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**Re: Globally Harmonized System (GHS) update
to Section 5194, Hazard Communication**

These comments submitted on behalf of California Rural Legal Assistance Foundation (CRLAF) are specific to the discussion draft presented at the DOSH Advisory Committee meeting and are intended to supplement comments CRLAF submitted prior to the meeting.

Source lists

It is critical to retain source lists because they provide an authoritative, transparent and consistent basis for including chemicals hazards on SDS' and are prepared by entities without commercial interest in continued use of any chemical. Source list reliance increases consistency rather than creating confusion as suggested by some industry representatives. Scientific evaluations which are utilized to add additional chemicals to source lists are accessible and developed according to established guidelines which have undergone peer review and sometimes public review. .

We feel that the modifications to sections 5194(d)(3) and (d)(4) in the proposed standard already submitted to the Standards Board are sufficient to bring the standard into GHS compliance. The additional language in the discussion draft specifying that chemicals listed "have met the total weight of evidence criteria . . ." seems unnecessary and should only be included if Federal OSHA insists that it is needed for conformity.

In addition, this is a unique opportunity to update the source lists by updating the Director's list to add HESIS Hazard Alerts and other required information, adding the Prop 65 lists for both reproductive and developmental toxins and carcinogens, adding DSEN and RSEN to chemicals on the Cal-OSHA PEL and ACGIH TLV lists identified as dermal and respiratory sensitizers, adding the health basis for Cal/OSHA PELs as recommended in comments by Dr. Quint and others. Additional sources/lists contained in the DTSC Safer Alternatives draft regulation should also be added.

One Positive Study Conducted in Accordance with Established Scientific Principles Should be retained in Definition of Health Hazard

We feel very strongly that the modification to section 5194(d)(2) included in the proposed standard already submitted to the Standards Board are sufficient to be consistent with GHS. Evidence from one positive, scientifically valid study should continue to be considered sufficient for establishing a health effect. Anything less will dangerously erode protections in California. As pointed out by DrQuint, other agencies, including USEPA, IARC and HESIS all have classified chemicals as causing health hazards based on results from single valid studies. In addition, for many chemicals only a single study may be available because toxicity testing is not required before marketing most

chemicals. It is also important to recognize that a negative study merely represents a lack of a positive finding. Lack of a positive finding may be due to an inadequate level of sensitivity of the study (size of test group or population exposed is too small to detect a statistically significant effect, level of exposure or range of doses tested is too low) or low level of susceptibility of a specific population or test species.

It is straightforward, not confusing, to provide full information to employers and workers in the health and physical hazards sections of the SDS worksheet. As Ron Espinoza of United Steelworkers stated at the advisory meeting, "I don't want (the SDS) to leave out things that might be significant for my health." It would, in contrast, add confusion to silo information for some chemical ingredients and health effects in a separate notation on the SDS because the SDS preparer has deemed that available studies do not provide sufficient weight of evidence for classification. We strongly oppose inclusion of language in Appendix A which allows chemical health effects information to be excluded from or merely "noted" on the SDS because an SDS preparer has deemed that available studies of possible health effects do not provide sufficient weight of evidence for classification of the chemical and health effects. This is too discretionary. Different SDS preparers will have widely different interpretations. If Appendix A is revised, it should be to provide more guidance, not less.

Additional Guidance in Appendix A

Appendix A should include the guidance detailed in the OSHA regulation, 29 CFR 1910.143-145, Identification, Classification, and Regulation of Carcinogens. Cal/OSHA should require that it be used to classify carcinogens that are not on the existing source lists (e.g., IARC, NTP, Cal/OSHA, OSHA) that CRLAF recommends be kept in the Standard. The regulation specifies the minimum human and animal evidence needed to determine if a chemical should be classified as a carcinogen, includes guidance on how to weigh evidence from non-positive studies, and specifies the criteria that must be met for non-positive studies to be considered.

Appendix A should also include EPA guidance for classifying neurotoxicants, developmental toxicants, and reproductive toxicants. The guidance describes what constitutes sufficient human evidence, specifies the minimum animal evidence needed to identify that a hazard exists, and specifies the minimum evidence needed to determine that a hazard does not exist. Chemicals that the EU (the European Chemicals Agency) has classified into various GHS-based hazard categories such as respiratory and dermal sensitizers, lactation hazards, target organ toxicants could be included in Appendix A. Searching the EU Classification and Labeling (CL) Inventory database for harmonized classifications using GHS-based hazard classes identifies the chemicals. For example, searching the online CL Inventory database for harmonized category 1 respiratory sensitizers identifies 193 chemicals. The database identifies 28 chemicals that are classified as category 1A reproductive toxicants.

Health Hazard Definition --Inconsistent Clarify in Appendix A

The Cal/OSHA proposed definition of health hazard needs to be revised as follows:

...The term "health hazard" includes chemicals which are classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity;

reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard. The criteria, authoritative sources, and guidance for determining whether a chemical is classified as a health hazard are detailed in Appendix A to this section—Health Hazard Criteria.

The following sections from Appendix A are not consistent with the definition of health hazard and need to be revised as shown. Other sections should also be checked for consistency and may also need to be revised.:

A.0.3.5

Both positive and negative results are considered together in the weight of evidence determination. However, a single positive study performed according to good scientific principles and with statistically and biologically significant positive results ~~may justify~~ies classification.

A.6.4 Classification of carcinogenicity

A.6.4.1 Chemical manufacturers, importers and employers evaluating chemicals ~~may~~ shall treat the following sources as establishing that a substance is a carcinogen or potential carcinogen for hazard communication purposes in lieu of applying the criteria described herein:

Note: The rest of this section should be revised to include the source lists that we are recommending remain in the standard (see Appendix A).

A.7.2.3.1 Weight of Evidence Reproductive Toxicants

However, a single, positive study performed according to good scientific principles and with statistically or biologically significant positive results ~~may justify~~ should be used for-classification (See also A.7.2.2.3).

Note: This section also needs to be revised to include Prop 65 as authoritative source for classifying reproductive and developmental toxicants.

Statement Regarding Testing

It is crucial that manufacturers conduct adequate testing to detect and classify all chemicals in a mixture including contaminants in primary ingredients, such as ethyl benzene in xylene. This rulemaking provides an opportunity to update threshold concentrations to currently feasible detection limits which are much lower than detection limits feasible in 1980. It is also crucial that manufacturers conduct testing needed to determine physical hazards specified in Appendix B.

On principle we think that the acute and chronic toxicity all chemicals should be thoroughly evaluated before the chemical is allowed to be used in California. However, since the hazard communications standard does not currently require toxicity testing, we do not object to addition of the statement “This section does not require manufacturers, importers or employers to conduct toxicological or epidemiological testing of the chemical to determine how to classify its hazards.”

Classification of Mixtures

Full disclosure of the ingredients in chemical products, including contaminants is crucial to comprehensive hazard communication. This rulemaking provides an opportunity to update disclosure requirements to take advantage of state of the art sensitive levels of quantification. Disclosure should be required to the level of quantification for each component chemical with an added requirement that any ingredient at levels of at least 0.01% of mixtures be disclosed unless the

manufacturer can demonstrate that quantification at that level is not feasible. A low cutoff for disclosure is especially important for endocrine disrupting chemicals which have a U-shaped dose response curve, for chemicals with high acute toxicity, asthmagens, other sensitizers, carcinogens, and other toxicants that have no toxicity thresholds or low toxicity thresholds. A low cutoff is also important for developmental toxicants, chemicals which can cause drowsiness or narcosis and for chemicals in products with high exposure potential due to high volatility or large volume of use. Disclosure is needed both on the SDS and the label because many workers and small employers never see the MSDS. The level of disclosure required on labels and SDS should not be decreased to conform to federal OSHA regulations because this would weaken Cal-OSHA's right to know regulation, and is inconsistent with the goals of the GHS.

Requirement for three month timeframe for manufacturers to update labels should be modified to "promptly, within a maximum of three months"

If manufacturers are allowed to wait 6 months to update labels, as now allowed on the federal level, this will allow an additional 3 months where employers and workers are denied access to updated information on health effects. This could increase risk of potential adverse health effects and delay recognition of symptoms related to exposure and need to reduce exposure and seek medical treatment. Manufacturers have been complying with the three month timeframe for updating labels for decades so maintaining this requirement will not add an extra burden and it is needed for consistency with the GHS requirement for promptly updating materials..

The requirement for written procedures for manufacturers, importers or employers classifying chemicals should be retained

This requirement in 5194(d)(6) should be retained for transparency and consistency. If a manufacturer, importer or employer who must classify chemicals predominantly relies on authoritative lists this requirement will be a minimal burden.

This Rulemaking Provides an Opportunity for Needed Improvement in Language Access

Many workers in California in agriculture, construction and service industry jobs including nail salons, custodial work and car detailing have limited or no literacy in English. There is a pressing need for multi-lingual materials at a low literacy level with understandable pictographs. Thank you for your careful consideration of these comments.

Sincerely,



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