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Docket No. OSHA-2019-0001
Occupational Safety and Health Administration
Via Electronic Submission to https://www.regulations.gov/commenton/OSHA-2019-0001-0283

RE: Docket No. OSHA-2019-0001. OSHA Update to the Hazard Communication Standard – 2019.

The California Division of Occupational Safety and Health (Cal/OSHA) appreciates the opportunity to submit comments regarding OSHA's draft Update to the Hazard Communication Standard (HCS) (OSHA Document #2020-28987). Cal/OSHA is the OSHA-approved workplace safety and health program administered by the State of California.

I. SUMMARY

After carefully evaluating the proposed changes in the body of the HCS and in Appendices A and B, Cal/OSHA recommends that federal OSHA withdraw this proposal. The proposal contains many provisions that we find will reduce the amount and quality of chemical hazard information available to workers, emergency responders and downstream users.

The proposal leaves several existing problems with the HCS unresolved and introduces numerous additional weaknesses. These include the following, each of which we describe in more detail in the following letter and in Appendix 1, attached:

1) Authoritative bodies (absent from the proposal)
   - For purposes of classification and labeling, the proposal continues to discount chemical hazard information developed by scientific bodies and disseminated through more than 20 comprehensive lists of well-established hazardous chemicals. These authorities include federal OSHA, NIOSH, U.S. EPA, the International Agency for Research on Cancer (IARC), the U.S. Agency for Toxic Substances and Disease Registry (ATSDR) and others.
   - In discounting scientific expertise, the proposal defaults to the judgement of producers in determining hazard classifications. Because producers do not have the scientific capacity of authoritative bodies, this introduces significant uncertainty and variability into the classification and labeling process, which translates into less robust information and greater risks for workers, downstream users and emergency responders.

2) Scientific findings (d)(2), (A.0.3.5) and (A.7.2.3.1)

- The proposal continues to defer to producers in considering a single positive study for purposes of classification and labeling; it does not require such a study to determine the hazard classification.
- This opens a means for producers to obscure important, scientifically valid health hazard information from workers, downstream users and emergency responders, and it allows producers to withhold the identity of chemicals that are present in a mixture.

3) Decision-making procedures (absent from the proposal)
   - The proposal continues to allow producers to not disclose the decision-making process they implement in classifying and labeling chemicals.
   - This means that workers, downstream users and regulators are unable to assess the extent to which producers consider the range of hazards associated with a chemical during the classification and labeling process.

4) Oxidizing solids (B.14.3.3)
   - In classifying and labeling oxidizing solids, the proposal continues to give deference to producers, based on their experience, over actual test results. The proposal does not stipulate that experience must be applied only when a test result is negative but experience in handling and storage shows otherwise.
   - The proposed language could result in a range of responses by producers in deciding whether or not to label a chemical as an oxidizing solid, which could obscure this information from workers, emergency responders and downstream users.

5) Exposure considerations (d)(1)
   - The proposal newly allows producers to withhold chemical hazard information from downstream users based on the producer's assumption that workers would not be exposed to the chemical under "normal conditions of use."
   - This change represents a departure from the hazard-based foundation of the HCS in a way that could affect how chemicals are classified and labeled; this could reduce the amount and quality of chemical hazard information available to workers, emergency responders and downstream users.

6) Bulk labeling (f)(5)(ii) and (f)(11)
   - The proposal no longer requires producers to identify chemical hazards on bulk containers in shipment, permitting the information to be transmitted only with the shipping papers or electronically to the destination, and it would not require relabeling of containers that have been released for shipment in the event new hazard information is identified.
   - This change would leave workers who handle a container during shipment with less hazard information about its contents, and it would leave emergency responders with less hazard information in the event of a loss of containment during transportation or use.

7) Reactivity information (f)(1)
   - The proposal newly exempts producers from labeling chemical hazards that result from a reaction with other chemicals under normal conditions of use.

- This change would leave workers throughout the supply chain and at the point-of-use with less hazard information about the inhalation, flammability, or reactivity hazards that can occur in chemical mixtures.

8) Multiple hazards (C.2.4.10)
   - The proposal newly allows producers to choose one hazard over others that are associated with a chemical and to label the chemical accordingly. A hydrocarbon chemical that is both flammable and toxic, for example, could be labeled as one or the other but not necessarily both.
   - This change would leave workers, emergency responders and downstream users with an incomplete view of the range of hazards associated with a chemical, which could lead to improper handling and to inappropriate use of engineering controls, PPE and other protections.

9) PPE instructions (C.4.2 to C.4.7))
   - The proposal no longer requires producers to specify on the SDS the types of personal protective equipment (PPE) that are required to handle specific types of chemicals.
   - This change would leave workers who handle chemicals during shipment and at the point-of-use with less information about the type of gloves, protective garments, eyewear and other PPE needed to protect themselves from exposure, and it would complicate an emergency response to a loss of containment during transportation or use.

10) Pyrophoric gas (B.2.3.3)
   - The proposal newly allows producers to avoid classifying and labeling a flammable gas as pyrophoric "when experience in production or handling shows that the substance does not ignite spontaneously on coming into contact with air at a temperature of 130 °F (54 ºC) or below." The proposal does not stipulate that experience must be applied only when a test result is negative but experience in handling and storage shows otherwise.
   - This change would give deference to the judgement of producers over test procedures for pyrophoricity, which could leave workers who handle chemicals during shipment and at the point-of-use with less hazard information, and it would leave emergency responders with less hazard information in the event of a loss of containment during transportation or use.

11) Serious hazards (A.3.2.3)
   - The proposal newly allows producers to discount and not disclose evidence of a serious health effect in toxicological studies if the effect occurs among a range of other effects.
   - This change would potentially allow producers to obscure important hazard information from workers and emergency responders regarding a serious, if less common, health effect associated with a chemical, or a health effect that might be more common among subpopulations.

12) Irritant asthmagens (A.4.2.1.3.1)
   - The proposal requires disclosure of chemical asthmagens that cause respiratory sensitization, but would not require disclosure of chemicals that produce asthma without a sensitization

(immune) effect, such as reactive airway dysfunction syndrome (RADS), also known as acute-onset, irritant induced asthma (IIA).
- The link between chemical exposures and this important form of occupational asthma continues to be obscured to workers and emergency responders.

Withdrawing the proposal will allow for broader consideration of the following:

(1) The intent of the HCS in its entirety and its effectiveness in meeting its stated purpose; i.e., to "ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees;"

(2) The impact that any proposed changes will have on the HCS's stated purpose for the full scope of stakeholders; and

(3) The input of proposed changes from labor, manufacturers and importers, distributors and downstream businesses, public health and worker advocacy organizations, and other stakeholders.

If withdrawing the proposal is not feasible at this time, we have submitted recommendations for improving the language in several areas below and in Appendix 1; these are not comprehensive, however, and should be viewed as initial recommendations only.

II. BACKGROUND

In 1980, the State of California adopted the first legislation to create a workers' "right-to-know," known as the Hazardous Substances Information and Training Act. The initial implementing regulation to this Act was modified several times in response to the federal Hazard Communication Standard (HCS)(29 CFR 1910.1200), and subsequently in response to mandates under California's Safe Drinking Water and Toxic Enforcement Act (Proposition 65), which were finally approved for adoption into California's State Plan in 1997.

The 2012 federal OSHA adoption of the Globally Harmonized System (GHS) removed several protections that had been in the existing federal Hazard Communication Standard (HCS). In considering how to respond to federal OSHA's adoption of GHS into the HCS, Cal/OSHA concluded that some changes were not as effective as California's existing regulations, or they were not consistent with California law, including the removal of a number of lists of hazardous chemical substances developed by authoritative bodies.

In 2014, California completed its adoption of parallel changes to its own HCS (8 California Code of Regulations (CCR) §5194), and federal OSHA approved the incorporation of the amendments in the California State Plan.

In the proposed changes to the federal HCS, Cal/OSHA recommends that OSHA adopt specific subsections of the California HCS that are more protective than the federal HCS. Currently, these provisions only apply to California manufacturers, importers and employers who classify chemicals.

Extending these more protective provisions to other classifiers, manufacturers, importers and distributors will improve protections for workers nationwide.

In recent years, the California Legislature has established additional chemical disclosure requirements, including a 2013 law (SB 193) granting additional authority to the Hazard Evaluation System and Information Service (HESIS) within the California Department of Public Health (CDPH) to request chemical information from manufacturers, and the Cleaning Product Right to Know Act of 2017 (SB 258), which requires public disclosure by product manufacturers and importers of chemicals listed as hazardous by any one of 22 different authoritative bodies. This list is referenced in our comments, below, to which we have added OSHA, NIOSH and the American Conference of Governmental Industrial Hygienists (ACGIH).

III. COMMENTS

1) Authoritative bodies (absent from the proposal)

- For purposes of classification and labeling, the proposal continues to discount scientific information contained on more than 20 lists of hazardous chemicals developed by authoritative bodies worldwide, including NIOSH, U.S. EPA, the International Agency for Research on Cancer (IARC), the U.S. Agency for Toxic Substances and Disease Registry (ATSDR) and others.

Cal/OSHA considers the availability of chemical hazard listings from authoritative bodies an important asset for achieving the standard's purpose. These authoritative bodies provide an objective and comprehensive review of chemical hazards that standardizes hazard information for manufacturers and importers in a way that effectively communicates hazards to downstream workers and emergency responders.

The systematic and transparent approach of these organizational classifications is consistent with the provisions of the United Nations Globally Harmonized System. For purposes of the HCS, Cal/OSHA recommends that chemicals on these lists be presumptively assigned to designated hazard classes determined by the authoritative body. In addition, Cal/OSHA recommends that the HCS require chemical manufacturers, importers or employers classifying chemicals to list the identity of the chemical on the SDS and the authoritative body on whose list the chemicals appear, and the specific reason for the listing.

The lists of chemicals developed by authoritative bodies were removed from the 2012 version of the federal HCS. These authoritative bodies and their respective lists should be restored to subsection (d) and to Appendix A, and the lists should be updated accordingly.

Cal/OSHA recommends incorporating the following language into a new paragraph in subsection (d):

> *"Manufacturers, importers, or employers classifying chemicals shall treat any chemical listed on one or more of the following sources as a hazardous chemical and shall classify the listed chemical using the criteria described in Appendix A."*

We recommend that OSHA adopt the following lists developed by authoritative bodies, 22 of which are included in the California Cleaning Product Right to Know Act of 2017:

1) Chemicals for which federal OSHA or a state OSHA plan has adopted a permissible exposure limits (PEL) including, but not limited to, chemicals listed in 29 CFR 1910.1000, and Tables Z-1, Z-2 and Z-3, and chemicals listed in Title 8 California Code of Regulations (CCR) §5155 Table 1.
2) Chemicals for which the U.S. CDC's National Institute for Occupational Safety and Health (NIOSH) has adopted recommended exposure limits (REL).
3) Chemicals for which the American Conference of Governmental Industrial Hygienists (ACGIH) has developed threshold limit values (TLV) or biological exposure indices (BEI).
4) Chemicals known to the State of California to cause cancer or reproductive toxicity that are listed pursuant to the Safe Drinking Water and Toxic Enforcement Act of 1986 (Chapter 6.6 (commencing with Section 25249.5 of Division 20)).
5) Chemicals classified by the European Union as carcinogens, mutagens, or reproductive toxicants pursuant to Category 1A or 1B in Annex VI to Regulation (EC) 1272/2008.
6) Chemicals included in the European Union Candidate List of Substances of Very High Concern in accordance with Article 59 of Regulation (EC) 1907/2006 on the basis of Article 57(f) for endocrine disrupting properties.
7) Chemicals for which a reference dose or reference concentration has been developed based on neurotoxicity in the federal Environmental Protection Agency's Integrated Risk Information System.
8) Chemicals that are identified as carcinogenic or likely to be carcinogenic to humans by the federal Environmental Protection Agency.
9) Chemicals included in the European Chemicals Agency Candidate List of Substances of Very High Concern in accordance with Article 59 of Regulation (EC) 1907/2006 on the basis of Article 57(d), Article 57(e), or Article 57(f) of Regulation (EC) 1907/2006 for persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative properties.
10) Chemicals that are identified as persistent, bioaccumulative, and inherently toxic to the environment by the Canadian Environmental Protection Act Environmental Registry Domestic Substances List.
11) Chemicals classified by the European Union in Annex VI to Regulation (EC) 1272/2008 as respiratory sensitizer category 1.
12) Group 1, 2A, or 2B carcinogens identified by the International Agency for Research on Cancer.
13) Neurotoxicants that are identified in the federal Agency for Toxic Substances and Disease Registry's (ATSDR) Toxic Substances Portal, Health Effects of Toxic Substances and Carcinogens, Nervous System.
14) Persistent, bioaccumulative and toxic priority chemicals that are identified by the federal Environmental Protection Agency National Waste Minimization Program.
15) Reproductive or developmental toxicants identified in Monographs on the Potential Human Reproductive and Developmental Effects published by the federal National Toxicology Program, Office of Health Assessment and Translation.
16) Chemicals identified by the federal Environmental Protection Agency's Toxics Release Inventory as Persistent, Bioaccumulative and Toxic Chemicals that are subject to reporting under Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (42 U.S.C. Sec. 11001, et seq.).

17) The Washington Department of Ecology's Persistent, Bioaccumulative, Toxic (PBT) Chemicals identified in Chapter 173-333 of Title 173 of the Washington Administrative Code.
18) Chemicals that are identified as known to be, or reasonably anticipated to be, human carcinogens by the federal National Toxicology Program.
19) Chemicals for which notification levels, as defined in Section 116455, have been established by the California Department of Public Health or the California State Water Resources Control Board.
20) Chemicals for which primary maximum contaminant levels have been established and adopted under Section 64431 or 64444 of Title 22 of the California Code of Regulations.
21) Chemicals identified as toxic air contaminants under Section 93000 or 93001 of Title 17 of the California Code of Regulations.
22) Chemicals that are identified as priority pollutants in the California water quality control plans pursuant to subdivision (c) of Section 303 of the federal Clean Water Act and in Section 131.38 of Title 40 of the Code of Federal Regulations, or identified as pollutants by the state or the federal Environmental Protection Agency for one or more water bodies in the state under subdivision (d) of Section 303 of the federal Clean Water Act and Section 130.7 of Title 40 of the Code of Federal Regulations.
23) Chemicals that are identified with non-cancer endpoints and listed with an inhalation or oral reference exposure level by the California EPA, Office of Environmental Health Hazard Assessment, pursuant to paragraph (2) of subdivision (b) of Section 44360.
24) Chemicals identified as priority chemicals by the California Environmental Contaminant Biomonitoring Program pursuant to Section 105449.
25) Chemicals that are identified on Part A of the list of Chemicals for Priority Action prepared by the Oslo and Paris Conventions for the Protection of the Marine Environment of the North-East Atlantic.

Cal/OSHA further recommends that the standard require chemical manufacturers or importers to use the classifications of IARC and NTP for hazard communication purposes, by including the following new paragraph in subsection (d):

> *"Manufacturers, importers, and employers classifying chemicals shall treat any chemical listed by one or more of the following sources as having met the total weight of evidence criteria described in Appendix A for classification as a known or presumed human carcinogen, or a suspected human carcinogen, for purposes of this section:*
> *(A) National Toxicology Program (NTP), Annual Report on Carcinogens, (latest edition);*
> *(B) International Agency for Research on Cancer (IARC) Monographs (latest editions);*
> *(C) Substances subject to regulation under the California Occupational Carcinogen Control Act or which are otherwise regulated by OSHA or by state plans as carcinogens;*
> *(D) Substances that meet the definition of "select carcinogen" in 29 CFR 1910.1450."*

A parallel change should be made in Appendix A.

2) Scientific findings (d)(2), (A.0.3.5) and (A.7.2.3.1)

- The proposal continues to defer to producers in considering a single positive study for purposes of classification and labeling; it would not require such a study to determine the hazard classification. The proposal will newly allow producers to withhold the precise chemical composition of product as a trade secret, even from health care providers.

This section raises several toxicological concepts (mode of action, mechanism and bioavailability) that are difficult to apply consistently across all chemicals and hazard levels. In addition, the section notes the multiple types of data that can be used for classification. While using a weight of evidence (WOE) approach for classification might improve the likelihood that appropriate classifications are made, this approach will not account for the different types of scientific data (epidemiological vs. animal vs in vitro) on which different classifications will be based.

Experience has shown that classifiers will differ in their WOE determinations, even for the same chemical. This lack of consistency can occur between different manufacturers, or in some cases between an SDS in one country and the SDS in another country from the same manufacturer. The resulting confusion impacts the safety of workers and emergency responders, as well as downstream businesses, worker representatives, regulators, health care personnel, and others who rely on the SDS for health hazard information.

Cal/OSHA recommends this section be expanded to provide more guidance on weighting the different types of data used in a classification.

In cases where no authoritative body has listed a chemical, or where a WOE classification is based largely on in vitro data but a single positive animal study is available, Cal/OSHA recommends that the animal study should determine the hazard classification.

Cal/OSHA recommends that subsection (d) and Appendix A be modified to require the disclosure of the identity of any chemical for which (A) there is statistically significant evidence of one or more harmful effect(s); and (B) the evidence is based on at least one positive study conducted in accordance with established scientific principles.

The 2012 HCS amendments replaced the requirement to disclose any chemical for which there is "one positive study" with the more detailed classification methodology. However, this creates an obstacle to employees and employers, and to public health agencies, which need to determine whether a specific chemical should be identified as a hazardous substance in the workplace. If a manufacturer, importer or employer who classifies chemicals concludes that the chemical need not be classified, they are not required to disclose the chemical's identity.

This has occurred recently in California, where tracking of exposures to 1-bromopropane (a chemical for which there is a Cal/OSHA but not federal permissible exposure limit) has been hampered because the presence of the chemical is sometimes not disclosed on the SDS, despite evidence of reproductive and neurological toxicity.

Cal/OSHA recommends adding a requirement to disclose the identity of any chemical at or above the mixture threshold in Appendix A on the SDS for which there is one positive study, whether or not the classifier determines that it meets the criteria in Appendix A.

We recommend modifying existing paragraph (d)(2) as follows:

> *"Chemical manufacturers, importers or employers classifying chemicals shall identify and consider the full range of available scientific literature and other evidence concerning the potential hazards. This section does not require manufacturers, importers, or employers to conduct toxicological testing or epidemiological studies of the chemical(s) to determine hazard classifications. Appendix A to §1910.1200 shall be consulted for classification of health hazards and Appendix B to §1910.1200 shall be consulted for the classification of physical hazards. In addition, the manufacturer, importer, or employer classifying chemicals shall ensure that the identity and health effect(s) of every chemical that they determine does not meet criteria in Appendix A for classification is noted on the safety data sheet if:*
> *(A) There is statistically significant evidence of one or more harmful effect(s); and,*
> *(B) The evidence is based on at least one positive study conducted in accordance with established scientific principles."*

Cal/OSHA recommends that Appendix A at A.0.3.5 require that a single positive study must determine the hazard classification, as follows:

> *"Both positive and negative results shall be considered together in the weight of evidence determination; ~~However,~~ however, a single positive study performed according to good scientific principles and with statistically and biologically significant positive results ~~may~~ shall determine the hazard classification."*

Requiring disclosure of the findings of a single positive study that reports "*statistically and biologically significant positive results"* is important for four reasons. First, the purpose of the HCS is to "ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees."[1] A single positive study that achieves "statistical and biological significance" represents the highest possible standard of evidence in establishing causation in health studies; this information should therefore be determinant in a weight of evidence evaluation, and it is essential that employees and employers are made aware of such findings.

To illustrate this point, David Gee describes a continuum of five standards of evidence that are applied in health studies and various areas of law (Figure 1): [2]

[1] §1910.1200 (a)(1).
[2] Gee, David (2006). Late Lessons from Early Warnings: Toward Realism and Precaution with Endocrine-Disrupting Substances. *Environ Health Perspect*; 114(Suppl 1): 152-160. (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1874173/) (Accessed April 14, 2021).

Figure 1. A continuum of standards of evidence for differing purposes: examples and illustrations (Gee 2006)

Probability (%)	Quantitative descriptor[a]	Qualitative descriptor	Illustrations
100	Very likely	Statistical significance	Part of strong scientific evidence for causation
	(90–99%)	Beyond all reasonable doubt	Most criminal law and the Swedish Chemical Law 1973 (McCormick 2001), for evidence of safety of substances under suspicion; burden of proof on manufacturers
	Likely	Reasonable certainty	Food Quality Protection Act (1996)
	(66–90%)	Sufficient scientific evidence	To justify a trade restriction designed to protect human, animal, or plant health under World Trade Organisation (WTO) Sanitary and Phytosanitary (SPS) Agreement, Article 2.2, (WTO 1994a)
	Medium likelihood	Balance of evidence	IPCC (1995, 2001)
	(33–66%)	Balance of probabilities	Much civil and some administrative law
		Reasonable grounds for concern	European Commission communication on the precautionary principle (European Commission 2000)
		Strong possibility	British Nuclear Fuels occupational radiation compensation scheme (20–50% probabilities triggering different awards $\geq$ 50%, which then triggers full compensation) (Mummery and Alderson 1989)
	Low likelihood (10–33%)	Scientific suspicion of risk	Swedish Chemical Law 1973 (McCormick 2001), for sufficient evidence to take precautionary action on potential harm from substances; burden of proof on regulators
		Available pertinent information	To justify a provisional trade restriction under WTO SPS Agreement, Article 5.7, where scientific information is insufficient (WTO 1994b)
	Very unlikely (1–10%)	Low risk	Household fire insurance
0		Negligible and insignificant	Food Quality Protection Act (1996)

[a] Probability bands based on IPCC (2001).

As Gee points out in column three, "statistical significance" is akin to "beyond all reasonable doubt," and equates to an Intergovernmental Panel on Climate Change (IPCC) quantitative descriptor of 90-99%, whereas the "weight of evidence," or "balance of evidence," is akin to a "balance of probabilities," or "reasonable grounds for concern," with an IPCC quantitative descriptor of 33-66% likelihood. If a chemical substance or mixture is shown "beyond all reasonable doubt" to produce health effects in a study of animals or humans, it is appropriate for OSHA to ensure that that information is communicated unequivocally to downstream users. A health study that achieves this standard of evidence clearly meets the purpose of the HCS and should not be discounted with the use of "may justify classification."

Second, it is well-recognized that scientific standards of evidence consistently bias health effects studies toward false negatives. David Gee describes 16 methodological features in such studies, all but three of which err in the direction of false negatives (Figure 2).

Figure 2. Methodological features of experimental and observational studies and their biases.

Scientific studies	Some methodological features	Main[a] directions of error increase chances of detecting:
Experimental studies	High doses	False positive
(animal laboratory)	Short (in biological terms) range of doses	False negative
	Low genetic variability	False negative
	Few exposures to mixtures	False negative
	Few fetal–lifetime exposures	False negative
	High fertility strains	False negative (developmental/ reproductive end points)
Observational studies	Confounders	False positive
(wildlife and humans)	Inappropriate controls	False positive/negative
	Nondifferential exposure misclassification	False negative
	Inadequate followup	False negative
	Lost cases	False negative
	Simple models that do not reflect complexity	False negative
Both experimental and	Publication bias toward positives	False positive
observational studies	Scientific/cultural pressure to avoid false positives	False negative
	Low statistical power (e.g., from small studies)	False negative
	Use of 5% probability level to minimize chances of false positives	False negative

a Some features can go either way (e.g., inappropriate controls), but most of the features err mainly in the direction shown in this table

If a single animal or human study defeats this array of false negatives, it generally means that an exceptionally strong association exists between a chemical hazard and a health outcome. This degree of evidence is sufficient for the disclosure and communication purpose of the HCS, which is not to build a body of scientific studies on the health effects of chemicals, but rather to simply inform, or warn, downstream employers and workers about a hazard. Allowing a manufacturer, importer or classifier to obscure critically important scientific information of this type from downstream users behind the phrase "may justify classification" is at odds with the purpose of the HCS.

Third, there is an economic incentive for a manufacturer, importer or classifier to apply the phrase "may justify classification" in *not* disclosing the findings of a single study if that study shows evidence of harm "beyond all reasonable doubt" for a chemical in which the manufacturer, importer or classifier has an economic interest.

Retaining the phrase "may justify classification" will allow some manufacturers, importers and classifiers to "undervalue" and obscure the findings of single, positive studies if those studies could damage their brand. To meet its stated purpose, the HCS must be unequivocal in requiring disclosure of such information to downstream employers and workers through classification, labeling and on the SDS.

Finally, by allowing manufacturers, importers and classifiers the option of obscuring the findings of single positive studies, as described here, the HCS will continue to generate "information asymmetries" between producers and downstream buyers in the market. This perpetuates a chemical economy in which the primary price drivers are the function, price and performance of

chemicals, and where adverse health effects—because they are obscured from downstream buyers—are unknown, and therefore are "undervalued" in the economy. [3]

Conversely, by requiring that a single, positive study be determinant in the weight of evidence evaluation, the HCS will drive hazard information into the market, which will provide downstream users with approximately the same level of information as producers. This allows downstream buyers to make more informed decisions about the chemical products they purchase, which enables the basic function of the market. Better information on chemical hazards in the market is an essential first step for downstream buyers to seek out and use safer alternatives, a goal that OSHA supports.

3) Decision-making procedures (absent from the proposal)

- The proposal continues to allow producers to not disclose the decision-making process they implement in classifying and labeling chemicals.

Cal/OSHA recommends that federal OSHA restore requirements from the 1994 HCS that manufacturers, importers and employers classifying chemicals have written hazard determination procedures. Written procedures document the basis for the decisions that underpin hazard classification, which allows customers, employees and regulators to understand the types of hazards that were considered in the classification process. Hazard determination procedures will be particularly important if OSHA pursues its proposal to require hazard classification only "under normal conditions of use" and "foreseeable emergencies," because it would at least require classifiers to disclose the types of exposures they considered in determining what would constitute "normal conditions of use" and "foreseeable emergencies."

We recommend inclusion of the following paragraph in subsection (d):

> *"Manufacturers, importers, or employers classifying chemicals shall develop, implement and maintain written procedures to determine the hazards of the chemicals they evaluate. The written procedures shall be made available, upon request, to employees, their designated representatives, the Assistant Secretary of Labor for Occupational Safety and Health and his/her designee(s) including representatives of OSHA State Plans, and NIOSH. The written procedures may be incorporated into the written hazard communication program."*

4) Oxidizing solids (B.14.3.3)

- In classifying and labeling oxidizing solids, the proposal continues to give deference to producers, based on their experience, over actual test results.

B.14.3.3 states that:

[3] Wilson M and Schwarzman M (2009). Toward a New U.S. Chemicals Policy: Rebuilding the Foundation to Advance New Science, Green Chemistry, and Environmental Health. *Env Health Persp* 177(8) 1202-1209 (Available http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2721862/). (Accessed April 22, 2021).

"In the event of divergence between test results and known experience in the handling and use of chemicals which shows them to be oxidizing, judgements based on known experience shall take precedence over test results."

This sentence allows undue discretion and introduces uncertainty that is inherent to a producer's "judgements based on known experience." It is unreasonable to expect that all producers will apply a common standard based on their individual judgement and known experience. The HCS should give deference to objective tests when a decision must be made about transmitting critical chemical safety information to downstream users.

At the same time, however, the HCS should require producers to disclose oxidizing hazards for a chemical if the producer has experience with those hazards, even when test results for the chemical are negative; for example, if the product has ignited during handling by the producer, even though the conditions for ignition were not present and/or an oxidizing test was negative.

As described in the attached Appendix 1, Cal/OSHA's recommended changes to this sentence are as follows:

"B.14.3.3 All chemicals with a positive oxidizing test shall be disclosed. In the event of divergence between test results and known experience in the handling and use of chemicals which shows them to be oxidizing, experience demonstrating an oxidizing hazard shall take precedence over negative test results ~~judgements based on known experience results.~~"

5) Exposure considerations (d)(1)

- The proposal newly allows producers to withhold chemical hazard information from downstream users based on the producer's assumption that workers would not be exposed to the chemical under "normal conditions of use and foreseeable emergencies."

The existing HCS language directs the chemical manufacturer or importer to determine the hazard classes of chemicals, and where appropriate, the category of each class that applies to the chemical being classified. The proposed language adds the qualifiers "under normal conditions of use and foreseeable emergencies."

There are a number of problems with this addition. First, manufacturers and importers have very little understanding of the ways in which their chemical products are used in commerce. There is very little, if any, information transmitted *back up supply chains* from end users to original manufacturers, formulators or importers of chemicals and chemical products. Characterizing "normal conditions of use" would therefore have to rely largely on assumptions, and yet with the proposed language, an incorrect set of assumptions could result in essential chemical hazard information being withheld from workers and downstream users, on the producer's assumption that exposures would not occur during "normal conditions of use."

For example, in investigating n-hexane exposures in the vehicle repair industry, researchers learned from the manufacturers of hexane-based, aerosol degreasing products that the expected "normal

conditions of use" for these products by automotive repair technicians was about one, 24-ounce can every two or three days.[4] However, in visits to 10 automotive repair facilities where the researchers observed 36 different technicians, they found that technicians who were assigned the dirtiest jobs in each shop used between six and 10 cans of degreasing solvent products *each day*. Some of the manufacturers later described this as "inappropriate use," but in fact it was the standard practice in the industry.

Under the proposed language change in (d)(1), a producer could declare any number of uses to be outside "normal conditions of use," and therefore not subject to classification and disclosure, even when those uses are standard in the industry.

Second, as a general rule, emergencies are not "foreseeable," particularly when they have the potential to produce catastrophic consequences; i.e., we can't easily visualize—and we don't usually expect and plan for—worst case scenarios. It is unrealistic to expect manufacturers or importers to generate realistic scenarios of serious chemical fires, explosions or releases that can occur during transport or handling, and then to classify and label their chemicals accordingly.

Providing unfiltered hazard classification to the employee and employer along with other information contained in the SDS is the most effective method for engaging the employee and employer in understanding chemical hazards and taking protective actions. Cal/OSHA recommends removing the new language from this paragraph, as follows:

> *"For each chemical, the chemical manufacturer or importer shall determine the hazard classes, and where appropriate, the category of each class that apply to the chemical being classified ~~under normal conditions of use and foreseeable emergencies.~~ The hazard classification shall include any hazards associated with a change in the chemical's physical form or resulting from a reaction with other chemicals."*

We note that the proposed language pertaining to exposure also appears to contradict Appendix A, Section A.0.1.1:

> "*The term 'hazard classification' is used to indicate that only the intrinsic hazardous properties of chemicals are considered."*

This statement excludes exposure scenarios, which in the proposed modification are introduced and allowed in (d)(1) by the phrase, "normal conditions of use."

6) <u>Bulk labeling (f)(5)(ii) and (f)(11)</u>

- The proposal no longer requires producers to identify chemical hazards on bulk containers in shipment, allowing the information to be transmitted only with the shipping papers or

[4] Wilson, Hammond, Nicas, Hubbard (2007). Worker exposure to volatile organic compounds in the vehicle repair industry. *J Occ Env Hyg.* (https://pubmed.ncbi.nlm.nih.gov/17454499/) (Accessed April 29, 2021).

electronically to the destination, and it would not require relabeling of containers that have been released for shipment in the event new hazard information is identified.

> *"(ii) The label for bulk shipments of hazardous chemicals may be on the immediate container or may be transmitted with the shipping papers, bills of lading, or other technological or electronic means so that it is immediately available to workers in printed form on the receiving end of shipment."*

The use of "or" in this phrase allows a manufacturer, importer or distributor to choose between labeling the container or simply sending an email to the receiver, who would be responsible for making it available to workers. Many types of workers may be exposed to bulk containers of hazardous materials prior to the container reaching its ultimate destination.

The proposed change leaves workers who handle a container during shipment unaware of its contents, and it leaves emergency responders with less information regarding potential hazards in the event of a transportation accident or other loss of containment, including (1) the appropriate use of PPE; (2) the hazards associated with using water to fight fires and protect exposures; (3) spill containment strategies; and (4) the need for evacuation by workers and the public. Shipping papers are not always available at the point of worker exposure, nor are emails necessarily communicated to those handling containers on shipping docks and in warehouses.

The elimination of chemical identity and hazard information from labelling requirements on the exterior of bulk containers denies many types of workers the right-to-know what they are handling in these containers, and it could lead to mishandling—and potentially catastrophic consequences—in the event of a spill. Cal/OSHA recommends that the proposed sentence be removed.

Under (f)(11), the proposal includes a modification that containers "released for shipment" need not be relabeled with new hazard information.

> *"Chemicals that have been released for shipment and are awaiting future distribution need not be relabeled; however, the chemical manufacturer or importer must provide the updated label for each individual container with each shipment"*

The 2012 amendments already extended requirements for relabeling to six months. The proposed additional delay in relabeling exposes workers throughout the supply chain to undisclosed chemical hazards, including workers at the manufacturing or importing site; those who handle the chemical during distribution; and those who handle and use the chemical at the destination. The potential risks to these workers outweigh any inconvenience to the industry that might occur as a consequence of relabeling. Cal/OSHA recommends that the proposed sentence be removed.

7) Reactivity information (f)(1)

- The proposal newly exempts producers from labeling chemical hazards that result from a reaction with other chemicals under normal conditions of use.

This section would create additional exceptions for the labelling of containers, which would not have to include information on "hazards resulting from a reaction with other chemicals under normal conditions of use…" Information on reactivity hazards is important to protect workers throughout the supply chain and at the point-of-use. It is essential that workers who handle mixed loads understand the potential explosive, toxic or flammability hazards that could occur from the mixing of specific types of chemicals.

As noted above at #5, it is unrealistic to expect that producers fully understand how their products are used in commerce and what the "normal conditions of use" are in actual practice. Cal/OSHA recommends that the proposed exception be removed.

8) Multiple hazards (C.2.4.10)

- The proposal newly allows producers to choose a single hazard among multiple hazards associated with a chemical, and to limit labeling of the chemical to the single hazard alone. A hydrocarbon chemical that is both neurotoxic and causes acute toxicity, for example, could be labeled as one or the other but not necessarily both. The great majority of chemicals in commerce present more than one hazard. Ammonia, for example, is toxic on inhalation but also presents an explosive hazard under the right conditions. This addition to the HCS leave workers, emergency responders and downstream users without the information they need to implement effective engineering controls, select PPE and take other protective actions.
- The addition runs counter to the purpose of the HCS, which is "to ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees."

9) PPE instructions (C.4.2 to C.4.7)

- The proposal would no longer require producers to specify on the SDS the types of personal protective equipment (PPE) that are required to handle specific types of chemicals.

Where the manufacturer was previously required to "specify type of equipment," the proposed use of the word "may" means that this is now optional. This is counter to the purpose of the HCS. Because they are the most knowledgeable about the hazards of their products, it is essential that manufacturers, importers and distributors be required to specify the types of protective gloves, protective garments and other PPE that are needed to safely handle specific chemicals. This is essential information for workers who handle the chemical and for emergency responders. Withholding this information introduces new risks to workers and complicates emergency response.

10) Pyrophoric gas (B.2.3.3)

- The proposal newly allows producers to avoid classifying and labeling a flammable gas as pyrophoric "when experience in production or handling shows that the substance does not ignite spontaneously on coming into contact with air at a temperature of 130 °F (54 ºC) or below."

In this subsection, the proposal warns about the variable behavior of pyrophoric gases (*B.2.2.1 NOTE 3: Spontaneous ignition for pyrophoric gases is not always immediate, and there may be a delay*.) and then, rather than calling for rigorous testing procedures in light of this variability, allows that "*the classification procedure for pyrophoric gases need not be applied when experience in production or handling shows that the substance does not ignite spontaneously on coming into contact with air at a temperature of 130 °F (54 ºC) or below*."

As with oxidizing solids (#4 above), this approach gives undue discretion to producers at the expense of workers and downstream users. It introduces uncertainty that is inherent when many producers assess their individual "experience in production or handling" and then classify and label their chemicals accordingly.

It is unreasonable to expect that all producers will apply a common standard based on their experience, particularly when economic pressures are introduced into the decision-making process. The HCS should give deference to objective tests when a decision must be made about transmitting critical chemical safety information to workers and downstream users. The proposal should, however, require manufacturers to disclose any hazards that have been identified in their experience, such as during handling or storage, even if those hazards are not identified through the applied test methods.

11) Serious hazards (A.3.2.3)

- The proposal newly allows producers to discount and not disclose evidence of a serious health effect in toxicological studies if the effect occurs among a range of other effects.

The proposal introduces a new approach to the interpretation of toxicological evidence for purpose of classification and labeling: "For those substances where there is pronounced variability among animal responses, this information may be taken into account in determining the classification." Cal/OSHA recommends that classification and labeling be based on the most serious toxicological response in animal studies, and that it is not sufficient for manufacturers and importers to simply take this information "into account." Just as test animals have variable responses during toxicological testing, humans, including workers, have variable responses to hazardous substances; omitting the full range of possible toxicological effects in deference to a single health effect may specifically under-warn vulnerable sub-populations and individuals.

If a chemical substance causes blindness in one animal, for example, but only moderate opacity in others, blindness should be the determining response for purposes of classification and labeling.

It is important that the HCS make this requirement explicit, rather than opening the interpretation of toxicological evidence to the discretion of manufacturers, importers and distributors, who will already be disinclined to highlight evidence of serious health effects that could affect the public perception of their chemical or product.

12) Irritant asthmagens (A.4.2.1.3.1)

- The proposal requires disclosure of chemical asthmagens that cause respiratory sensitization, but does not require disclosure of chemicals that produce bronchospasm without a sensitization (immune) effect, also known as reactive airway dysfunction syndrome (RADS), or acute-onset, irritant induced asthma (IIA).

Bronchospasm induced by inhalation of vapors, gas, fumes or particles is an important and potentially serious form of occupational asthma that is typically characterized by the following:

  - Absence of preexisting asthma symptomatology;
  - Onset of asthma symptoms after a single specific inhalational exposure or accident;
  - Exposure to an irritant vapor, gas, fume, or smoke in very high concentration;
  - Onset of asthma symptoms within minutes to hours and <24 h after the exposure;
  - Presence of airflow limitation with a significant bronchodilator response or nonspecific bronchial hyperresponsiveness to histamine/methacholine; and,
  - Exclusion of other pulmonary disorders that can explain the symptoms or simulate asthma. [(5)]

Cal/OSHA recommends that this type of occupational asthma be included as a health effect in the HCS classification and labeling requirements.

Please see the attached Appendix 1, which details Cal/OSHA's concerns with HCS Appendices A and B and, in some cases, recommends alternative language.

Thank you for considering comments from Cal/OSHA.

Sincerely,

Eric Berg

Eric Berg, Deputy Chief of Health

Attach: California Senate Bill 193-2014, California Senate Bill 258-2017, Title 8 California Code of Regulations Section 5194

[5] Vandenplas et al (2014). EAACI Position Paper: Irritant-induced Asthma. *Allergy 69* 1141-1153. (Available: EAACI position paper: irritant-induced asthma - Vandenplas - 2014 - Allergy - Wiley Online Library). Accessed April 29, 2021.