

This document contains suggested language to amend existing 8 CCR § 5194 (Hazard Communication) to address specific changes to 29 CFR 1910.1200 made by Federal OSHA. This is not a rulemaking proposal. This language will be discussed at the April 9, 2013, advisory meeting and will be made available on the Web for comments. The Division requests that any comments be provided prior to May 1, 2013, via email to Mike Horowitz at [mhorowitz@dir.ca.gov](mailto:mhorowitz@dir.ca.gov). Mr. Horowitz can also be contacted by phone at (510) 286-7009.

---

## Discussion Draft for Section 5194

### Topic 1: Source lists

The intent of this language is to ensure that the Labor Code mandate requiring California manufacturers, importers, and employers who prepare SDSs for California workplaces and commerce includes substances on the Director's List (LC 6380 et seq.) and other lists. These modifications are also intended to address how other weight-of-evidence determinations by recognized authoritative bodies, currently referenced in Section 5194 of Title 8 Cal. Code Regs., are to be incorporated into the weight-of-evidence classification system in the Globally Harmonized System, as described in Appendix A to 29 CFR 1910.1200, and as temporarily adopted on March 29, 2013, by the Occupational Safety and Health Standards Board as Appendix A to Section 5194. This is consistent with the GHS principle at 1.3.2.4.4 regarding previously classified chemicals.

- **Amend existing subsection (d)(3) to read:**

~~(3) The manufacturer, importer, or employer evaluating substances~~ Manufacturers, importers, and employers classifying chemicals shall treat any of the following sources as establishing that the ~~substances~~ chemicals listed in them ~~have met the total weight of evidence criteria as described in Appendix A for classification for the hazard upon which their listing is based:~~

(A) The list of hazardous substances prepared by the Director pursuant to Labor Code section 6382 and as promulgated in title 8, California Code of Regulations, section 339. The concentrations and footnotes which are applicable to the list shall be understood to modify the same substance on all other source lists or hazard determinations set forth in sections 5194(d)(3)(B)-5194(d)(5)(D).

(B) 29 CFR part 1910, subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration (OSHA).

(C) Threshold Limit Values for Chemical Substances in the Work Environment, American Conference of Governmental Industrial Hygienists (ACGIH) (latest edition).

The manufacturer, importer, or employer is still responsible for ~~evaluating~~ classifying and categorizing the hazards associated with the substances in these source lists in accordance with the requirements of ~~the standard~~ this standard and its appendices.

- **Amend existing subsection (d)(4) to read:**

~~(4) Manufacturers, importers, and employers evaluating substances~~ classifying chemicals shall treat any of the following sources as establishing that any ~~substance is a carcinogen or potential carcinogen for hazard communication purposes:~~ chemical listed has met the total weight of evidence criteria as 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) 29 CFR Part 1910, Subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration.

Note to (d)(4): The Registry of Toxic Effects of Chemical Substances published by the National Institute for Occupational Safety and Health indicates whether a substance has been found by NTP or IARC to be a potential carcinogen.

This document contains suggested language to amend existing 8 CCR § 5194 (Hazard Communication) to address specific changes to 29 CFR 1910.1200 made by Federal OSHA. This is not a rulemaking proposal. This language will be discussed at the April 9, 2013, advisory meeting and will be made available on the Web for comments. The Division requests that any comments be provided prior to May 1, 2013, via email to Mike Horowitz at [mhorowitz@dir.ca.gov](mailto:mhorowitz@dir.ca.gov). Mr. Horowitz can also be contacted by phone at (510) 286-7009.

-----

## **Topic 2: One positive study conducted in accordance with established scientific principles**

The intent of this language is to retain existing protection in the California regulation, which ensures that employers, employees, and health care providers are notified of all chemicals in a product that may pose a health hazard, even if the SDS preparer believes that there is an insufficient weight of evidence at the time of preparation of the SDS to require further classification. This would expand on a requirement OSHA incorporated in Appendix A to disclose "one positive study" for carcinogens and to ensure that the presence of all chemicals having an human health effect which may be adverse are disclosed on the SDS.

- **Amend 5194(d)(2) to read: (note, language regarding testing discussed in topic 3)**

(d)(2) Manufacturers, importers, or employers ~~evaluating substances~~ classifying chemicals shall identify and consider the full range of available scientific literature and other evidence concerning such the potential hazards. ~~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. For health hazards, evidence which is statistically significant and which is based on at least one positive study conducted in accordance with established scientific principles is considered to be sufficient to establish a hazardous effect if the results of the study meet the definitions of health hazards in this section. Appendix A to Section 5194 shall be consulted for the scope of classification of health hazards covered, and Appendix B to Section 5194 shall be consulted for the criteria to be followed with respect to the completeness of the evaluation, and the data to be reported classification of physical hazards. In addition, the manufacturer, importer, or employer classifying chemicals shall ensure that the identity and health effect for 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 evidence of a statistically significant health effect, and,

(B) the evidence is based on at least one positive study conducted in accordance with established scientific principles.

- **Amend OSHA Appendix A (to 29 CFR 1910.1200), as adopted in California (as Appendix A to Section 5194) to read:**

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 classification. Where available studies of possible health effects of a chemical are deemed by the SDS preparer to not provide sufficient weight of evidence for classification of the chemical, the SDS preparer shall nonetheless note on the safety data sheet the identity of the chemical and the health effect for those chemicals for which there are studies conducted in accordance with established scientific principles and which report statistically significant findings regarding a potential health effect.

- **Amend the definition of health hazard in subsection (c) to read:**

A substance chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees. The term "health hazard" includes ~~substances~~ chemicals ~~which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic system, and agents which damage the lungs, skin, eyes, or mucous membranes.~~ Appendix A provides further definitions and explanations of the scope of health hazards covered by this section,

This document contains suggested language to amend existing 8 CCR § 5194 (Hazard Communication) to address specific changes to 29 CFR 1910.1200 made by Federal OSHA. This is not a rulemaking proposal. This language will be discussed at the April 9, 2013, advisory meeting and will be made available on the Web for comments. The Division requests that any comments be provided prior to May 1, 2013, via email to Mike Horowitz at [mhorowitz@dir.ca.gov](mailto:mhorowitz@dir.ca.gov). Mr. Horowitz can also be contacted by phone at (510) 286-7009.

-----

~~and Appendix B describes the criteria to be used to determine whether or not a substance is to be considered hazardous for purposes of this standard~~ 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 for determining whether a chemical is classified as a health hazard are detailed in Appendix A to this section-- Health Hazard Criteria.

### **Topic 3: Statement regarding testing**

*The intent of this language is to codify the current policy of both Cal/OSHA and federal OSHA that the Hazard Communications Standard does not, in itself, require toxicological or epidemiological tests to be conducted to classify health hazards. Because manufacturers are required to classify all chemicals in a mixture (above certain threshold concentrations), chemical analysis may be required to determine the actual contents of a product. Also, Appendix B lists required test methods for determining certain physical hazards.*

- **Amend Section 5194(d)(2) to read:**

(d)(2) Manufacturers, importers, or employers evaluating substances classifying chemicals shall identify and consider the full range of available scientific literature and other evidence concerning such the potential hazards. 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.

- **Amend Appendix A to read:**

A.0.2.1 There is no requirement for toxicological or epidemiological testing of a chemical to determine how to classify its hazards.