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RE: Globally Harmonized System (GHS) Update to the Cal/OSHA Hazard Communication Standard (CCR, Title 8, § 5194)

On behalf of the San Francisco chapter of Physicians for Social Responsibility (SF PSR), I appreciate the opportunity to submit written comments for the advisory committee meeting that will be held on April 9, 2013. The purpose of the meeting is to discuss draft language for subsections of the Cal/OSHA Hazard Communication Standard (Section 5194) that differs from language in the federal Hazard Communication Standard. SF PSR is pleased that Cal/OSHA is initiating a rulemaking process to ensure that revision of Hazard Communication Standard to incorporate the GHS does not weaken protections for workers, and to solicit input from stakeholders.

My name is Dr. Julia Quint. I am a member of the SF PSR Steering Committee. I also serve on a number of other advisory committees that have a toxic chemicals focus, including the Science Guidance Panel of the California Biomonitoring Program, the DTSC Green Ribbon Science Panel, and the World Trade Center Scientific and Technical Advisory Committee. I have served on several National Academy of Sciences committees, including a recent IOM committee that reviewed the chemical-disease links and other information in the Department of Labor's Site Exposure Matrix Database. I am retired from the California Department of Public Health and am a former Research Scientist and Chief of the Hazard Evaluation System and Information Service (HESIS), in the CDPH Occupational Health Branch. The following comments are submitted on behalf of SF PSR, only, and are not intended to represent the views of other organizations with which I am affiliated.

General Comments

SF PSR supports the adoption of Cal/OSHA's draft language in Section 5194 that differs from the language in the 2012 federal Hazard Communication Standard. As detailed below under Specific Comments, the proposed draft language is consistent with GHS principles, ensures greater protections for workers than language in the federal standard, and is consistent with the actions taken by the California Legislature to prevent occupational illness and disease after workers were made sterile from exposure to dibromochloropropane or DBCP in the late seventies. Adoption of Cal/OSHA's draft language should not have a significant impact on interstate commerce. The California standard has always been different than the federal standard, and the draft language is essentially the same as the language in the existing California standard.

Because of the unfortunate DBCP incident, California learned some important lessons about exposure to toxic chemicals in the workplace. California learned that: (1) a chemical could cause

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“silent” chronic health damage such as sterility and cancer that is difficult to link to workplace exposures; (2) scientific information published 17 years earlier could have prevented the health damage but did not reach the employer and workers; and (3) most physicians and other health care practitioners are not trained to identify work-related illness and disease.

In response, the California Legislature established the Hazard Substances Information and Training Act to ensure that employers and workers had access to information on the health hazards of chemicals, the Hazard Evaluation System and Information Service (HESIS) to translate scientific information into practical language and provide “early warnings” to prevent work-related chronic disease, and the University of California Centers for Occupational and Environmental Health to train physicians in occupational and environmental medicine.

SF PSR recognizes the importance of harmonizing the classification and labeling of chemical hazards and acknowledges the many improvements in the Hazard Communication Standard that should result from incorporating the GHS into the standard. However, based on our review and analysis, we have concluded that failure to adopt the draft language proposed by Cal/OSHA into subsections of 5194, or adopting the intact federal standard through the Horcher process, is inconsistent with the early actions taken by the California Legislature to prevent occupational illness and disease related to exposures to toxic chemicals. It also will have a negative impact on the progress California is making in harmonizing protections against toxic chemical exposures for workers, communities, consumers, and the environment through overlapping requirements in the labor code, the draft safer alternatives to consumer products regulation, the safe cosmetics act, and the safe drinking water act or Proposition 65.

Specific Comments and Recommendations

- 1. Retain the Director’s List of Hazardous Substances pursuant to Labor Code Section 6382 and the other source lists under “Hazard Determination” [(d)(3)(A)-(C)] in the current California Hazard Communication standard. Specify these lists in the definition of “hazardous chemical” and in the section on “Hazard Classification” in the revised Section 5194. Require manufacturers and importers to establish as “hazardous” chemicals on the Director’s List and on the other existing source lists.**

The Director’s List and existing source lists comprise the following:

- (a) IARC List of Carcinogens
- (b) 29 CFR part 1910, subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration (OSHA)
- (c) NTP Report on carcinogens
- (d) ACGIH TLVs
- (e) EPA’s designated chemicals pursuant to the federal Clean Water Act and Clean Air Act, which have known, adverse human health risks
- (f) Cal/OSHA PELs
- (g) Substances designated by the Director of Food and Agriculture as restricted materials pursuant to section 14004.5 of the Food and Agriculture Code which have known, adverse human health risks
- (h) HESIS Hazard Alerts

Retaining the current requirement in section 5194 that manufacturers establish chemicals on the list as hazardous will help to ensure:

- ◆ Adherence to the GHS principle that *protection offered to workers should not be reduced as a result of harmonizing the classification and labeling systems* (GHS 1.1.1.6)
- ◆ Consistent classification of chemicals that have been identified as carcinogens by authoritative organizations, thus helping to reduce workers' cancer risks.

Under the OSHA standard, manufacturers and importers *may* use the IARC and NTP carcinogen lists to classify chemical hazards (emphasis added). If some manufacturers use the criteria in the standard to conduct weight of evidence determinations and others use the NTP and IARC lists, this could result different classifications for the same chemicals. It is unclear how such classification differences would be resolved. The federal standard refers to the use of "expert judgment" in conducting classifications, but "expertise" is not defined.

The EU GHS-based Classification and Labeling (C&L) legislation does not require manufacturers to use authoritative lists to classify chemical hazards. A search of the EU C&L Inventory database for harmonized sulfuric acid notifications showed that only 80 of the 2020 notifications classified sulfuric acid as a human carcinogen (<http://clp-inventory.echa.europa.eu/SummaryOfClassAndLabelling.aspx?SubstanceID=9111&HarmOnly=no?fc=true&lang=en>). IARC listed sulfuric acid as a human carcinogen (Group 1) in 1992. The EU European Chemicals Agency (ECHA) provides scientific oversight for implementation of the C&L legislation and other chemicals legislation, and helps companies comply with the legislation, but does not review the submitted notifications for accuracy.

- ◆ Consistent classification of chemicals that cause respiratory and dermal sensitization. The ACGIH uses a "SEN" notation to identify sensitizers. The ACGIH TLV list is one of the few sources for this information.
- ◆ Inclusion of Cal/OSHA PELs, which are lower than OSHA PELs for the same chemicals, and chemicals that are uniquely regulated by Cal/OSHA that do not have OSHA PELs or ACGIH TLVs. 1-Bromopropane (n-propyl bromide), and the glycol ethers, ethylene glycol dimethyl ether (1,2-dimethoxyethane) and ethylene glycol diethyl ether (1,2-diethoxyethane) are examples.
- ◆ Inclusion of emerging or unappreciated chemical hazards identified by HESIS. This is consistent with the intent of the California Legislature to take early action to prevent new DCBP incidents or chronic disease. HESIS Hazard Alerts or Health Hazard Advisories on diacetyl (2006); N-methyl pyrrolidone (2006); 1-bromopropane (n-propyl bromide) (2003); and diesel engine exhaust (2002) warned of lung disease, developmental and reproductive harm, nerve damage, and cancer, and identified safer alternatives to the chemical hazards.
- ◆ Less time and resources spent identifying and evaluating studies and conducting weight of evidence classifications for manufactures and importers. Simplifies compliance with the standard.

- ◆ Less potential liability for manufacturers and importers who are required to consider the full range of available scientific literature and other evidence concerning potential hazards when classifying health hazards.
- ◆ Assurance for physicians who are not trained in occupational medicine that the chemical-disease associations are based on sound science. This may increase the likelihood that they will take occupational and environmental histories from their patients.
- ◆ Increased transparency since the scientific evaluations which are the basis for adding chemicals to authoritative lists are accessible, are developed according to established guidelines, have undergone peer review, and in some cases, public review.
- ◆ Enforcement of the standard would be simpler, and more transparent and consistent, if the classifications are based on authoritative lists as opposed to individual, criteria-based weight of evidence determinations that would be difficult to retrieve and review.

Recommendation

1. Update the Director's List of Hazardous Substances to include the HESIS Hazard Alerts and other required information.
 2. Add the Proposition 65 List to the Director's List of Hazardous Substances to provide an authoritative source for identifying reproductive and developmental toxicants.
 3. Add "DSEN" and "RSEN" to chemicals on the Cal/OSHA PEL list and ACGIH TLV list to identify dermal and respiratory sensitizers, respectively.
 4. Add the health basis for the Cal/OSHA PELs to aid in the classification of the health hazards.
- 2. Retain the language regarding statistically significant evidence from one study in the definition of "health hazard" in Section 5194.**

Retaining the one study language in Section 5194 is important because it is consistent with (a) the OSHA regulation pertaining to carcinogens; (b) EPA risk assessment guidelines for neurotoxicants, carcinogens, reproductive toxicants, and developmental toxicants; and (c) IARC's classification of carcinogens. Authoritative organizations, including NIOSH, Cal/EPA OEHHA, and US EPA have classified chemicals as health hazards based on evidence from a single study.

- ◆ The OSHA regulation, Identification, Classification, and Regulation of Carcinogens (29 CFR 1990.143) states:

*Positive human studies. Positive results obtained in **one or more** human epidemiologic studies will be used to establish the qualitative inference of carcinogenic hazards to workers.*

*Positive animal studies. Positive results obtained in **one or more** experimental studies conducted in one or more mammalian species will be used to establish the qualitative*

inference of carcinogenic hazard to workers. Arguments that positive results obtained in mammalian species should not be relied upon will be considered only if evidence is presented which meets the criteria for consideration specified in 1990.144(c) or 1990.144(f).

◆ EPA's risk assessment guidelines for neurotoxicants state:

Sufficient experimental animal evidence/limited human data

*The minimum evidence necessary to judge that a potential hazard exists would be data demonstrating an adverse neurotoxic effect in a **single** appropriate, well-executed **study** in a **single experimental animal** species.*

◆ EPA's risk assessment guidelines for developmental toxicants state:

Sufficient Experimental Animal Evidence/Limited Human Data

*The minimum evidence necessary to judge that a potential hazard exists generally would be data demonstrating an adverse developmental effect in a **single**, appropriate, well-conducted study in a **single** experimental animal species.*

◆ EPA's risk assessment guidelines for reproductive toxicants state:

Sufficient Experimental Animal Evidence/Limited Human Data

*The minimum evidence necessary to determine if a potential hazard exists would be data demonstrating an adverse reproductive effect in a **single** appropriate, well-executed study in a **single** test species.*

◆ IARC's Preamble

*Sufficient evidence of carcinogenicity in animals: The Working Group considers that a causal relationship has been established between the agent and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms in (a) two or more species of animals or (b) two or more independent studies in one species carried out at different times or in different laboratories or under different protocols. An increased incidence of tumours in both sexes of a **single species in a well- conducted study**, ideally conducted under Good Laboratory Practices, **can also provide sufficient evidence.***

*A **single study** in one species and sex might be considered to provide sufficient evidence of carcinogenicity when malignant neoplasms occur to an unusual degree with regard to incidence, site, type of tumour or age at onset, or when there are strong findings of tumours at multiple sites.*

◆ Non-Positive Cancer Studies

OSHA (1990.143(c) -143(d)

Non-positive human studies. Positive results in human or mammalian studies generally will be used for the qualitative identification of potential occupational carcinogens, even where

non-positive results from human studies exist. Such non-positive results will be considered by the Secretary only if the studies or results meet the criteria set forth in 1990.144(a).

Non-positive animal studies. Positive results in one or more mammalian studies will be used for the qualitative identification of potential occupational carcinogens, even where non-positive studies exist in other mammalian species. Where non-positive and positive results exist in studies in the same species, the non-positive results will be evaluated.

The relationship of the information in 29 CFR 1990.143-144, Identification, Classification, and Regulation of Carcinogens, to the criteria and weight of evidence guidance in Appendix A of the 2012 federal standard Hazard Communication Standard is unclear.

◆ Minimum Evidence to Establish No Potential Hazard

EPA Risk Assessment Guidelines for Neurotoxicants

Animal Data

The minimum evidence needed to judge that a potential hazard does not exist would include data from an appropriate number of endpoints from more than one study and two species showing no adverse neurotoxic effects at doses that were minimally toxic in terms of producing an adverse effect. Information on pharmacokinetics, mechanisms, or known properties of the chemical class may also strengthen the evidence.

EPA Risk Assessment Guidelines for Reproductive Toxicants

Animal Data

The minimum evidence needed to determine that a potential hazard does not exist would include data on an adequate array of endpoints from more than one study with two species that showed no adverse reproductive effects at doses that were minimally toxic in terms of inducing an adverse effect. Information on pharmacokinetics, mechanisms, or known properties of the chemical class may also strengthen the evidence.

EPA Risk Assessment Guidelines for Developmental Toxicants

Animal Data

The minimum evidence needed to judge that a potential hazard does not exist would include data from appropriate, well-conducted laboratory animal studies in several species (at least two) which evaluated a variety of the potential manifestations of developmental toxicity and showed no developmental effects at doses that were minimally toxic to the adult.

Guidelines on classification of health hazards such as those developed by EPA, Cal/EPA OEHHA and other authoritative organizations are needed. This will help to ensure that application of the criteria in the standard and weight of evidence determinations are consistent, and do not result in conclusions about potential health hazards that have negative impacts on the health of workers.

◆ Examples of Health Hazard Classifications Based on Evidence From One Study

Chemical	Organization	Health Hazard	Reference Document
Epoxybutane	OEHHA	Respiratory	Chronic REL (cREL)
Toluene	OEHHA	Developmental	MADL
Propylene Oxide	NIOSH	Cancer	Current Intell. Bull (CIB)
Diesel Exhaust	NIOSH	Cancer	CIB
Methylene Chloride	NIOSH	Cancer	CIB
Toluene Diisocyanate	NIOSH	Cancer	CIB
Hexamethylene Diisocyanate	ACGIH	Respiratory	TLV Documentation
Hydrogen Cyanide	US EPA	Male Repro.	IRIS
Diethanolamine	OEHHA	Respiratory	cREL
Ethylene Oxide	NIOSH	Cancer	CIB
Napthalene	OEHHA	Respiratory	cREL

3. Retain the testing requirement in Section 5194 to ensure that ingredients in mixtures are identified prior to classification of the health hazards.

The statement in the federal standard that “no testing is required” is confusing since it implies that manufacturers and importers do not have to test mixtures to identify ingredients when they do not have existing test data. Identification of the ingredients in a mixture is essential for classifying the health hazards. It also is inconsistent with the requirement in Appendix B to use “test” methods to classify certain physical hazards. The GHS states that no testing is required to determine health hazards. This is different than stating that no testing is required.

For example, if a mixture contains xylene, which can contain up to 20% ethylbenzene (a carcinogen) as a contaminant, and there are no test data on the ethylbenzene content, the manufacturer should be required to test the xylene or the mixture before classification.

Unless the language in the federal standard is revised to “no *toxicity* testing” is required, or to the same language used in the GHS document, Cal/OSHA should retain the language currently in Section 5194 and ensure that it is clear that the requirement to test does not mean testing for health hazards.

4. Require warnings on SDSs and labels for all chemicals classified as carcinogens, including Category 2 carcinogens, when they are present at concentrations of 0.1% or greater.

Labels are the primary, and many times the only, means of communicating information about the health hazards or chemicals to workers in small businesses. In spite of the requirements of the Hazard Communication Standard, many small businesses such as auto repair shops, dry cleaners, and nail salon shops do not get SDSs from vendors from whom they purchase solvents and other chemical-containing products, and do not provide training on health hazards.

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In addition, Category 2 carcinogens are often upgraded to Category 1B carcinogens based on relevant data. The IARC Carcinogen List shows that the agency upgraded over 25 substances that were initially classified as “limited” evidence of carcinogenicity (2B) to “sufficient” evidence of carcinogenicity (2A) based on relevant data. This is equivalent to a GHS carcinogen classification change from Category 2 to Category 1B. Given the emerging nature of the science, it is important to ensure that workers are warned appropriately about cancer hazards and, to the extent possible, that labels for the same chemicals are consistent. As a result, it seems prudent to require manufacturers and importers to include cancer warnings on labels for all categories of carcinogens in addition to requiring warnings on SDSs.

5. Retain the three-month time frame for manufacturers to update labels.

Manufacturers have been complying with the three month time frame, and a compelling reason for extending the time frame to six months as not been presented. Since increasing the time frame to six months prolongs the time that known health hazards are communicated, it could increase potential risks of adverse health effects for workers. Given the serious consequences that could result, this important decision should be based on a sound rationale.

Respectfully,

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