

TO: Occupational Safety and Health Standards Board
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California Construction and Industrial Materials Association
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California Healthcare Institute
California Manufacturers and Technology Association
California Professional Association of Specialty Contractors
Chemical Industry Council of California
Consumer Specialty Products Association
International Fragrance Association – North America
National Association of Chemical Distributors
Pharmaceutical Research and Manufacturers of America (PhRMA)
Residential Contractors Association
Western States Petroleum Association
Styrene Information and Research Center

DATE: March 18, 2013

SUBJECT: Globally Harmonized System Update to Hazard Communication – Health

Dear Board Members:

Thank you for considering these comments on the proposed rule to address Globally Harmonized System (“GHS”) updates to OSHA’s Hazard Communication Standard (“HCS”). We are a coalition representing employers, distributors and manufacturers impacted by the proposed rule and in full agreement with its stated purpose: to classify and communicate chemical hazards in a manner “consistent with the provisions of the United Nations Globally Harmonized System of Classification and Labeling of Chemicals Revision 3” [Proposed Section 5194(a)]. We respectfully submit that the proposed rule has not achieved that purpose. As a result, and for the following reasons, we urge the Board to reject the pending proposal and instead adopt the new federal standard (“HCS 2012”) verbatim.

- Improvement through harmonization is the overriding purpose of GHS updates
- Harmonization is a protective measure
- The proposed standard creates more discord than existed before HCS 2012
- Proposed differences are substantial without being more protective
- “Pass now – fix later” is bad policy and legally questionable

IMPROVEMENT THROUGH HARMONIZATION IS THE OVERRIDING PURPOSE OF GHS UPDATES

OSHA's side-by-side comparison of HCS 1994 and HCS 2012 says [Rationale for Section 1900.1200(a) *Purpose*.]:

“The HCS 1994 is a performance-oriented standard that provides guidance for defining hazards and for performing hazard determinations. However, the current standard does not specify an approach or format to follow. The Globally Harmonized System of Classification and Labeling of Chemicals has certain aspects that are performance-oriented, **but the key provisions are a uniformity-oriented** approach for the classification and presentation, through labeling and safety data sheets, of hazard information.” [emphasis added]

HCS 2012 added this statement to Section 1900.1200(a) *Purpose*: “The requirements of this section are intended to be consistent with the provisions of the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Revision 3.”

OSHA amended Section 1900.1200(a)(2) as follows: “This occupational safety and health standard is intended to address comprehensively the issue of ~~evaluating~~ classifying the potential hazards of chemicals, and communicating information concerning hazards and appropriate protective measure to employees, and to preempt any ~~legal requirements~~ legislative or regulatory enactments of a state...”

HARMONIZATION IS A PROTECTIVE MEASURE

OSHA provided the official rationale for GHS updates in its final rulemaking [77 Fed. Reg at 17605 (cols. 2-3)]:

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

OSHA determined that harmonization is a protective measure. Conversely, the rationale of this rulemaking includes a determination that disharmony has adverse impacts on the safety and health of employees. OSHA estimated the safety and health benefits of GHS updates [77 Fed. Reg at 17606 (col. 2)]:

“It is difficult to quantify precisely how many injuries, illnesses, and fatalities would be prevented due to the revisions to the HCS. The benefits associated with the current HCS may indirectly help provide a general sense of the potential magnitude of the benefits of the revisions to the HCS. OSHA estimates that if the rule could capture one percent of the benefits estimated for the original 1983 and 1987 HCS rules, the revisions would result in the prevention of 318 non-lost-workday injuries and illnesses, 203 lost-workday injuries and illnesses, 64 chronic illnesses, and 43 fatalities annually. The monetized value of the corresponding reduction in occupational risks among the affected employees is an estimated \$250 million on an annualized basis.”

THE PROPOSED STANDARD CREATES MORE DISCORD THAN EXISTED BEFORE HCS 2012

Rather than harmonize with OSHA HCS 2012, the proposed standard goes in the opposite direction. It further separates California by creating more discord than existed before HCS 2012. In its review of the proposed California standard, in the letter dated November 14, 2012 to the board’s Executive Officer, OSHA said:

“The proposed occupational safety and health standard does not appear to be commensurate with the federal standard. The definition of health hazards is different than the Federal standard. Changing the definition could pose significant issues between the State and Federal regulations, and needs to be studied.”

The OSHA comment identifies one substantial difference. Previous comments submitted by this coalition and others identified a number of substantial differences. Some of them have been recounted in the following section. All of them were retained for adoption, despite the expressed concerns of OSHA and the regulated community.

The assumed benefits of proposed differences have not been validated and weighed against the loss of health and safety created by the additional discord.

PROPOSED DIFFERENCES ARE SUBSTANTIAL WITHOUT BEING MORE PROTECTIVE

The place to evaluate proposed differences is in an advisory committee with time for careful consideration of all the consequences. However, the “pass it now, fix it later” approach of this rulemaking forces us to provide enough details to fully amplify the problems.

LEGACY DEADLINE TO UPDATE LABELS

Proposed Section 5194(f)(11) retains the three month timeline to update labels based on new hazard information. HCS 2012 [Section 1900.1200(f)(11)] extends that timeline from three months to six months in recognition of the real time required to reevaluate hazard classifications, update labels and distribute them. The extension also provides a reasonable amount of time to deplete existing inventories that must otherwise be recalled and relabeled at great expense. Before HCS 2012, under HCS 1994, OSHA suspended enforcement of the three month deadline. In its Inspection Procedures for HCS Labeling, OSHA said:

“No citations shall be issued on paragraph (f)(11). An indefinite stay-of-enforcement has been placed on the requirement that manufacturers update label information within 90 days of becoming aware of significant information regarding the hazards of the chemical.”

So the three month deadline has not been a real protection. However, the confusion generated should California actually enforce a three month deadline, in direct conflict with the federal six month deadline, would be very real. Among other impacts, the short timeline would drive some suppliers to maintain lower inventories resulting in higher unit products costs, lost sales, and more out of stock items.

LEGACY FLOOR OF CHEMICALS (SOURCE LISTS)

Proposed Sections 5194(d)(3) and 5194(d)(4) retain lists of source lists that defer to other agencies (such as the American Conference of Governmental Industrial Hygienists list of Threshold Limit Values) for hazard classifications. This “floor of chemicals” was deleted in OSHA HCS 2012 in favor of detailed classification criteria for each health hazard in Appendix A. In the Notice of Proposed Rule Making for HCS 2012, OSHA said [74 Fed. Reg at 50396 (col. 1)]:

“The current HCS does not provide a specific and detailed approach to hazard determination or classification of hazards, and thus there was concern during its promulgation about the relative ability of chemical manufacturers and importers to follow a performance-oriented approach and reach the same conclusions. The floor of chemicals...reflected this concern by providing additional guidance regarding the types of chemicals that would be considered hazardous were an appropriate hazard determination conducted. The proposed modifications provide a specific and detailed approach, and thus this additional guidance is no longer necessary or appropriate. OSHA believes that the detailed and specific criteria would provide equal or improved protection for exposed employees since they would improve consistency in evaluations, as well as help to ensure a thorough and comprehensive classification.

LEGACY ONE-STUDY RULE

Proposed Section 5194 retains the legacy one-study rule by which “one positive study conducted in accordance with established scientific principles is considered to be sufficient to establish a

hazardous effect...” Under HCS 2012, “positive and negative results are considered together in the weight of evidence determination” that “may justify classification”. These are incompatible approaches to establishing the certainty of a hazardous effect. The following is a realistic example of their incompatibility.

Suppose a data set in which one positive study suggests a cancer hazard and ten negative studies suggest otherwise. Assume that all studies, including the negative studies, were conducted in accordance with established scientific principles. Under OSHA HCS 2012, one would go to the cancer criteria in Appendix A and determine what if any cancer classification is warranted. In the face of scientifically valid negative studies, the weight of evidence may dictate a negative determination. However, the proposed one-study rule dictates a positive determination that a hazardous effect exists. In this case, the two methods obtain opposite results.

The one-study rule is not more protective when it goes beyond scientific reason to protect against non-existent hazards. When the scientific evidence establishes that a hazard does exist, the weight of evidence approach results in a positive determination. In comments to OSHA, NIOSH said:

“NIOSH agrees that the proposed modifications to the HCS would align the standard to the GHS approach, and thus do not require the floor of chemicals or the universal one-study rule to achieve the same level of protection as the current standard.”

In its Adoption Memorandum [page 3, para. 2], the division asserts that the one-study rule is more effective “because it does not permit a manufacturer or distributor to avoid classifying substances because the SDS preparer decides, prior to classification, that based on ‘weight of evidence’ the substance need not be evaluated.” However, “weight of evidence” does not exist as a method of evaluation prior to classification. “Weight of evidence” is the method of classification, and nothing more. The division’s assertion essentially restructures the classification process by redefining the role of classification criteria in Mandatory Appendixes A and B.

HCS 2012 eliminated the one-study rule along with other language from HCS 1994 that was not compatible with the new approach. California should eliminate that same language as well. Otherwise, the proposed rule leads to conflicting determinations that will confuse the regulated community and undermine the credibility of the hazard communication program.

“PASS NOW – FIX LATER” IS BAD POLICY AND LEGALLY QUESTIONABLE

This board has a history of deliberate rulemaking – using advisory committees to build consensus in the regulated community and craft reasonable rules the division can enforce. The proposal to “pass it now and fix it later” is unprecedented for this board on matters of such gravity. The problems may never be fixed.

While the regulated community has lived with California's HCS until now, California's HCS has been substantially the same as the federal HCS. One difference, Proposition 65 compliance, has not required different hazard classifications. If California retains legacy classification criteria, the regulated community will be faced with a new proposition – conflicting hazard classifications. Automated SDS systems have not been developed to accommodate those conflicts. They may be rendered unreliable. Should SDS preparers begin to solve that problem now or wait to see whether California fixes the problem later by harmonizing with HCS 2012?

As it stands, this rulemaking is subject to numerous legal questions:

- Can a state standard that defeats the primary purpose of the federal standard – greater protection through harmonized standards – be at least as effective as required by the OSH Act?
- Does the rulemaking record have sufficient rationale without a real evaluation of the impacts further disharmony will have on:
 - worker health and safety;
 - economic burdens; and
 - interstate trade?
- Is it permissible to use the Horcher process when the proposed differences conflict with the remaining standard being adopted and require novel constructs of the remaining standard to resolve those conflicts?
- Do the problems created by the proposed standard pass the clarity and consistency standards of California's Administrative Procedures Act?
- Can the board honestly say that a harmonized rule would not be:
 - more effective in carrying out the purpose for which the action is proposed; or
 - as effective and less burdensome to affected private persons; or
 - more cost-effective to affected private persons and equally effective?

We recommend that the board adopt the federal standard verbatim and use the advisory process to substantiate the value of proposed differences before adopting them. Had the board taken this course from the beginning, HCS 2012 could have been adopted easily, well before the six month deadline for new federal standards. It is not too late to put this rulemaking on its proper course.