

Proposition 65: OEHHA Proposes Revisions to Its Proposed Proposition 65 Warning Regulations

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On [March 25, 2016](#), the [California Office of Environmental Health Hazard Assessment \(OEHHA\)](#) [modified its November 27, 2015, proposed rule](#) that would repeal and replace the Proposition 65 (Prop 65) Article 6 regulations covering "clear and reasonable warnings" requirements. OEHHA states that the proposed changes are based on its response to the written comments it received on the proposed rule, and on oral comments provided during a January 13, 2016, public hearing. The modifications proposed are intended to clarify OEHHA's intent with the proposed regulations, and to ensure consistency throughout the regulations. Although there are some modest improvements, the substantive, and more controversial, elements of the regulations remain, which makes it more likely than not that such elements will be retained in the final version of the regulations.

Comments on the Proposed Rule are due by **April 18, 2016**.

General (Section 25600)

OEHHA proposes the following modifications:

- Section 25600(b) provides a two-year delayed effective date to allow businesses time to comply with new requirements. The regulation initially stated, in part: "A person may provide a warning that complies with this article prior to its two-year effective date." OEHHA is proposing to modify the language to clarify that a warning that complies with Article 6 that is provided before the two-year effective date "will be deemed to be clear and reasonable."
- Section 25600(c) allows an "interested party" to request OEHHA to adopt additional regulations that address exposures to listed chemicals in products or the environment, to the extent they are not already sufficiently covered by the regulations. OEHHA proposes to revise this section to clarify that a person may request the adoption of a warning method or content for a "specific product, chemical or area exposure warning" rather than a specific consumer product.
- Based on stakeholder comments, OEHHA proposes to remove Section 25600(d), which addresses when a person can provide information that is supplemental to a warning, from the general provisions of Subarticle 1 to the safe harbor provisions of Subarticle 2, Section

- Section 25600(e) [formerly numbered as (f)] addresses the sufficiency of warnings covered by court-ordered settlements or final judgments establishing a method or content for a consumer product or environmental warning. This section is proposed to be modified by striking the phrase "for a consumer product or environmental warning," in response to stakeholder comments. OEHHA also adds the word "warning" before "method" for clarity. Section 25600(e) now states: "A person that is a party to a court-ordered settlement or final judgment establishing a warning method or content is deemed to be providing a 'clear and reasonable' warning for that exposure for purposes of this article, if the warning fully complies with the order or judgment."

Definitions (Section 25600.1)

OEHHA proposes the following modifications:

- In the definition of "affected area," OEHHA is adding "listed" before "chemical" for clarity and the phrase "known to the state to cause cancer or birth defects or other reproductive harm" is being removed as being "unessential and redundant." OEHHA is proposing to change the term "is at a level that requires a warning" to "can occur at a level that requires a warning" for consistency with the rest of the regulation.
- OEHHA is adding the phrase "producers, packagers, importers" to the definition of "authorized agent" for internal consistency; this change is being made throughout the regulation.
- OEHHA proposes to add a new term "consumer information" for clarity: "'Consumer information' includes, but is not limited to, warnings, directions for use, ingredient lists, and nutritional information. 'Consumer information' does not include the brand name, product name, or product advertising."
- OEHHA also proposes to add a new term "consumer product" for clarity: "'Consumer product' means any article, or component part thereof, including food, that is produced, distributed, or sold for the personal use, consumption or enjoyment of a consumer."
- In the definition of "retail seller," OEHHA proposes to add the phrase "or otherwise provides" after "sells" to cover the distribution of consumer products to consumers. OEHHA is proposing to remove the phrase "including foods" as redundant in light of the definition of consumer products that already incorporates foods. OEHHA proposes to change the term "purchasers" to "consumers" here and throughout the regulation for internal consistency.

Responsibility to Provide Consumer Product Exposure Warnings (Section 25600.2)

Section 25600.2 sets forth the circumstances under which the manufacturer, producer, packager, importer, supplier, or distributor has primary responsibility for providing the warning, and the more limited circumstances when the retail seller is responsible for providing the warning. OEHHA

proposes the following modifications:

- In Section 25600.2(b) OEHHA proposes, for consistency, to add "supplier" to those parties that may be required to comply with this section. The addition of "supplier" is proposed to be added to other sections (e.g., 25600.2(e)(5)), also for consistency.
- Section 25600.2(b) provides the conditions when a party required to comply with warning requirements can satisfy that responsibility by providing a written notice directly to the authorized agent for a retail seller. OEHHA is proposing to modify Section 25600.2(b)(3) by removing the requirement that a company can offer to provide warning materials at no charge. OEHHA states: "Based on comments received, OEHHA believes that the manufacturer, producer, packager, importer, supplier or distributor should provide the warning materials to the retailer unless the parties agree otherwise pursuant to subsection (i) [formerly (h)]." The phrase "and warning language for products sold on the Internet" was added to clarify the responsibility to provide warning language for consumer products sold online."
- For consistency, OEHHA proposes to revise Section 25600.2(b)(4) to include "producer, packager, importer, supplier or distributor" in addition to manufacturer. OEHHA also proposes to revise this subsection to clarify that confirmation of receipt of the notice must be provided "electronically or in writing." OEHHA states that it is proposing this change in response to stakeholder requests for the ability to provide electronic confirmation of receipt.
- OEHHA proposes to renumber and subdivide Section 25600.2(b)(5) into two paragraphs for clarity. The new subparagraph (c)(1) clarifies that the renewed notice to be provided to the authorized agent for a retail seller must be confirmed electronically or in writing within six months (previously 180 days) during the first year after the effective date of the regulation and annually thereafter. In the new subparagraph (c)(2), OEHHA is proposing to strike the term "new" and replace it with the phrase "different or additional" to clarify when an additional renewal notice is required under the subsection.
- In Section 25600.2(d) [formerly numbered as (c)], OEHHA is clarifying that the retail seller is responsible for posting and maintaining warning materials, including warnings for products sold over the Internet, that it receives pursuant to Sections 25600.2(b) or (c).
- Section 25600.2(e) [formerly numbered as (d)] describes the specific conditions when a retail seller is responsible for providing the warning.
 - Section 25600.2(e)(2) [formerly numbered as (d)(2)] initially stated: "The retail seller has knowingly and intentionally introduced a listing chemical into the product, or caused a listed chemical to be created in the product." For alignment with the relevant statutory framework, OEHHA states it is proposing to remove the phrase "and intentionally" and adding "knowingly" before "caused..."
 - OEHHA proposes to modify Section 25600.2(e)(4) [formerly numbered as (d)(4)] by removing the offer to provide warning materials consistent with the change in 25600.2(b)(3). For clarity, OEHHA also added the term "or displaying" to "conspicuously posting," when describing when a retail seller has received warning requirements and sold the product "without conspicuously posting or displaying those warning materials."

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- Section 25600.2(f) [formerly numbered as (e)] describes when a retail seller has "actual knowledge" of the potential consumer product exposure requiring the warning, and that there is no manufacturer, producer, packager, importer, supplier, or distributor of the product who is a "person in the course of doing business" under Section 25249.11(b) of the Act, and has designated an agent for service of process in California, or has a place of business in California. In response to stakeholder requests for an extension of the time period in which a retail seller is deemed to have "actual knowledge" of an exposure, OEHHA proposes to allow five (5) business days, rather than two (2).
 - OEHHA proposes to modify Section 25600.2(g) [formerly numbered as (f)] to clarify that a retail seller must "promptly" provide the information required in this section. OEHHA states it is proposing this change to require action on behalf of the retail seller in response to the request.
 - In Section 25600.2(i) [formerly numbered as (h)], OEHHA proposes to clarify that responsible parties may enter into a written agreement with the retail seller that allocates responsibility differently, provided that the consumer receives a compliant warning prior to exposure.

Safe Harbor Clear and Reasonable Warnings -- Methods and Content (Section 25601)

Section 25601 describes when a warning meets the requirements set forth in these regulations, including the significant and controversial provision that the warning must include the name of one or more of the listed chemicals for which the warning is being provided.

In response to several comments on the scope and content of this Section, OEHHA proposes the following modifications:

- OEHHA proposes to modify Section 25601(c) to clarify that any one of the listed chemicals for which the person has determined a warning is required can be included in the warning and that if the warning is for more than one endpoint, then one or more chemicals for each endpoint must be included in the warning unless the named chemical is listed for both endpoints. In response to stakeholder comments, OEHHA is proposing to remove the phrase "to the extent an exposure to that chemical is at a level requiring a warning."
- OEHHA proposes to add a new subsection (d) to Section 25601 to clarify how a consumer product exposure warning must be provided. The proposed subsection, which mirrors the existing regulations, states: "Consumer product exposure warnings must be prominently displayed on a label, labeling, or sign, and must be displayed with such conspicuousness as compared with other words, statements, designs or devices on the label, labeling, or sign, as to render the warning likely to be read and understood by an ordinary individual under customary conditions of purchase or use." OEHHA states it is proposing this provision to provide safe harbor guidance regarding consumer product exposure warnings.
- OEHHA proposes to add a new subsection (e) to Section 25601 to clarify how an environmental exposure warning must be provided. The proposed subsection states: "Environmental exposure warnings must be provided in a conspicuous manner and under such conditions as to make the warning likely to be seen, read, and understood by an ordinary individual in the course of normal daily activity." OEHHA states it is proposing this

provision to provide guidance regarding safe harbor environmental product exposure warnings.

- OEHHA proposes to add subsection (f) to Section 25601, which is language that previously appeared at 25600(d) regarding providing information supplemental to a warning. OEHHA also proposes to clarify the types of supplemental information that may be provided in a warning, stating: "The warning may contain information that is supplemental to the warning content required by this article only to the extent that it explains the source of the exposure or provides information on how to avoid or reduce exposure to the identified chemical or chemicals."

Consumer Product Exposure Warnings -- Methods of Transmission (Section 25602)

Prop 65 regulations currently provide several methods of transmission for warning messages, including signs, notices, stickers, or labels. Section 25602 proposes to expand the list of acceptable methods for providing a warning for an exposure to a listed chemical from a product to incorporate warnings via electronic means (*i.e.*, allow a product-specific warning to be provided via any electronic device or process that automatically provides the warning to the purchaser prior to or during the purchase of the product, without requiring the purchaser to seek out the warning). OEHHA now proposes the following modifications:

- **Posted Sign, Shelf Tag, or Shelf Sign:** Section 25602(a)(1) describes the requirements for a product-specific warning on a shelf tag or on a shelf sign for the consumer product at each point of display of the product. OEHHA proposes to add the term "posted sign" to this type of warning. OEHHA is proposing to eliminate language regarding specific type size and instead rely upon the new language in Section 25601(d), discussed above, with regard to the prominently displayed and conspicuous warning requirements.
- **Label:** Regarding labels that comply with the content requirements in Section 25603(a), OEHHA is proposing to eliminate language regarding specific type size and instead rely upon the new language in Section 25601(d), discussed above, with regard to the prominently displayed and conspicuous warning requirements.
- **Short Version On-Product Label:** OEHHA is not proposing any changes to Section 25602(a)(4) that would allow an on-product label that complies with the content requirements in Section 25603(b). OEHHA continues to propose that the entire warning must be in a type size no smaller than the largest type size used for other consumer information on the product, and in no case shall the warning appear in a type size smaller than 6-point type.
- **Internet Purchases:** For internet purchases, Section 25602(b) currently provides that the warning message must: (1) be provided by a clearly marked hyperlink on the product display page, or otherwise prominently displayed to the purchaser before the purchaser completes his or her purchase of the product; (2) use the word "**WARNING**" on the product display page; and (3) ensure the warning is in a type size no smaller than the largest type size used for other consumer information on the page. OEHHA is proposing to modify Section 25602(b) to: (1) clarify that for products sold on the Internet the warning must either be included on the product display page or provided as a clearly marked hyperlink on the product display page or otherwise displayed "prior to completing the purchase;" (2) remove the reference to type size

consistent with the addition of the new Section 25601(d); and (3) add language to clarify that if the product has an on product label, the website warning can use the same warning content.

- **Catalog Purchases:** With regard to Section 25602(c) warning requirements for catalog purchases, OEHHA is proposing, in response to stakeholder comments, language to clarify that if the product has an on-product label, the catalog warning can use the same warning content. OEHHA also proposes to remove the reference to type size consistent with the addition of the new Section 25601(d).

Consumer Product Exposure Warnings -- Content (Section 25603)

Section 25603 contains some of the most significant proposed revisions regarding the mandatory elements required for a warning to be considered "clear and reasonable," including the warning symbol, the "WARNING" signal word, and the requirement that the warning state: "This product *can expose you to* [name of one or more chemicals], a chemical known to the State of California to cause [cancer or birth defects or other reproductive harm]. For more information go to www.P65Warnings.ca.gov/product." (Emphasis added).

OEHHA now proposes the following modifications:

- OEHHA states it is proposing to modify Section 25603(a)(2)(A) and (B) for "clarity and readability." Specifically, OEHHA proposes the new warning requirement language, which allows a warning that a product contains chemicals "such as" [name of one or more chemicals]:
 - For exposures to listed carcinogens, the warning would be: "This product can expose you to chemicals such as [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov/product."
 - For exposures to listed reproductive toxicants, the warning would be: "This product can expose you to chemicals such as [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov/product."
- In Section 25603(a)(2)(C), OEHHA proposes to clarify those situations in which a warning is required for multiple chemicals that each cause a different toxicity endpoint. For exposures to both listed carcinogens and reproductive toxicants, the warning would be: "This product can expose you to chemicals such as [name of one or more chemicals] which is [are] known to the State of California to cause cancer, and [name of one or more chemicals] which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/product."
- OEHHA proposes to add a new Section 25603(a)(2)(D) to clarify the situation in which a warning is required for a chemical that causes both toxicity endpoints. For exposures to a chemical that is listed as both a carcinogen and a reproductive toxicant, the warning would be: "This product can expose you to chemicals such as [name of one or more chemical], which is [are] known to the State of California to cause cancer and birth defects or other

Environmental Exposure Warnings -- Methods of Transmission and Content (Sections 25604 and 25605)

Sections 25604 and 25605 generally retain the same requirements for the methods of transmission for environmental exposure warnings, with some updates to reflect changes in technology. OEHHA proposes the following modifications:

- In response to stakeholder comments concerning adequacy of the safe harbor environmental exposure provisions, OEHHA is proposing to modify Section 25604 to more clearly state that the requirements in this section relate to transmitting an environmental exposure warning. OEHHA also proposes to add the following language: "For indoor environments or outdoor spaces with clearly defined entrances, in which case the warning specified under subsection (a)(1) must be used."
- OEHHA proposes to delete the provision at 25604(a)(1)(B) that the warning "clearly identify the area for which the warning is being provided, including the location and source or exposure," and instead add Sections 25604(a)(2)(A) and 25604(a)(3)(A) that the warning "clearly identify the source of the exposure."
- OEHHA proposes to add to Sections 25605(a)(3), (a)(4), and (a)(5) to clarify that a description of the exposure source should be included in the warning. The warning language also has been modified to include the "such as [name of one or more chemicals]" discussed above.
- OEHHA proposes to add a new Section 25605(a)(6) to clarify the situation in which a warning is required for a listed chemical that causes both toxicity endpoints. For exposures to a chemical that is listed as both a carcinogen and a reproductive toxicant, the warning would be: "[Name of one or more exposure source(s)] in this area can expose you to chemicals such as [name of one or more chemical], which is [are] known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/environmental."

Occupational Exposure Warnings (Section 25606)

The proposed Section 25606 warnings regarding the methods of transmission and content for occupational warnings is the same as that set forth in prior proposed rules. OEHHA states it has modified Section 25606 "for clarity and readability." Specifically, OEHHA proposes to replace the term "chemical in question" with "listed chemical" and adds the word "warning" in "complies with all warning information" to clarify the type of information required.

Specific Product, Chemical and Area Exposure Warnings (Sections 25607-25607.29)

Proposed Sections 25607 through 25607.29 provide tailored methods for transmission of warnings and warning language for the following products, chemicals, and area exposures:

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- Food (including dietary supplements);
 - Alcoholic beverages;
 - Food and non-alcoholic beverages in restaurants;
 - Prescription drugs;
 - Dental care and emergency medical care;
 - Raw wood;
 - Furniture;
 - Diesel engines;
 - Passenger vehicles or off-road vehicles;
 - Recreational vessels;
 - Parking garages;
 - Amusement parks;
 - Petroleum products;
 - Service stations and vehicle-repair facilities; and
 - Designated smoking areas.

OEHHA is proposing several changes to these provisions, some of which are consistent with other modifications discussed above (e.g., removing references to specific warning type size), while others are related to specific exposure scenarios (e.g., adding an additional caution, "Do not idle the engine except as necessary," to diesel engine exposure warnings).

Commentary

Most of the changes proposed are intended to clarify the rule or enhance consistency. Some of the proposals improve the requirements, including the removal of specific type size warning requirements (but for short version on-product labels), the extension of the time period in which a retail seller is deemed to have "actual knowledge" of an exposure, and the warning language that a product can expose one to a chemical *such as* [name of one or more chemicals], which helps effectuate the requirement that the warning need only include "one or more of the listed chemicals for which the person has determined a warning is required." In other respects, the proposal reflects a stubborn insistence upon the earlier proposal, with no change in sight.

OEHHA is providing a brief comment period, with comments to be submitted by **April 18, 2016**. Once the regulations are issued in final, responsible entities will have two years to come into compliance, but may need to start preparing for fairly immediately, considering production and distribution chain

challenges and logistics. Companies, thus, should review carefully the proposal and how the significant changes to the warning requirements will affect cost and compliance capabilities.

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