hazard banding schemes but no obvious best practice, NIOSH could help to develop a single model hazard banding system that employers could follow voluntarily. Such a model system would promote consistency across the United States. At a minimum, NIOSH should publicize existing, authoritative hazard banding schemes by linking to them on the NIOSH website and referencing them in its educational and outreach efforts. Doing so would enable employers to easily locate hazard banding schemes for use in their workplaces.

2. NIOSH Should NOT Promote Mandatory Control Banding

A recent NIOSH review of the literature on control banding and efforts to validate the approach cited concerns about its effectiveness and potential to produce "potentially inappropriate workplace

[8] *See* http://www.coshh-essentials.org.uk/assets/live/CETB.pdf, Table 3.
[9] *See* Susan Ripple, "Setting Global Environmental Health and Safety Standards" (Dec. 10, 2008), slide 34, available at http://www.cihconline.com/conf08_presentations/Completed%20Presentations/26.1%20Susan%20Ripple%20-%20Dow%20Setting%20Global%20Standards.pdf

confidence" in it.[10] NIOSH concluded that "[a]dditional development, evaluation, and discussion are required before widespread implementation of control banding in the United States can be recommended.[11]" ARASP agrees that control banding can present substantial risks of under- or over-control and has not been sufficiently validated.

B. Exposure-based Action Levels Should be Justified on a Case-by-Case Basis

An action level "initiates certain required activities such as exposure monitoring and medical surveillance.[12]" This level has historically been half (50%) of the permissible exposure limit (PEL) and is intended to prompt action to minimize the potential for exposure above the PEL. NIOSH's December 1975 report "Exposure Measure Action Level and Occupational Environmental Variability" provides a thorough review of the history and background on action levels.

ARASP supports techniques to minimize exposure limit exceedances. However, there are a variety of approaches (e.g., real time monitors/alarms, periodic evaluations of exposure monitoring results, past experience with tasks/operations, etc.) that can be used to minimize exposure limit exceedances. Further, while action levels may have been very useful for new occupational exposure management programs to provide a basis for prompting action, as programs mature and gain greater experience they often develop techniques to better control exposures and maintain them below the PEL, REL or other exposure limits. Given this, it's not clear that setting a standard or default action level provides any better worker protection than other approaches.

Exposure limits are ultimately performance-based standards where employers must determine the appropriate approach to achieve the required standard. Professional judgment and experience by industrial hygienists, safety experts, facility operators, etc. in evaluating monitoring results and other information about workplace conditions and comparing these results to appropriate exposure limits is likely to provide as good, if not better, performance results than the use of action levels. NIOSH could potentially have a role in providing guidance for how operations can achieve compliance with exposure limits through the evaluation of monitoring results, operations, etc.

C. No Single Approach or Policy is Appropriate for All Complex Mixtures

There is no single solution to establishing suitable exposure limits for complex mixtures. Hazard characterization and risk assessment of different types of complex mixtures may require different approaches, and the usefulness of a certain approach depends on several factors, including the amount, type and quality of the available data on the chemistry and toxicity of the mixture and its components. Additional considerations, such as commerce operations and handling practices may also be appropriate to consider when setting exposure limits for complex mixtures. Safety evaluations of complex mixtures should bring together all the available relevant information. Procedures for chemical mixture health risk assessment and their limitations have been described by U.S. EPA and others.[13,14,15] There are several

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[10] NIOSH, Qualitative Risk Characterization and Management of Occupational Hazards: Control Banding (CB), A Literature Review and Critical Analysis (Aug. 2009), available at http://www.cdc.gov/niosh/docs/2009-152/pdfs/2009-152.pdf.

[11] *Id.* at vii.

[12] 29 CFR § 1910.1450 (b)

[13] U.S. EPA. 2000. Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures. EPA/630/R-00/002 August 2000

[14] Groten TP et al. 2001. Toxicology of Simple and Complex Mixtures. TRENDS in Pharmacological Sciences 22 (6): 316-322.

examples of occupational exposure limits for complex mixtures provided by the American Conference of Industrial Hygienists (ACGIH), in the Threshold Limit Values (TLV) Handbook, including the TLV for gasoline and Appendix H: Reciprocal Calculation Method for Certain Refined Hydrocarbon Solvent Vapor Mixtures. It is important to recognize in the evaluation of volatile and semi-volatile complex liquids (e.g. gasoline) that the vapor profile from the complex mixture/substance can often be very different from the liquid due to the greater volatility of the lighter components of mixture. The assessment of chemical mixtures is an area of active scientific investigation. NIOSH should rapidly integrate new information relevant to assessing health risks from exposure to chemical mixtures.

V. Summary

ARASP supports the efforts by NIOSH to update its policy for classifying carcinogens and its approach to setting RELs. NIOSH has an important role in providing leadership and guidance on issues of workplace exposure and cancer risk and therefore should strive to ensure that its policies and activities are fully aligned with OSHA in order to provide the greatest utility.

As we have emphasized in these comments, one means of improving coordination is through the adoption of a NIOSH carcinogen classification policy that utilizes the GHS scheme. GHS has already been implemented in the European Union (EU), Japan, and other countries and OSHA is in the process of implementing it in the U.S. under the Hazard Communication Standard. This system is becoming the common basis for hazard classification of substances, including cancer hazards, in workplaces around the world.

ARASP also agrees with NIOSH that greater consideration of technological feasibility in the development of RELs will greatly improve the usability of the RELs. NIOSH can play an important role in the research and development of exposure measurement and control technologies to support improvements in workplace exposure protection.

Thank you for the opportunity to provide these comments. Should you have any questions please contact me at 202-249-6707.

Respectfully,

Kimberly Wise Ph.D.
Senior Director
Chemical Products & Technology Division
American Chemistry Council

[15] Price PS and Han X. 2011. Maximum Cumulative Ration (MCR) as a Tool for Assessing the Value of Performing a Cumulative Risk Assessment. *Int. J. Environ. Res. Public Health 8*: 2212-2225.

December 29, 2009

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

Subject: Comments of the American Chemistry Council (ACC) on OSHA's Proposed Rule to Modify the Existing Hazard Communication Standard (HCS) to Conform with the United Nation's Globally Harmonized System of Classification and Labeling (GHS) - 29 CFR Parts 1910, 1915 and 1926 Hazard Communication Proposed Rule (74 Fed. Reg. 50280, Sep 30, 2009)

The American Chemistry Council (ACC)[1] is pleased to submit the following comments on the Occupational Safety and Health Administration's (OSHA) Notice of Proposed Rulemaking (NPRM) to modify the existing Hazard Communication Standard (HCS) to conform with the United Nation' Globally Harmonized System of Classification and Labeling of Chemicals (GHS). ACC and its member companies support efficient implementation of the GHS for workplace chemicals and appropriate modification of OSHA's HCS.

General Comments

GHS is often promoted as a means of trade facilitation potentially simplifying the opportunity to trade internationally. ACC has been an active participant in the development of GHS and has consistently supported implementation of the GHS. ACC firmly believes that the U.S. must be a leader in implementation of the GHS system, and that the U.S. government must take timely action to assure that, insofar as possible, the U.S. implements the GHS on a schedule roughly equivalent to that of other countries.

In ACC's view, many countries in many different regions are looking to the U.S. for leadership in GHS implementation, particularly given the experience of the U.S. in workplace hazard communication. U.S. leadership will help promote consistent implementation among our trading partners and will help U.S. interests realize the full benefits of a globally harmonized system. Additionally, one of the objectives of the Strategic Approach to International Chemicals Management (SAICM) is implementation of the GHS. OSHA is demonstrating its commitment and contributing to the U.S. government's meeting this objective through this NPRM.

[1] ACC represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $664 billion enterprise and a key element of the U.S. economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports.

Further, ACC strongly supports harmonized implementation of GHS among the NAFTA trading partners and, in particular, between Canada and the U.S. 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 protections. Therefore, ACC urges OSHA to work together with the Government of Canada to harmonize the U.S. OSHA HCS and Canada's Workplace Hazardous Material Information System (WHMIS) during implementation of GHS.

Importantly, GHS implementation in the U.S. should be synchronized, to the extent feasible, among all responsible agencies. OSHA should work closely with other governmental agencies (e.g., EPA. CPSC, DOT) that could be impacted by OSHA's implementation of GHS to facilitate consistent and synchronized implementation. Domestically, a coordinated effort on hazard communication activities in the U.S. would be practical.

ACC is also the secretariat for two American National Standards Institute (ANSI) hazard communication standards (the Z400.1 and Z129.1 standards). The ANSI Work Group is currently in the process of combining the two documents into a single standard. They plan to make future versions of the standard as compatible as possible with the GHS but will not be able to incorporate those changes until they know with some certainty what OSHA ultimately comes out with in its final rule to modify the HCS to conform to the GHS.

ACC believes that OSHA regulations designed to implement GHS in the context of the HCS regulations should reflect the following principles:

- Application of the "Building Block Approach" should take into account the specific needs of different user groups to assure and enhance understanding by the user.
- Maximum use of existing data without mandated test methods or additional mandatory tests.
- Professional judgment and human experience should continue to apply.
- Classification decisions should be based on a weight-of-evidence approach.
- Risk should be considered, especially when determining hazard labeling for chronic endpoints.
- Confidential Business Information must be protected.

ACC and its members hope that OSHA's final rule will continue to reflect these principles.

Additionally, OSHA can help minimize the burden on industry by adopting only those components of the GHS that match existing HCS provisions. ACC strongly supports OSHA's intent to maintain the scope, application, exemptions, and interpretations of the current HCS.

In addition to the general comments above, ACC has also provided detailed comments in response to the specific questions OSHA posed in the September 30, 2009 NPRM - see Attachment 1.

Conclusion

Thank you for your consideration of ACC's input to this important activity. We support OSHA's NPRM to modify the HazCom Standard to implement the GHS. ACC is committed to the process for harmonizing chemical hazard classification and labeling and the development of quality systems. Should you have any questions or need additional information regarding this letter, please feel free to contact me at 703-741-5606 or by e-mail at robert_kiefer@americanchemistry.com.

Sincerely,

Robert J. Kiefer

Robert J Kiefer
Director, Regulatory and Technical Affairs

Attachments (2)

Attachment 1
ACC Comments on OSHA GHS HazCom Standard NPRM

Executive Summary

- **Hazard Classification (Question 6)** - ACC agrees that Acute Toxicity Category 5, Skin Corrosion/Irritation Category 3 and Aspiration Hazard Category 2 should be excluded from the proposed rule. In addition,
  - *Germ Cell Mutagenicity (GCM)* – Some ACC members recommend that OSHA remove GCM from its definition of "health hazard";
  - *Sensitizers* – Technical guidance requested because proposed criteria not adequate to differentiate between potential and severe sensitizers;
  - *Aspiration Hazard* – ACC previously recommended that OSHA not adopt the aspiration hazard class because it is not considered a workplace hazard. In addition, some members have expressed concern over the appropriateness of the health hazard symbol;
  - *Cut-offs* – ACC urges OSHA to reconsider its proposed cut-offs (i.e., reproductive toxicity and respiratory/skin sensitizers) on the basis that they are not scientifically-based and likely to lead to over-labeling to extent that worker protection could be compromised.

- **Unclassified Hazards (Question 7)** – ACC agrees in principle with the approach of using "Hazards Not Otherwise Classified" (HNOCs) rather that the term "Unclassified Hazards" as long as definitions and criteria for inclusion in this category are clearly identified.
  - *Combustible dust* - ACC recommends that OSHA not include this material as an unclassified hazard because it is a processing issue (extrinsic, use-specific) and not an intrinsic product hazard.
  - *Other hazards* for which criteria should be developed and added include: pyrophoric gases, static accumulators, and release of gases that are health hazards.

- **Simple Asphyxiants (Question 8)** – ACC disagrees with the specific coverage for "simple asphyxiants" as currently proposed.

- **Floor of Chemicals (Question 9)** – ACC supports the OSHA proposal to remove the "floor" of chemicals and the one-study rule. ACC supports a weight-of-evidence approach.

- **Additional OSHA Guidance on Classification of Physical and Health Hazards (Question 10)** –
  - Two hazard statements (for skin/eye corrosives and reproductive/development hazards) are linked and need to be de-coupled.
  - ACC recommends that for serious eye/damage/irritation, the Category 2B criteria be included in Appendix A.

- **Concentration Limit for Chemical Mixtures Containing Target Organ Toxicity Hazards (Question 12)** – ACC requests that OSHA provide further clarification on the rationale for the 20% concentration limit.

- **Labels (Questions 13-16)**
  - *Pictogram Frames* - ACC supports the option to use the black pictogram frame on domestic packages;
  - *Precautionary Statements* – OSHA should require the presence of precautionary statements, but not mandate the text used.
  - *Updating Labels* – A minimum of six months to a year is needed to update labels based on new information.

- **Safety Data Sheets (SDSs) (Question 17)** – ACC supports OSHA's proposal to require permissible exposure limits (PELs) on SDSs and allow manufacturer discretion to include other occupational exposure limits (OELs), provided they are properly identified.

- **Other Standards Affected (Questions 19, 20, 24)** – ACC agrees with aligning/harmonizing other standards to GHS. We agree with OSHA's proposal not to change standards that incorporate consensus standards by reference (i.e., design criteria). If OSHA were to not codify this approach, the impact would be significant to many ACC companies.

- **Effective Dates (Questions 25-27)** – ACC strongly recommends that OSHA consider a five (5) year transition period to the new GHS requirements and consider a phase-in approach for substances and mixtures.

- **Classification Database (Question 29)** – Any database of chemical classifications should be for reference only and not mandatory.

- **Alternative Approaches (Question 30)** –
  - ACC does not support alternatives to the scope and application of the proposed rule as described in the preamble.
  - There needs to be resolution of an apparent dual regulatory conflict between OSHA's proposal under GHS and pesticide labeling requirements under EPA for SDSs.

- **Process for US Stakeholder Input into GHS Revisions at UNSCEGHS (Additional Comments)** – OSHA needs to develop a process to obtain U.S. stakeholder input into the development of U.S. positions for the UN GHS "Purple" Book

- **Unclassified Hazards (Additional Comments)** - The product identifier should be required for both classified and unclassified hazards.

- **Trade Secrets (Additional Comments)** –Trade secret provisions requiring disclosure of specific identification of a hazardous chemical should apply to the label as well as the SDS.

ACC Comments on OSHA GHS HazCom Standard NPRM

Need and Support for the Standard

1. *OSHA has made a preliminary determination that the proposed modifications to the HCS would increase the quality and consistency of information provided to employers and employees. Specifically, OSHA believes that standardized label elements would be more effective in communicating hazard information; standardized headings and a consistent order of information would improve the utility of SDSs; and training would support and enhance the effectiveness of the new label and SDS requirements. Is this assessment correct? OSHA requests information that reflects on the effectiveness of the proposed modifications to the HCS in protecting employees from chemical hazards in the workplace.*

Comment – In some ways, OSHA's assessment is correct. There have been comments for many years that standardized Safety Data Sheet (SDS) formatting would improve comprehensibility, ease of use, and training for SDSs - a conclusion by the National Advisory Committee on Occupational Safety & Health (NACOSH) HazCom Work Group. However, this logic applies less to labels because the volume of information on a label is much less than is contained in a SDS, and there is a greater need to customize the non-standardized GHS label elements to meet the needs of the target audience.

In the USA, total standardization should not be the goal. Along with effective hazard communication there must be flexibility/discretion to allow for liability and toxic tort considerations. This is one of many reasons that establishing an OSHA/USA process for discussion of United Nations Subcommittee of Experts on GHS (UNSCEGHS) issues and papers is critical.

The business of chemistry is a $664 billion enterprise and a key element of the U.S. economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. As a global trade association, ACC supports implementation of the GHS and what it means for consistency of hazard classification approaches.

Some companies see GHS implementation as a challenge especially with regard to training employees, but believe it will be beneficial in the long run. The global consistency of symbols may be beneficial for workers who do not read/understand English.

OSHA should align with revision 3 of the GHS. This includes taking advantage of the choice of building blocks and the selection among the options contained in the GHS. However, certain provisions of the OSHA proposal do not adhere to GHS, i.e., unclassified hazards. This would be exactly the "country-specific" additions that render compliance more difficult.

Economic Impacts and Economic Feasibility

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

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

   Comment: Implementation of GHS will have a major impact on company workloads and resources. Estimates from some companies run as high as 15,000 affected employees who will need to be trained and approximately 40,000 SDSs that will need to be updated based on GHS. Companies will also need to update their current SDS systems to reflect these changes.

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

   Comment – ACC member companies do not expect the OSHA proposed standard to have any major safety impacts. They expect a positive economic and time impact on developing and reviewing SDSs. The closer the proposed standard follows the UN model, the larger the benefit. Significant time and workload will be required to implement the proposed rule in the short term with the hope of long term harmonization and benefits. The addition of pictograms will be helpful. Increased standardization between suppliers will help in the workplace. ACC member companies believe that it will take more time to author SDSs with the GHS system.

   Benefits of GHS should be a goal; and alignment with GHS moves the U.S. towards this goal. GHS was meant to be implemented globally and OSHA needs to continue to take opportunities to ensure coordination of GHS implementation internationally and within the US agencies.

   As GHS is implemented into regulations around the world, industry is working to comply. A number of business advantages that will arise from the implementation of GHS have been put forward. While initial costs will likely be high to change to GHS from current systems, it is anticipated that there will be an overall cost reduction and decreased time to market because of the presumed need to classify a product only once

for the global market. As governments review existing regulations and adopt (or adapt) GHS into their own management schemes, there is an opportunity to make in-country regulations more consistent.

We believe that as we have international harmonization, we will see greater consistency of SDS globally because we are not creating SDSs to different standards and criteria (for example, an acute oral toxicity category 2 is the same globally vs. how this may be looked at with the current OSHA HazCom standard vs. the EU and set phrases.) There seems to be deviation in the proposed EU SDS subheadings and numbering and in the NPRM SDS subheadings and lettering that needs clarification.

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

Comment - Some global companies will have synergy because they have already implemented GHS in Asia and are moving forward with compliance in Europe due to REACH and the Classification, Labeling and Packaging (CLP) Regulation. Those companies that have only domestic or American business activity may not have done as much in the way of training. Even so, some domestic companies have conducted some familiarization training by working through the "Purple Book" but these companies are still a long way from being ready to implement a GHS program. Companies will need to reconfigure their systems to adapt to GHS and train their employees and contractors on how to use the system, beginning with development of new Standard Operating Procedures, training materials, and SDS and label templates to accommodate GHS.

The largest economic impact is re-labeling of finished goods, raw materials, and site-limited chemical intermediates; including the time and cost to translate the new labels into Spanish for the Hispanic user community in the U.S. An unknown impact will be the applicability/realignment of industrial codes, in particular, companies' Risk Management Program for Chemical Accidental Release Prevention/Process Safety Management of Highly Hazardous Chemicals (RMP/PSM) plans.

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

Comment – OSHA needs to identify who will be responsible for training/re-training all the civil agencies and emergency responders (i.e., fire & rescue companies, police, etc.)? What will be the collateral or unintended downstream impact on National Fire Protection Association and building codes?

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

Comment – OSHA needs to determine how this will impact NAFTA.

Effects on Small Entities

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

Comment - No comment.

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?*

Comment – ACC does not believe that alternatives should be created for small entities to convert to GHS. However, of note is the additional time and resources large companies will need to invest in training small contract manufacturers to ensure compliance with the standard.

Companies that have international business will be required to have GHS SDSs and will depend on suppliers to provide GHS information on their products that are incorporated into mixtures that they sell outside of the U.S. Without the supplier GHS information, companies which have international business would need to create this information themselves. This could be extremely difficult as they may only have the vendor SDS to which to refer. Without all companies in the supply chain participating in GHS, a chemical company's ability to export products could be hampered. A complete adoption of GHS is essential to be effective; otherwise the benefits of GHS are eliminated. Not implementing GHS completely would cause confusion and negate its main benefit.

Environmental Impacts

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

Comment – ACC agrees with the determination that the proposed standard will not have any adverse effects on the environment.

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.*

Comment – ACC agrees that Acute Toxicity Category 5 and Aspiration Hazard Category 2 should be excluded from the proposed rule. We also agree that Skin Corrosion/Irritation Category 3 should be excluded from the proposed rule to avoid needless over-classification of chemicals as irritants. Substances need to be classified first before this can be applied to mixtures. We support the current HCS criteria as sufficiently protective of worker health and safety and do not believe that additional NPRM building blocks are needed beyond the current scope of HCS.

Additional comments on hazard classifications:

Germ Cell Mutagenicity - With regard to GHS hazard classes that are not currently covered by the HCS, some of ACC's members recommend that OSHA should 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). 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, inclusion of a separate GCM endpoint would not provide additional protection.

In addition, implementation of the GCM hazard could result in confusion and inappropriate warnings, especially as regards to GCM category 2. It would place significant burdens on companies to understand the new classification criteria for this endpoint and to 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 or SDS.

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, some of ACC's members recommend that the GCM hazard class should not be adopted in the final rule.

Sensitizers - We understand and support the need to adequately warn users of substances if they are respiratory or skin sensitizers. The current proposal appears to build on the regulatory activities already in place in the EU. It goes further by introducing criteria that will be used to classify substances as either those that are presumed to have the potential to cause *significant* skin sensitization in humans, or those that are presumed to have the potential to cause sensitization in humans. It is certainly justifiable to differentiate between potential sensitizers and severe sensitizers based on their potency or other measurements of the severity of response observed in valid studies. What is not clear from this proposal is whether or not the proposed criteria are adequate to make such a distinction. It would be very helpful if a technical guidance document could be made available that gives examples of known human sensitizers and how they would be classified under this proposal compared to how their severity as sensitizers are currently perceived in the market place. One source of information for human skin sensitizers is the human data that was used to validate the Local Lymph Node Assay as an assay that would accurately predict the potential for a substance to be a human skin sensitizer. We are willing to support a dialogue with the agency to discuss this proposal further.

Aspiration Hazard - ACC in previous comments on the ANPR recommended that OSHA not adopt the aspiration hazard class under GHS, because aspiration hazard is not considered a workplace hazard. However, information should be allowed if a company chooses to label because of global marketing reasons.

If OSHA decides to include the aspiration hazard in the final rule, some ACC members have concerns regarding the appropriateness of the Health Hazard symbol because it does not correctly represent the severity of the hazard and could be potentially misleading; while other members feel it may not be appropriate to deviate from the UN GHS recommendations for symbols. Other hazards' endpoints in the Health Hazard category include carcinogens, respiratory sensitizers, reproductive toxicants, target organ toxicants, and mutagens. Most of the described conditions for the Health Hazard category are not representative of an aspiration incident which may present an urgent situation requiring first aid. With the exception of target organ toxicants, all of the conditions in the Health Hazard category and the injury that results are chronic conditions resulting from repeated exposures. As a result, the use of the Health Hazard symbol for the aspiration hazard end point is not appropriate or adequate to trigger requisite action as all other toxic endpoints are systemic, chronic conditions versus targeted and immediate situations requiring direct and instant intervention. Thus, the Health Hazard symbol may actually be misleading and misunderstood by the worker delaying appropriate first aid treatment during an aspiration episode. We believe that the hazard warning alone provides adequate warning if an appropriate symbol is not offered by GHS.

In contrast to the Health Hazard symbol, use of the Exclamation Mark hazard symbol and pictogram is a more appropriate hazard symbol for aspiration hazards. Specifically, the Exclamation Mark pictogram includes the hazard endpoints of: irritant, dermal sensitizer, acute toxicity (harmful), narcotic effects, and respiratory tract irritation. The hazard represented by aspiration of a liquid is associated with irritation of the lower respiratory tract and can produce a cough, difficulty breathing or anxiety, and in severe situations can lead to chemical pneumonitis. Such symptoms are more closely aligned with the hazard endpoints proposed for the Exclamation Mark pictogram and hazard statement. Moreover, the types of adverse effects categorized under this symbol call for more immediate countermeasure responses in the event of exposure. Accordingly, the Exclamation Mark symbol and hazard statement would be more appropriate for aspiration hazards while still maintaining the goal of the GHS. BIAC has urged the OECD to re-examine the aspiration hazard classification and pictogram because of these concerns. ACC's Hydrocarbon Solvents Panel expands on this position in separately filed comments. We ask that OSHA take these considerations into account when deciding whether to include the aspiration hazard class in the final rule.

Cut-Offs

Reproductive Hazards - The OSHA HCS has a 1% mixture cut-off value for all reproductive hazards and is currently considered protective. OSHA has not provided a scientific basis for proposing in the NPRM a 0.1% cut-off value/concentration limit for Reproductive Toxicity Category 1. The GHS provides a 0.3% cut-off value/concentration limit for Reproductive Toxicity Category 1 that is closer to the current scope of the HCS. ACC recommends that OSHA adopt 0.3% as the cut-off value/concentration limit for Reproductive Toxicity Category 1 or provide scientific justification for adopting the lower cut-off value/concentration limit.

GHS Reproductive Toxicity Category 2 criteria include substances for which there is not sufficient human or animal evidence for classification in Category 1. Since the GHS Reproductive Toxicity Category 2 criteria state that "*deficiencies in the study make the quality of evidence less convincing*", this category does not meet the HCS adequacy and reporting of data requirement. This makes Reproductive Toxicity Category 2 more protective than the HCS. The GHS provides a 3% cut-off value/concentration limit for Reproductive Toxicity Category 2. Since Reproductive Toxicity Category 2 goes beyond the scope of the HCS, OSHA should adopt the 3% cut-off value/concentration limit for Reproductive Toxicity Category 2.

Sensitizers - OSHA should require a SDS and/or supplemental labeling for mixtures containing a respiratory/skin sensitizing ingredient at concentrations between 0.1 and 1.0% (or between 0.1 and 0.2% for a gaseous respiratory sensitizer). When present in mixtures below the cut-off values/concentration limits, some sensitizers may elicit a response in already sensitized individuals. To protect these individuals the name of the ingredient should be provided as supplemental label information even if the mixture as a whole is not classified as sensitizer.

ACC supports the following mixture cut-off values/concentration limits:

- For Category 1 respiratory/skin sensitizers the mixture cut-off value/concentration limit should be ≥1% (or ≥0.2% for gaseous respiratory sensitizers).
- For Categories 1A respiratory/skin sensitizers the mixture cut-off value/concentration limit should be 0.1%.
- For Category 1B respiratory/skin sensitizers the mixture cut-off value/concentration limit should be ≥1% (or ≥0.2% for gaseous respiratory sensitizers).

General – OSHA should adhere to the 3rd revised GHS edition and apply the "Purple Book" guidance for mixtures cut-off values/recommendations, which states:

> *1.3.3.2.1 When classifying an untested mixture based on the hazards of its ingredients, generic cut-off values or concentration limits for the classified ingredients of the mixture are used for several hazard classes in the GHS. While the adopted cut-off values/concentration limits adequately identify the hazard for most mixtures, there may be some that contain hazardous ingredients at lower concentrations than the harmonized cut-off value/concentration limit that still pose an identifiable hazard. There may also be cases where the harmonized cut-off value/concentration limit is considerably lower than could be expected on the basis of an established non-hazardous level for an ingredient.*
>
> *1.3.3.2.3 On occasion, conclusive data may show that the hazard of an ingredient will not be evident when present at a level above the generic GHS cut-off values/concentration limit(s). In these cases the mixture could be classified according to those data. The data should exclude the possibility that the ingredient would behave in the mixture in a manner that would increase the hazard over that of the pure substance. Furthermore, the mixture should not contain ingredients that would affect that determination.*

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. a) Will this approach provide sufficient interim coverage for hazards such as combustible dust? b) 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.*

Comment – ACC agrees in principle with this approach to provide sufficient interim coverage for unclassified hazards until criteria can be established by the GHS. This proposal is consistent with procedures already in use by some companies to cover known hazards that are conveyed on OSHA-compliant SDSs, but would not fit into an existing GHS hazard category. We suggest that OSHA use the phrase "Hazards Not Otherwise Classified (HNOC)" rather than the more ambiguous "Unclassified Hazards". The use of a "catch all" section for HNOCs should not present undue problems so long as the definitions and criteria for inclusion in this category are clearly established.

Regarding combustible dust, ACC recommends that OSHA not include this material as an unclassified hazard since chemicals in dust form are not inherently hazardous (it is an

extrinsic, use-specific property) and most products are not shipped in dust form. This is a processing issue and not a product hazard. If a chemical is shipped in a dust form, the SDS should state whether the material as shipped has the potential to explode under certain conditions. The product should not be classified as hazardous under OSHA or require a label. Because the conditions under which a customer may use the product are varied and cannot be predicted by the manufacturer, no additional information can be provided on the SDS. The physical form, as shipped, is most important with regard to SDS statements as almost any carbon-containing or metal-containing solid could be combustible dusts if processed to small enough particle size.

Other hazards for which criteria should be developed and added to the GHS include: Pyrophoric gases; Static accumulators (see CSB comments to ACC); and release of gases that are health hazards. OSHA currently has a pyrophoric hazard that applies to all three states. Under GHS there are only classes for pyrophoric solids and liquids. Therefore, a pyrophoric gas would not be labeled or classified appropriately.

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. They are also already covered under the existing HCS. Is the definition suggested by OSHA sufficient to cover this effect? Do you have suggestions for modifying this definition? Are the label elements suggested appropriate?

Comment – ACC disagrees with the specific coverage for "simple asphyxiants" as currently proposed. Providing specific coverage for simple asphyxiants is not so simple. Literally any gaseous substance can displace oxygen and when used in a confined space or enclosed area, it will pose an asphyxiation risk and would have to be labeled under this proposed definition. The intent is not to overwarn, but to put it in context and place a limit on the conditions that pose the greatest hazard. ACC would encourage that the logic be more along the lines of usage warning for all gaseous materials (i.e., "may displace oxygen in breathing air and lead

to suffocation and death in confined or enclosed spaces"). If the "simple asphyxiants" hazard is used it should be required, as applicable, for Class 2 Division 2.2 (non-flammable, no-toxic gases) per the GHS section A4.3.2.3 - Other hazards which do not result in classification. In addition, data from a confined space entry test should demonstrate whether oxygen deprivation can occur before labeling for this hazard.

If OSHA proceeds with adoption of this hazard, we recommend the following label elements: that it contains a signal word, no symbol and a precautionary statement. We disagree with the hazard statement "May be harmful if inhaled" which is the H phrase for acute toxicity inhalation category 5 and does not necessarily imply asphyxiation. Using this statement is misleading since the substance itself is not harmful if inhaled; it is the displacement of oxygen in the ambient atmosphere. Harmful if inhaled is typically used for toxic inhalation hazards. A statement like "May be harmful in enclosed spaces", "Asphyxiation hazard", "Suffocation hazard" or "May cause suffocation" should be used so that there is no confusion about the acute toxicity.

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

Comment - ACC supports the OSHA proposal to remove the "floor" of chemicals and the one-study rule. ACC supports 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, ACC supports OSHA's proposal to remove the one-study rule. In addition, a floor list of chemicals would deter companies from accurate self classification and not identify the proper hazards associated with the product. Companies would tend to gravitate toward using the list of floor chemicals only and nothing more. The proposed GHS criteria are sufficient and should provide a consistent classification scheme, across all companies, by use of toxicity criteria.

For example, the same underlying data used by IARC, OSHA or NTP to classify individual chemicals as carcinogenic would be examined as part of the GHS classification process. Further, Appendix F to the GHS provides additional guidance on cancer classification; this

has been excerpted from IARC Monographs programme on the evaluation of the strength and evidence of carcinogenic risks to humans (Proposed Appendix A, footnote at Pg. A-39). However, additional guidance on how to ensure consistent interpretations and therefore harmonization would be helpful (e.g., authoritative body conclusions along with a company's self evaluation based on any additional information/data).

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

Comment - The EU's extensive CLP guidance has been published. OSHA's GHS interpretations of this guidance would be helpful. For example, two of the hazard statements are linked and need to be separated out.

For example, skin corrosives are not eye corrosives if there is test data to so indicate. In such cases, the phrase "*and eye damage*" should be omitted from the hazard statement "*Causes severe skin burns and eye damage*". Depending on the GHS skin/eye chapter revisions, more clarification could be helpful.

Another example is for reproductive hazards; the dual reproductive/development hazard statements should only be required when both effects are present:

- *May damage fertility or the unborn child (state specific effect if known)*
- *Suspected of damaging fertility or the unborn child (state specific effect if known)*

In ACC's supplemental comments to OSHA on the ANPR, for serious eye/damage/irritation, we recommended that the Agency adopt categories 1, 2A and 2B. Appendix A includes 2A but there is no reference to the 7-day or 2B listed. Appendix C includes the HazCom elements for both 2A and 2B. ACC would like for the 2B criteria to be included to prevent overwarning of this hazard. Clarification is requested.

A layman translation of Appendix F in regards to IARC carcinogens could be helpful, especially for small businesses.

OSHA needs to indicate very clearly 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 I of the GHS Purple Book (Section 1.3.3.2) – OSHA needs to implement accordingly. The percentage cutoffs where labeling becomes required are not provided for some categories.

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.

Comment - The GHS transport hazard criteria for self-reactive chemicals, organic peroxides, self-heating chemicals, and explosives are more suitable to packaged goods.

The storage and warehousing of hazardous material represents one of the major risk exposures to employees. Leveraging the hazard classification based on packaging type and quantity would seem to remain a consistent practice. ACC believes that the packaging quantity criteria for these chemicals are useful in the workplace as well as for transportation purposes. These criteria provide fundamental and sufficient qualitative information about their hazards. Providing additional information, such as that of a quantitative nature, is unnecessary and could mislead the user.

The Flammable gas category is consistent with GHS; however, this change may create a data need.

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.*

Comment – ACC requests that OSHA provide further clarification on the origins and rationale for the 20% concentration limit, since it does not appear to be well grounded in science.

Respiratory tract irritation and narcotic effects are to be evaluated separately in accordance with the criteria given in A.8.2.2. When conducting classifications for these hazards, the contribution of each ingredient should be considered additive, unless there is evidence that the effects are not additive.

The Federal Register text at A.8.3.4.5 states this 20% cutoff applies to mixtures containing *Category 3* target organ toxicants (*emphasis added*), and permits expert judgment. OSHA needs to clarify this question.

Revision 3 of the GHS does not mandate this limit. When determining appropriate cut-off values/concentration limits in mixtures, OSHA should apply the guidance from the GHS "Purple Book", which states:

> *1.3.3.2.1 When classifying an untested mixture based on the hazards of its ingredients, generic cut-off values or concentration limits for the classified ingredients of the mixture are used for several hazard classes in the GHS. While the adopted cut-off values/concentration*

limits adequately identify the hazard for most mixtures, there may be some that contain hazardous ingredients at lower concentrations than the harmonized cut-off value/concentration limit that still pose an identifiable hazard. There may also be cases where the harmonized cut-off value/concentration limit is considerably lower than could be expected on the basis of an established non-hazardous level for an ingredient.

1.3.3.2.3 On occasion, conclusive data may show that the hazard of an ingredient will not be evident when present at a level above the generic GHS cut-off values/concentration limit(s). In these cases the mixture could be classified according to those data. The data should exclude the possibility that the ingredient would behave in the mixture in a manner that would increase the hazard over that of the pure substance. Furthermore, the mixture should not contain ingredients that would affect that determination.

Labels

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

Comment – ACC supports OSHA's acceptance of the flexibility in GHS to use either black or red pictogram frames on packages shipped domestically. Several countries are allowing the black GHS pictogram frame domestically such as Japan, China, Korea and Singapore. OSHA should allow the black GHS pictogram frame domestically thereby saving printing costs (e.g., there is added cost to purchase new color label printers) and placing fewer burdens on small companies that might only have domestic business.

As most industry shipping labels are printed using durable thermal labels, the red diamond outline for pictograms will be pre-printed on label stock. For some products, not all of the diamonds will be required for pictograms. We suggest OSHA allow (or require) printing the word "BLANK" on the unused diamonds to eliminate any confusion. Other coverage options could include: 1) leaving the pictogram blank; 2) blacking it out or printing over it; or 3) printing the words "pictogram intentionally left blank" inside of the unused diamond.

14. *In addition to the pictograms, signal word and hazard statements, GHS labels must include precautionary statements. OSHA is proposing to require the text in the precautionary statements in the GHS to be on HCS labels. As discussed in Section XV Summary and Explanation of the Proposed Standard, these statements are codified under the GHS, meaning that numbers have been assigned to them. In addition, the appropriate statements to use for each hazard class and category have been indicated in the GHS annexes. This means that label preparers will know exactly what precautionary statements to apply once they complete their hazard classification, and chemical users will see consistent language on labels to indicate the necessary precautionary measures. However, the statements are not yet considered to be part of the harmonized text like hazard statements are; rather they are included in the GHS as suggested language. OSHA expects that other countries may adopt the codified precautionary statements when they put GHS in place. For example the EU has required*

that labels use the GHS codified precautionary statement text in adapting the GHS. Since OSHA did not previously require the use of precautionary statements, and had no such recommended statements to provide, the Agency is proposing to use those currently in the GHS as the mandatory requirements with the option of consolidating statements where appropriate (See Appendix C). OSHA anticipates this approach will provide the maximum benefit. OSHA is also seeking comment on whether any of these statements should be modified or if other precautionary statements should be included.

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

Comment - With GHS implementation, the approach to precautionary statements varies among countries. Some countries are only requiring a limited number of the precautionary statements (EU) or prioritized precautionary statements. In other countries, precautionary statements are required but their text is not mandated. The GHS precautionary statements are still under discussion at the UNSCEGHS and have not been negotiated as standardized language, but only as guidance.

ACC supports flexibility in the text used in the GHS precautionary statements. It is reasonable and consistent with the GHS to require the presence of precautionary statements, but not mandate their specific verbiage. We believe that flexibility in this area will help the end user understand the safe use and handling of the product, because the manufacturer knows the hazards associated with their products. OSHA should allow label preparers to develop their own precautionary statements.

The GHS first aid statements are not the typical statements found on US labels. Manufacturers should be allowed flexibility to change these statements at their discretion. Because there is some liability associated with first aid statements as well as other precautionary statements, OSHA should not be mandating the first aid statements or the 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? Describe any requested changes and explain why such revisions are necessary.*

Comment – No comment.

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.

Comment - In implementing the EU CLP Regulation, the EU has established a 2-year on the shelf grace period for labels. It is our understanding that US DOT typically allows 1 to 2 years for packaging changes. Three months seems too short for US GHS label changes.

Three months is too aggressive to get new labels designed, translated, approved and printed. A minimum of six months to a year is needed as a more appropriate time interval to update labels based on new information. The timing for re-labeling can be separated from the 90-day requirement to update SDSs with new information.

Pre-printed labels are the driving force. A three month update for labels is somewhat unrealistic especially for manufacturers that have pre-printed containers. In this case it is not just an exercise of discarding the old labels and ordering new ones, but (with pre-printed containers) there are lead times to get new containers ordered (at minimum quantities) and the dies created that are needed to create the label on the container. Six months to a year is a more realistic timeframe to coordinate and properly manage these changes.

Additionally, some members' product lines have wide variability in their sell-through time. Many products in one business move quickly from the site to the customers, due to shelf-life and the production scheduling model used. Having new labels on the outside package could occur within three months. Some products have third-party printed labels on the inner package that may have a stock timeframe longer than 3 months, due to printing cycle agreements and the time required to get new labels designed, printed, and approved. Some product lines are packed in returnable cylinders for which their fleets are managed globally. These cylinders likely are cycled back to the company sites within a year, but not on a regular schedule. And finally some products are packaged in pre-printed bags. These products are certified for quality for a year, but don't have information on how long the non-US plant stocks the material before sending it out. These products are currently non-hazardous, but in the event that would change, we believe the sell-through for the pre-printed bags would exceed three months.

Safety Data Sheets (SDSs)

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

Comment – ACC supports OSHA's proposal to require PELs on SDSs and allow manufacturer discretion to include other occupational exposure limits (OELs), provided that the other limits are properly identified. This approach maximizes the flexibility for the preparers of SDS.

ACC does not object to requiring the PELs, however for multi-national companies, we are asking for clarification on this provision. It states, in addition to the OSHA PEL, that companies can (must) include any other exposure limits used or recommended by the manufacturer. Since many companies do use or recommend other country-specific OELs in the generation of SDSs for those countries, are they also expected to include these OEL values in their US SDS? This provision should be more specific to state that inclusion of the OSHA PELs is required and that the manufacturer, may include any other (or no other) properly identified OELs that it wishes.

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

Comment - Section 15 should remain non-mandatory. The inclusion of Section 15 is necessary to remain consistent with the standard 16-section format for SDSs. However, manufacturers should be allowed flexibility in the type of information provided in this section to sufficiently explain the regulatory consideration for the SDS substance.

Clarification is needed as to what "substance specific standards" means or includes. If substance specific standards means "OSHA substance specific standard," we agree that information should be referenced in section 15. We believe it would be helpful to employees and downstream customers to be aware of substance specific standards that a product /chemical is subject to and could increase awareness and compliance with these standards.

Other Standards Affected

19. *OSHA is proposing to align the definitions of the physical hazards to the requirements of the GHS categories in safety standards for general industry, construction, and maritime standards, which either directly reference the HCS or provide information pertinent to the Safety Data Sheets (SDSs). In most cases OSHA has modified the standards to maintain scope and protection. However, the changes in definitions for flammable liquids Category 1 and 2 and flammable aerosols appear to be more than simply rounding to the nearest significant number.*

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

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

OSHA's decision to change these definitions to be consistent with the GHS is based not only upon harmonizing its standards with those of other countries that have adopted or may adopt the GHS, but OSHA is also concerned with making its standards internally consistent. OSHA believes the methods used to classify these physical hazards are similar enough so that substances that are currently

regulated by OSHA would continue to be regulated and that few, if any, changes would result in a shift in regulatory coverage. Would the proposed changes have any impact on your operations? If so, describe the anticipated effects.

Comment - We agree with aligning/harmonizing other standards to GHS. GHS combines what had previously been Flammable Class IC and Combustible Class II into the single Flammable Category 3. There are many regulations, including those that refer to consensus standards that specifically refer to Class I materials. It appears that OHSA is not proposing to change standards that incorporate consensus standards by reference, such as those used for internal design criteria only and which do not reference HCS for applicable scope or incorporation into SDS, (e.g., Subpart S-Electrical in CFR 1910 [General industry], Subpart K -Electrical in CFR 1926 and CFR 1910.106 [Flammable and Combustible Liquids]). We agree with this approach and therefore would expect that there would be no impact on Electrical Area Classification, 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, etc.

If OSHA were not to codify this approach, the impact would be significant to many ACC companies that operate facilities handling flammable and combustible liquids in the US. For example, adopting 140° F as the definition of a flammable liquid would create unintended consequences. 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 would fundamentally change this OSHA definition, which is a long-established and effective risk management practice with regard to the design and operation of flammable liquid systems.

Again, under an approach opposite to that which OSHA is adopting, changes to the definition of flammable liquids would cause significant costly and unwarranted changes to facility design and operation, such as those listed above that pertain to CFR 1910.106.

We believe, however, that OSHA should clarify in its final rule that this proposed change also will not affect the International Building Code and the International Fire Code such that users will not be unduly required to upgrade buildings to conform to requirements for Hazardous Occupancies. The Maximum Allowable Quantities of flammable and combustible materials in buildings, which can change the building to a Hazardous Occupancy, distinguish between Class IC and Class II material quantities. Combining Class IC with Class II removes this distinction and could impose significant costs on users, particularly small users, of Class II materials if forced to upgrade to a Hazardous Occupancy status.

Concerning the proposed reduction in the boiling point cutoff for Category 1 and 2 flammable liquids, we believe that OSHA's proposed regulatory language for CFR 1910.119 - Process Safety Management, appropriately reflects this new cutoff without changing the scope of the regulation. In addition, we understand that the lowering of the boiling point cut-offs by 2.8 °C by OSHA will result in all current handling and storage facilities being in

compliance, and that storage and handling of chemicals with boiling points between 37.8 °C and 35 °C would be allowed to be stored according to the lesser flammability Category 2. We agree with this approach.

20. *OSHA is proposing to eliminate the term "combustible liquid" in 29 CFR 1910.106. 1910.107, 1910.123, 1910.124, 1910.125, and 1926.155 for liquids with a flashpoint above 100°F. To reflect consistency with the revised HCS where appropriate, OSHA is proposing to add the specific flashpoint criteria. This will maintain equivalent protection. Are there other standards that OSHA should update with the new terminology?*

Comment – Modifying the OSHA standards to conform to GHS will deviate from the national consensus standards they were based on. For example, the definitions in 29 CFR 1910.106 are largely based on National Fire Protection Association (NFPA) 30.

OSHA did not include reference to CFR 1910.120 (HAZWOPER) Process Safety Management standards as being affected by change in the definition of flammable liquid. We would encourage evaluation of OSHA 1910.120 (HAZWOPER) be included in the combustible liquid terminology change, and for OSHA to clarify in the final rule if and how this standard may be affected by the new definition.

OSHA has proposed in the NPRM to eliminate the combustible liquid designation from several of its standards. The only standard that impacts companies is 29 CFR 1910.106 (Flammable and combustible liquids). The other standards impact relate to spraying and dipping operations that use flammable liquids. In OSHA's proposal to align the Hazard Communication Standard with GHS, the elimination of the term 'combustible liquid' in 1910.107 does not significantly change the requirements of the standards and should not adversely affect industry's ability to comply with the standard.

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?*

Comment – ACC supports consistency of language on labels and signs. Yes, the proposed wording appears to be better. Inclusion of the chemical name is helpful. Employee training is needed to improve comprehension and interpretation of the new format.

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.

a) *How would the removal of required language for labels from substance-specific standards affect your work place?*

b) *Are there hazard warnings that will be lost that do not have an equivalent hazard or precautionary statement?*

c) *Are there alternatives to OSHA's approach for the substance-specific standards that will assure information is disseminated in a manner that is consistent with the modified HCS labeling requirements?*

Comment - Some companies rely on the training of employees and use of SDS for broadform communication of chemicals hazards of materials, with less reliance on the labels. We do not see where the proposed changes to the labels would present much "end user" problems.

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

Comment - These are not primary sources – only secondary resources. ACC seeks clarification from OSHA on this item. This provision seems arbitrary and dated. ACC needs to better understand the purpose and impact on how this data is to be used. 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. What happens if the new HCS is in conflict with existing Substance-Specific Standards? Is this driving OSHA's proposal here?

What about the impact resulting from the EU Classification Labeling and Packaging (CLP) regulation? Substances must be classified and labeled according to the CLP criteria by December 1, 2010. Further, EU-level harmonized classifications may be available before OSHA finalizes its rule. Scientific data on the specific substance should be the primary source of information to classify chemicals.

24. *As detailed in the Summary and Explanation section of this document, OSHA is not proposing in this rulemaking to update the electrical standards (general industry 1910 subpart S and construction 1926 subpart K) or Explosives and blasting agents (general industry 1910.109 and construction 1926.914). These subparts are "self-contained" in that they do not rely on other OSHA standards for regulatory scope or definitions, but reference external organizations (such as the National Fire Protection Association [NFPA]). OSHA believes that these standards could be updated when the*

referenced external organizations adopt applicable GHS elements. If OSHA were to change these standards to comply with the GHS, how would this impact your operations?

Comment – See information provided in question #19. We are not sure if this solves the fire code/standard issue. Are there applicable codes/standards that use the qualitative terms "flammable" and "combustible" without referring to numerical flashpoints and boiling points? Overall, we'd like all these organizations to align; when/how they do this is unclear.

Should OSHA decide to change subpart S, the most significant potential impact would be on electrical area classification (delineation of which areas are subject to the use of ignition resistant wiring methods). Depending on the final determination of the definition of flammable hazard classification and its impact on the evaluation procedures, this could create significant work for chemical manufacturers.

Effective Dates

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

Comment - ACC supports a minimum of 2 years for training implementation if there is a 3-year implementation period for classification, SDSs, and labeling. The training implementation period could be longer if there is a 5-year implementation period. The timing requirements for training should be aligned with the timing requirements for classification, SDSs, and labeling. The proposed time is appropriate. This would be greatly simplified if OSHA could provide a standardized computer based training module to deliver the consistent "general" information, with a small space for any company specific provisions.

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.*

    a) *Does this allow adequate time to review hazard classifications and amend them as necessary, and to revise labels and safety data sheets to reflect the new requirements?*

    b) *Would a shorter time frame be sufficient?*

Comment – ACC strongly recommends that OSHA consider a five (5) year transition period to the new GHS requirements and consider a phase-in approach for substances and mixtures. We support a step-wise transition period after the effective date of a final regulation for the various stages in the supply chain so that downstream users of substances and industrial mixtures can utilize the hazard classification decisions and information developed by their upstream chemical suppliers. A minimum of 3 years will be needed for chemical manufacturers to comply with the provisions of the final rule. A period of at least an additional 24 months after the compliance deadline for chemical manufacturers will be

needed for formulators of workplace end use products to obtain the GHS classification and other information about the component materials that they purchase from their upstream suppliers in order to classify their formulated products.

Many countries adopting GHS (i.e., Japan, EU, etc.) have made the distinction and have mandated separate phase-in periods for both substances and mixtures.

A three year implementation for substances and mixtures is inadequate. Based on the fact that a hazard evaluation is dependent on assessment of the substances in mixtures, it is necessary to have a phased-in approach. Formulators need to have all substances evaluated prior to completing a review of their mixture. If a supplier waits until the end of the three year implementation period, then the formulator is at a standstill to do the mixture review. With current resources it could take companies about 5 years for all SDSs and labels to be updated, and for SDS systems to be re-configured.

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

Comment – ACC needs clarification on whether there will be any grandfathering for chemicals that are 'in-process' for more than three years - e.g., gas cylinders that are in use. Or will OSHA require re-labeling while chemicals are in use? Additionally, will there be a grace period for relabeling "on the shelf" items or products downstream in the supply chain? Non-bulk containers of original contents that are OHSA hazardous that were properly labeled in accordance with the Hazard Communication Standard in effect at the time the container entered the workplace, including all appropriate transition provisions, should be allowed to remain in the workplace without requiring the employer to re-label for GHS compliance.

It would be helpful if substances were phased in first as the further classifications for mixtures can be based on the substances. With current resources it could take about 5 years for all SDSs and labels to be updated. SDS systems will need to be re-configured

OSHA side-by-side comparison (from OSHA website) states under (j) effective dates:
(3) "Chemical manufacturers, importers distributors and employers may comply with either 29 CFR 1910.1200 revised as of *October 1, 2009* (*emphasis added*), or the modified version of this standard or both during the 3-year transition period." Italics are probably just an inadvertent error in the side-by-side. OSHA needs to clarify -- can companies comply with the existing HCS (prior to Oct. 1 2009) during transition?

Compliance Assistance and Outreach

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

interest (e.g., classification criteria, labels, safety data sheets), and the best means of distributing these materials.

Comment – The biggest assistance in compliance would be for OSHA to have an on-line training system that allowed employers to direct employees to take a standardized training program on GHS, with records being available for employers to download into their learning records systems. We would propose a computer education method similar to what Department of Homeland Security has done for National Incident Management System (NIMS) training for fire service, law enforcement, and emergency management personnel.

Additional 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 in Japanese; guidance like the EU CLP; and classification and mixture examples on the web. A quick reference guide and OSHA workshops and webinars would be helpful.

ACC supports the concept of sector-specific guidance to promote consistency in the application of GHS to sectors where guidance is needed. There can be subtle issues associated with the application of the GHS to specific materials. Industry can assist in fostering global harmonization by developing sector-specific guidance on GHS applications.

29. *OSHA received a number of comments that suggested that a data base of chemical classifications should be developed and maintained to assist chemical manufacturers and importers in performing hazard classifications. This approach has been adopted in some other countries.*

    a) Would such a data base be helpful?

    b) Who would be responsible for doing the classifications and maintaining them?

    c) How would the data base be kept aligned with other countries' classifications?

Comment – Any database that OSHA creates should be non-mandatory and focused on providing guidance only. ACC has developed a position paper (see Attachment 2) on Maintaining GHS Principles and Objectives in Global Implementation for Regional GHS Classification Lists. Government classifications lists should be for reference only, not mandatory, and include an update mechanism, stakeholder input, and global accessibility. ACC's position is that lists are for guidance purposes but classification decisions for a substance or mixture should be made by the producer (i.e., self-classification) based on available information and in adherence with all the principles outlined in the GHS.

Alternative Approaches

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

Comment – ACC does not support alternatives to the scope and application of the proposed rule as described in the preamble. None of these approaches would improve hazard communication and comprehensibility as much as OSHA's proposal. These approaches do not support the GHS concept of harmonization. ACC supports OSHA's adoption of revision 3 of GHS. We support the Building Block Approach which does call for "adopting some components of GHS but not others."

Allowing customers to not adopt the GHS approach voluntarily will cause confusion and misconception in the workplace. For a particular product, where a hazard becomes escalated under the GHS classification criteria, it may put a company at a commercial disadvantage if they adopt GHS but another company doesn't. By allowing voluntary adoption, this defeats the purpose of standardization and harmonization of hazard communication. The intent of GHS is to promote consistency. Instead, this option would promote inconsistency.

FIFRA Pesticide SDS – Implementation of GHS within the U.S. should be coordinated among all agencies with jurisdiction. While acknowledging that pesticides products are excluded from labeling requirements under 29 CFR 1910.1200(b)(5)(1), OSHA maintains that SDS for pesticide products must be consistent with GHS provisions under the proposed changes (NPRM, pg. 50399). Pesticide products are regulated by the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), and EPA considers SDSs to be pesticide labeling (see EPA PR Notice 92-4 and EPA Pesticide Labeling Questions & Answers website response to Question 12 at www.epa.gov/pesticides/regulating/labels/label_review_faq.htm). Registrants whose SDS conflict with the FIFRA-required labeling could be subject to EPA enforcement action. OSHA's proposal to require pesticide SDSs to be consistent with GHS therefore creates a serious inconsistency between the two federal Agencies.

OSHA and EPA must cooperate in an effort to alleviate this dual regulatory jurisdictional dilemma and to assure pesticide registrants are provided a path that enables them to be compliant with all applicable regulations of both programs. EPA's view that, under FIFRA, SDSs constitute part of the pesticide labeling, and should be deferred to by OSHA. For pesticides, OSHA therefore should make clear that all "labeling" of pesticides is governed by FIFRA, including SDSs. SDSs will still be available, but in a form that is consistent with the label approved by EPA. This has the additional advantage of avoiding the potential for worker confusion. When EPA adopts GHS for pesticides, pesticide SDSs should be updated as well. ACC's Biocides Panel expands on this position in separately filed comments.

ADDITIONAL COMMENTS

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

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.

OSHA notes in the above preamble text that the GHS is a living document and that there are US mechanisms available to update OSHA's Hazard Communication Standard in the future. However, this approach doesn't allow any US stakeholder input into the negotiations and discussion while the GHS technical decisions are being made at the UNSCEGHS. All this approach allows is an after-the-fact decision on whether to update the US GHS to be compatible with the global GHS. It does not allow notice and comment on the technical issues.

US stakeholder input into the discussions and technical issues at the UNSCEGHS and into decisions taken by the US representatives/delegation is needed. Comments at an early stage are more effective in shaping issues/decisions than after-the-fact comments. The absence of a mechanism for US stakeholders to give comments on the UNSCEGHS papers bypasses the US notice and comment process as required by the Administrative Procedures Act (APA) in favor of international negotiations/rulemaking.

The US DOT recognized this as a concern many years ago for US transportation stakeholders with regard to the *UN Recommendations on the Transport of Dangerous Goods - Model Regulations*. US DOT routinely solicits public comments on positions for the UNSCETDG papers and on the outcome of the UNSCETDG meetings through DOT public meetings and outreach activities. This ensures that US stakeholder interests are communicated and considered in the development of international standards.

OSHA needs to develop a similar process to obtain US stakeholder input into the development of US positions for the GHS Purple Book during the UNSCEGHS discussion stage. Issuing SIPS or DFR after the revisions to the GHS Purple Book have been finalized bypasses the intent of the US notice and comment process.

NPRM Clarifications

There are several additional issues in the NPRM where clarification could be helpful:

Definitions

- The definition of "health hazard" 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. For consistency, the "health hazard" definition should cite the three routes of exposure for which there are classification criteria.

- The definitions for "label elements" and "pictogram" are not verbatim from the GHS.

- In the definition of "product identifier", OSHA refers to a "required list of hazardous chemicals". It is not clear in this definition to what list they are referring, though we suspect it is the list of all hazardous chemicals maintained on site, mentioned in section (e)(1)(i). OSHA should include a reference to section (e)(1)(i) in the definition so it is clear what list they mean.

Appendix A

- Table A.1.2 correction – In the November 5, 2009 *Federal Register* correction for the NPRM aligning Table A.1.2 to the 3rd edition of GHS Table 3.1.2, there is an error in the dust/mist exposure route (values for vapour and not dust/mist were used) which needs to be corrected in both Table A.1.2 and GHS Table 3.1.2

- In Appendix A, paragraph A.0.5.1.1(a), the proposal says "the new diluted mixture SHALL BE classified as equivalent to the original tested mixture" [emphasis added]. The GHS for this same topic says "the new mixture MAY BE classified as equivalent to the original mixture" [emphasis added]. This is one minor wording change that could have an impact on how the GHS is implemented in the USA .

- Appendix A, Section A.3 deals with eye effects. Unfortunately, OSHA has neglected to include both Categories 2A and 2B. Category 2B is very important because it will help differentiate between severe (but reversible) and mild eye irritants. Appendix C (at C.4.5) includes label information for category 2B, but Appendix A does not include the criteria for this hazard category. It should be added to Appendix A.

- Appendix A, Section A.7 deals with Reproductive effects. It includes Effects on or via lactation. Unfortunately, there is not a standard assessment method for such an effect. OSHA should not implement this building block.

- Appendix A, Section A.8 deals with Specific Target Organ Toxicity - Single Exposure (STOS-SE) STOS-SE Category 1 is appropriate since it is based primarily on human

experience. STOS-SE Category 2 is problematic in that it could lead to inappropriate classification due to its reliance on animal tests, many of which may not be relevant to the human outcomes. STOS-SE Category 3 is appropriate if applied judiciously, using expert judgment.

- Although the NPRM includes the GHS definition of substance and mixture, the definitions do not address some issues concerning classification of individual constituents of a substance or mixture. To promote consistency and harmonization of classification, particularly for complex substances, OSHA should consider including the GHS 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.*

Cut-off values/concentration limits

- In *A.0.4.3 Use of Concentration Limits*, only the term "concentration limits" is used. In the corresponding GHS Purple Book discussion both terms are used. Throughout Appendix A, both terms are frequently used together as in the Purple Book. There are no definitions under section (c) for the terms "cut-off values" and "concentration limits". For consistency, understanding and clarity it would make sense to follow the Purple Book and use both terms in A.0.4.3 and/or provide definitions for these terms.

Appendix C

Pictogram Precedence

- In NPRM Appendix C, the NPRM deviates from the GHS concerning pictogram precedence. The NPRM states in Appendix C/C.2.1 Precedence of hazard information

> *If the skull and crossbones pictogram is included, the exclamation mark pictogram shall not appear* ***where it is used for acute toxicity*** (emphasis added)

The GHS states in 1.4.10.5.3.1 Precedence for the allocation of symbols

(a) If the skull and crossbones applies, the exclamation mark should not appear;

The EU CLP is in agreement with the GHS. Labels need to be harmonized where possible. OSHA should adhere to the 3rd revised GHS concerning the precedence for pictograms on labels and delete the phrase "where it is used for acute toxicity".

Hazard Statements

- In Appendix C several hazard statements include two hazards and no option for separating the hazard statements is provided if only a single hazard is present:

1. *Causes severe skin burns and eye damage*
2. *May damage fertility or the unborn child*
3. *Suspected of damaging fertility or the unborn child.*

Where definitive data is available (e.g., data indicate a skin corrosive but not an eye corrosive, a fertility hazard but not a developmental hazard, a developmental hazard but not a fertility hazard) then separating the hazard statements should be permitted. OSHA should allow individual hazard statements for skin corrosives, for fertility hazards and for developmental hazards.

Appendix D

- Appendix D deals with the SDS. Table D. 1 lists the information requirements in the SDS. 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." In Annex 4 Guidance on the Preparation of Safety Data Sheets, the GHS is a bit 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*]. For clarity and consistency OSHA should include in Table D.1 SDS Section 3 the phrase "*and are present above their cut-off levels*".

- In Appendix D, Table 1, SDS Section 1 Identification (c), clarification is needed regarding what is meant by "recommended use of chemical and restriction on use."

- Section (g) and Appendix D of the NPRM state that SDS sub-headings are mandatory. A clarification or a definition of SDS Sub-headings is needed. Are the sub-heading letters required on SDSs? The goal of the GHS was to have a globally harmonized SDS. It appears that the EU CLP will require mandatory numbered sub-headings. The GHS allows flexibility in both SDS format (subsections) and wording to allow companies to globally provide appropriate hazard information, advice and warnings even though there may be national/regional differences. It is also more difficult to provide pertinent health information if the statements must be separated into distinct subsections. Companies need to be able to provide consistent safety and health advice on SDSs globally. The OSHA proposal should allow this flexibility for SDSs.

Unclassified Hazards

- In (f) Labels and other forms of warning, the name of the chemical is required on the label for unclassified hazards. But in (f) and Appendix C the product identifier and not the chemical name is required for classified hazards.

  The product identifier should be required for both classified and unclassified hazards. 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 confusing and inconsistent and might lead to the conclusion that the chemical responsible for the unclassified hazard is responsible for all the classified hazards.

Trade Secrets

- In the NPRM, the trade secret provisions apply to the specific chemical identity, including the chemical name and other specific identification of a hazardous chemical, as well as to the exact percentage of the substance in a mixture. However, both these provisions apply only to the SDS and not to labels. The proposed labeling requirements could require the disclosure of this same information on the label.

  OSHA is proposing to require the name of the chemical on the label for unclassified hazards. OSHA is also requiring a statement such as x percent of the mixture consists of ingredient(s) of unknown toxicity on both the SDS and label when an ingredient with unknown acute toxicity is used in a mixture at a concentration $\geq 1\%$. Since the name of the chemical and x percent of the mixture consists of ingredient(s) of unknown toxicity can potentially be required label elements, trade secret claims should apply to labels as well as to SDSs.

- For global harmonization companies need flexibility to use terms such as "confidential", "trade secret" and "proprietary" on SDSs to indicate that the specific chemical identity and/or percentage of composition are being withheld. OSHA should allow "confidential", "confidential business information (CBI)", "trade secret", "proprietary" and similar terms as acceptable ways of indicating a trade secret.

Attachment 2 - Maintaining GHS Principles and Objectives in Global Implementation Regional GHS Classification Lists

Governments across the globe have begun or will soon begin the process to implement the UN Globally Harmonized System for Classification and Labeling (GHS). For many regions, this process will be complicated and potentially costly, and efforts to ease problems in transition will be considered. But as governments and stakeholders weigh options to minimize potential complications, they should remain focused to maintaining the overall approaches and principles articulated in the GHS

The architects of the GHS recognized that changes to "national systems will be required to achieve a single globally harmonized system…" In their efforts to make these changes, some regions are publishing lists of GHS classifications for specific chemicals. Other groups are considering a global database for chemical classifications. There may be benefits to such lists, particularly for some small enterprises that may not have the resources necessary to re-classify their chemical products. Such companies may appreciate the opportunity to use a published classification list.

But governments should remain cognizant to the potential pitfalls of such lists. For example, it is almost certain that as different regions develop chemical classification lists, they will come to different conclusions on classifications for some chemicals. This outcome runs counter to the overall objective of the GHS – which is harmonization across the globe. In addition, regional chemical classification lists do not typically address potential impurities in chemical products. This is important because in some cases, it is the impurities that would typically drive the hazard classification.

If a region opts to move forward with a classification list, it should clearly state that adherence to the list is voluntary. This action would preserve the GHS objective of self-classification[2], which is stated in the GHS framework (Section 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 (emphasis added)*

In order to provide the flexibility needed for self-classification, a region with a classification list should provide a mechanism that allows companies to classify their products differently if they have data to support that new classification.

Additionally, if a region moves forward with a GHS classification list, it should provide clear explanation of the data used for the classifications listed. It should also remain flexible and capable to quickly change classifications, as new data becomes available.

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[2] As articulated in the GHS framework (Section 1.1.4.1), "The GHS is designed to permit self-classification."