

**Initial Statement of Reasons
Title 27, California Code of Regulations**

**Proposed Amendments to Article 6
Clear and Reasonable Warnings**

July 21, 2017



**California Environmental Protection Agency
Office of Environmental Health Hazard Assessment**

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Summary

The Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency that implements Proposition 65¹ and has the authority to promulgate and amend regulations to further the purposes of the Act. The Act requires businesses to provide a clear and reasonable warning before they knowingly and intentionally cause an exposure to a chemical listed as known to the state to cause cancer or reproductive toxicity². These proposed amendments to the regulations would further clarify the guidance OEHHA provides to businesses and the public concerning the warning requirements under Proposition 65.

Background - Problem to be Addressed by the Proposed Rulemaking

On August 30, 2016, the Office of Administrative Law (OAL) approved the regulatory amendments submitted by OEHHA for Article 6 Clear and Reasonable Warnings, Title 27 Cal. Code Regs., Sections 25600 – 25607.31³. The amended regulations will become operative on August 30, 2018, though businesses may use the new regulations now. Subsequent to the adoption of the August 2016 amendments, OEHHA has received a number of inquiries and has determined that clarification of certain provisions of these new regulations would be beneficial to the regulated community.

Purpose

Each proposed amendment to the warning regulations is discussed below.

§ 25600.1. Definitions.

“Authorized Agent”

The definition of “authorized agent” in subsection (b) was modified to provide clarification regarding the entities that can receive a notice and warning materials on behalf of a retail seller from a manufacturer, producer, packager, importer, supplier or distributor pursuant to Section 25600.2 and to clarify that any email or post office box used for such notices must be monitored. This modification is consistent with Section 25600.2, subsections (b) and (c), which include electronic methods for confirmation and renewal of the notice provided to the authorized agent for the retail seller. The proposed modification would add an electronic

¹ Health and Safety Code section 25249.5 et seq., The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as “Proposition 65”. Hereafter referred to as “Proposition 65” or “the Act”.

² Health and Safety Code section 25249.6

³ All further references are to sections of Title 27 of the California Code of Regulations unless otherwise stated

mailbox as an “authorized agent,” to the extent that mailbox is “monitored.” The term “monitored” was included in the definition to ensure that a person will open and review messages in the electronic mailbox for the person or entity designated as the authorized agent. It is important for retailers to ensure that they monitor their email box or post office box so that they timely receive notices from manufacturers and other businesses in the distribution chain.

“Label”

The definition of “label” in subsection (i) was modified to clarify that a display of written, printed, or graphic material may be “printed” directly on a product or its immediate container or wrapper. Thus, there is no requirement to place a separate label with the warning on the product if the warning is printed on the product or the immediate container or wrapper.

“Labeling”

The definition of “labeling” in subsection (j) was modified by adding a “package insert” as an example of “labeling.” The phrase “including tags at the point of sale or display of a product” was removed from the definition because it lacked clarity and did not conform to OEHHA’s intent in adopting the regulations. Shelf tags are a form of signage, not labeling. “Tags at the point of sale” lacked clarity and is not a clear and reasonable warning method for most product exposures as such tags would be unlikely to be associated with the products they are referring to.

“Sign”

The definition of “sign” in subsection (m) was modified by striking the phrase “requiring a warning” and replacing it with “for which the warning is being provided” for internal consistency with other provisions of the regulations and is not intended to change the purpose or intent of the provision.

§ 25600.2. Responsibility to Provide Consumer Product Exposure Warnings.

Subsection (b) was modified by replacing the phrase “affixing a label to the product bearing a warning” to “providing a warning on the product label or labeling” for clarity and for consistency. The phrase “providing a warning on the product label” is consistent with the definition of “label,” which has been clarified to provide that warning materials may be either printed on a product or affixed to the product or its immediate container or wrapper. The phrase “providing a warning” encompasses both printing and affixing. The term “labeling” was added because a business is not required to use the safe harbor warning methods in Subarticle 2 in order to comply with Section 25600.2. Subsection (b)(4) has been

modified to clarify that the “authorized agent for the retail seller” is the correct party to receive written notice pursuant to Section 25600.2. Subsection (c) was changed to clarify that the “authorized agent” refers to the authorized agent for the retail seller. In subsection (c)(1), the date by which a notice must be renewed and receipt of the notice confirmed by the retail seller’s authorized agent was modified to specify that the date for renewal and receipt of notice is “by no later than February 28, 2019.” This is six months from the operative date of the regulations; the specific date was unknown prior to the final adoption of the regulations.

§ 25601. Safe Harbor Clear and Reasonable Warnings – Methods and Content.

The term “seen” was added for consistency within Article 6 where the term “seen, read, and understood” is used, rather than “read and understood.” Ensuring that consumer product warnings are visible to a consumer is an important requirement for the provision of safe harbor warnings.

§ 25602. Consumer Product Exposure Warnings – Methods of Transmission.

In subsection (a)(3) the term “label” was changed to the phrase “warning on the label”. This change is consistent with the clarifying change in the definition of “label” in Section 25600(i) to include written, printed or graphic material that is printed on a product or its immediate wrapper or container.

In subsection (a)(4) the term “on-product” was replaced with the term “short-form” because the term “on-product” was confusing to some stakeholders. The new term describes the truncated warning content in Section 25603(b). The term “on-product” was confusing because it appeared to refer to a new warning *method* as opposed to warning *content*. The phrase “on the label” was added to clarify that the safe harbor method in subsection (a)(4) refers to a warning provided on a “label” as defined in Section 25600(i).

Subsection (b) was changed for consistency with the revised reference to “short-form” warning content in Section 25603(b).

Subsection (c) was changed to clarify that the safe harbor warning content in Section 25603(a) is required for a safe harbor catalog warning. The term “on product” was replaced by the term “short-form” for consistency with the other changes proposed in this rulemaking. The phrase “on the label” was added, for purposes of clarity and the phrase “as the on-product warning” was deleted for purposes of clarity and consistency.

Subsection (d) was modified for clarity. The term “shelf tag” was removed, and the defined term “sign” was retained because it includes shelf tags, which are a type of signage. The intent of this provision is to clarify situations in which alternative language warnings must be provided. Thus, a warning must be provided in an alternative language where other consumer information about that product is included on a sign or label in an alternative language. The existing language was not clear.

§ 25603. Consumer Product Exposure Warnings – Content.

In subsection (a)(2)(E), the reference to subsection (a)(2)(C) was stricken because the deletion of the phrase “chemicals including” applies only to warning content for a single chemical, and is thus not applicable to subsection (a)(2)(C). In subsections (b) and (c), the term “on-product” was replaced with “short-form” for consistency with other changes to the regulations. The phrase “on the product label” was added to clarify that the truncated warning may be used on a product label and is not required to be directly printed on the consumer product. Subsections (b)(2)(A)-(C) were modified for clarity by deleting “consumer products that cause” for consistency with the warning content provisions in subsection (a)(2).

§ 25607. Specific Product, Chemical and Area Exposure Warnings.

Subsection (a) was modified by adding the missing term “Section” before the section number. Subsection (b) was modified by striking the phrase “requiring a warning” and replacing it with “for which the warning is being provided” for internal consistency with other provisions of the regulations.

§ 25607.2. Food Exposure Warnings – Content.

In subsection (a)(6), the reference to subsection (a)(4) was stricken because the deletion of the phrase “chemicals including” applies only to warning content for a single chemical, and is thus not applicable to subsection (a)(4).

§ 25607.5. Food and Beverage Exposure Warnings for Restaurants – Methods of Transmission.

The term “non-alcoholic” was stricken from the caption for this section and in subsection (a) to clarify that the food and beverage warning may include exposures to listed chemicals in alcoholic beverages. The phrase “exposures to listed chemicals in” was added for clarity. Subsection (c) was added to specify that if alcoholic beverages are served or sold in a restaurant, warnings pursuant to Sections 25607.3 and 25607.4 must also be provided. This is because there are specific provisions of the regulations pertaining to warnings for exposures to

ethyl alcohol in alcoholic beverages and alcoholic beverages when associated with alcohol abuse, which are separately listed under Proposition 65.

§ 25607.6. Food and Beverage Exposure Warnings for Restaurants – Content.

The terms “non-alcoholic” and “not including alcoholic beverages,” were stricken from the caption for this section and from subsection (a) for consistency with Section 25607.5.

§ 25607.7. Prescription Drug Exposure and Emergency Medical or Dental Care Exposure Warnings.

OEHHA intended to retain subsection (a) of the existing regulation verbatim which provides that for prescription drugs the labeling approved or otherwise provided under federal law *and* the prescriber’s accepted practice of obtaining a patient’s informed consent complies with Subarticle 2. During the previous Article 6 rulemaking the word “and” was inadvertently replaced with “or” contrary to OEHHA’s intent. The modification reinstates the language of the September 2008 version of Article 6 consistent with this intent.

§ 25607.12. Furniture Product Exposure Warnings – Methods of Transmission.

In subsection (a)(1), the term “on a label” was added for consistency with other changes being made to these regulations discussed previously. The term “is” was stricken in subsections (a)(1)(A) and (a)(1)(B) for consistency with the change in subsection (a)(1).

§ 25607.13. Furniture Product Exposure Warnings – Content.

In subsection (a)(1), the term “on-product” was stricken for consistency with other changes being made to these regulations discussed previously. The phrase “on a label printed on or affixed to the furniture product” was added for clarity and consistency. The reference to Section 25607.12(a)(1) was stricken for consistency. In Section 25607.13(a)(2)(B), the term “and” was added to the warning notice content for clarity to denote that some furniture products can expose a person to both carcinogens *and* reproductive toxicants. The language in its current form incorrectly suggests that exposure to chemicals listed for only one endpoint is possible from furniture products. Additional, non-substantive changes were made to subsections (a)(2) and (a)(2)(B).

§ 25607.14. Diesel Engine Exposure Warnings (Except Passenger Vehicle, Pickup Truck, or Van Engines) – Methods of Transmission.

In the caption to this section and in subsection (a), “pickup truck” and “van” were added to clarify that the tailored warnings for diesel engine exposures do not apply to these vehicle types. The safe harbor warning methods of transmission for pickup trucks and vans are found in the Section 25607.16 Vehicle Exposure warnings.

§ 25607.15. Diesel Engine Exposure Warnings (Except Passenger Vehicle, Pickup Truck, or Van Engines) – Content.

In the caption to this section and in subsection (a), “pickup truck” and “van” were added to clarify that the tailored warnings for diesel engine exposures do not apply to these vehicle types. The safe harbor warning content for pickup trucks and vans are found in the Section 25607.17 Vehicle Exposure warnings.

§ 25607.16. Vehicle Exposure Warnings – Methods of Transmission.

Subsections(a), (a)(1) and (a)(2) were modified to clarify that the vehicle exposure warning methods in Section 25607.16 also apply to “pickup trucks” and “vans” that are passenger vehicles. This provision does not apply to commercial or other large vehicles which may have different types of exposures and exposure patterns.

§ 25607.17. Vehicle Exposure Warnings – Content.

Subsections (a) and (a)(3) were modified to clarify that the vehicle exposure warning content in Section 25607.17 also applies to “pickup trucks” and “vans” consistent with the reasoning stated above for Section 25607.16.

Necessity

Subsequent to the adoption of the August 2016 revision of Article 6, OEHHA has received a number of inquiries about certain provisions of the regulations and determined that certain sections of the regulations require clarification in advance of the August 2018 operative date. The proposed changes are necessary to add clarity and specificity for businesses preparing to comply with the revised Article 6 regulations.

Economic Impact Assessment Required by Gov. Code section 11346.3(b)

Creation or Elimination of Jobs within the State of California

The proposed regulatory action will not impact the creation or elimination of jobs within California. The amendments will simply clarify and add specificity to the existing regulations.

Creation of New Businesses or Elimination or Expansion of Existing Businesses within the State of California

The proposed regulatory action will not impact the creation of new businesses or the elimination or expansion of existing businesses within California. The amendments will simply clarify and add specificity to the existing regulations.

Benefits of the Proposed Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment

The proposed regulatory action will benefit California residents by further enabling businesses to better understand how to comply with the warning requirements such that warnings considered to be clear and reasonable are provided to Californians using consistent and uniform methodology and content. The action furthers the right-to-know purposes of the statute and therefore promotes public and worker health and safety.

Technical, Theoretical, and/or Empirical Study, Reports, or Documents Relied Upon

OEHHA did not rely on any technical, theoretical, and/or empirical studies, reports, or documents as part of this rulemaking.

Benefits of the Proposed Regulation

Regulated businesses are not required to comply with the warning methods and contents specified in Subarticle 2 of Article 6, but may voluntarily do so in order to receive the safe harbor benefit of the regulations. Regulated businesses will likely benefit from the proposed amendments because the amendments provide clarifying guidance concerning the provision of safe harbor warnings under Proposition 65. The health and welfare of California residents will likely benefit by increasing the public's ability to understand the warnings they receive for the various products they may choose to purchase or places they visit.

Reasonable Alternatives to the Regulation and the Agency's Reasons for Rejecting Those Alternatives

OEHHA has determined there are no reasonable alternatives to the proposed regulatory action that would carry out the purposes of the Act. The amendments simply clarify and add specificity to the existing regulations.

Reasonable Alternatives to the Proposed Regulatory Action that Would Lessen Any Adverse Impact on Small Business and the Agency's Reasons for Rejecting Those Alternatives

OEHHA has determined that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to the attention of OEHHA, including alternatives that would lessen any adverse impact on small business, would be as effective or less burdensome on small business. In addition, OEHHA has determined that the proposed regulatory action will not impose any mandatory requirements on small businesses. Proposition 65 expressly exempts businesses with less than 10 employees⁴ from the requirements of the Act.

Evidence Supporting Finding of No Significant Adverse Economic Impact on Business

The proposed regulatory action will not have a significant adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The action does not impose any new requirements upon private persons or businesses.

Efforts to Avoid Unnecessary Duplication or Conflicts with Federal Regulations Contained in the Code of Federal Regulations Addressing the Same Issues

Proposition 65 is a California law that has no federal counterpart. OEHHA has determined that the regulatory action does not duplicate and will not conflict with federal regulations.

⁴ Health and Safety Code section 25249.11(b).