

**INITIAL STATEMENT OF REASONS  
TITLE 27, CALIFORNIA CODE OF REGULATIONS  
PROPOSED REPEAL OF ARTICLE 6 AND  
ADOPTION OF NEW ARTICLE 6  
REGULATIONS FOR CLEAR AND REASONABLE WARNINGS**

**November 27, 2015**

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

**Table of Contents**

Summary.....5

Background.....6

Subarticle 1: General.....10

    § 25600 General.....10

    § 25600.1 Definitions.....14

    § 25600.2 Responsibility to Provide Consumer Product Exposure Warnings .17

Subarticle 2: Safe Harbor Methods and Content.....22

    § 25601 Safe Harbor Clear and Reasonable Warnings  
    – Methods and Content.....23

    § 25602 Consumer Product Exposure Warnings – Methods of Transmission 24

    § 25603 Consumer Product Exposure Warnings – Content.....27

        Warning Symbol .....27

        Signal Word “WARNING” .....28

        Change in Language from “Contains” to “Can Expose” .....29

        OEHHA URL.....30

    § 25604 Environmental Exposure Warnings – Methods of Transmission .....31

    § 25605 Environmental Exposure Warnings – Content.....32

    § 25606 Occupational Exposure Warnings .....33

    § 25607 Specific Product, Chemical and Area Exposure Warnings.....33

    § 25607.1 Food Exposure Warnings – Methods of Transmission .....34

    § 25607.2 Food Exposure Warnings – Content.....34

    § 25607.3 Alcoholic Beverage Exposure Warnings  
    – Methods of Transmission .....36

    § 25607.4 Alcoholic Beverage Exposure Warnings – Content .....38

    § 25607.5 Food and Non-Alcoholic Beverage Exposure Warnings for  
    Restaurants – Methods of Transmission .....38

    § 25607.6 Food and Non-Alcoholic Beverage Exposure Warnings for  
    Restaurants – Content .....39

    § 25607.7 Prescription Drug Exposure and Emergency Medical or Dental Care  
    Exposure Warnings .....39

    § 25607.8 Dental Care Exposure Warnings – Methods of Transmission .....39

    § 25607.9 Dental Care Exposure Warnings – Content.....40

    § 25607.10 Raw Wood Product Exposure Warnings – Methods of  
    Transmission .....41

§ 25607.11 Raw Wood Product Exposure Warnings - Content.....	41
§ 25607.12 Furniture Product Exposure Warnings – Methods of Transmission .....	42
§ 25607.13 Furniture Product Exposure Warnings – Content .....	42
§ 25607.14 Diesel Engine Exposure Warnings (Except Passenger Vehicle Engines) – Methods of Transmission .....	43
§ 25607.15 Diesel Engine Exposure Warnings (Except Passenger Vehicle Engines) – Content.....	43
§ 25607.16 Vehicle Exposure Warnings – Methods of Transmission.....	44
§ 25607.17 Vehicle Exposure Warnings – Content .....	44
§ 25607.18 Recreational Vessel Exposure Warnings – Method of Transmission .....	44
§ 25607.19 Recreational Vessel Exposure Warnings – Content.....	45
§ 25607.20 Enclosed Parking Facility Exposure Warnings – Method of Transmission.....	45
§ 25607.21 Enclosed Parking Facility Exposure Warnings– Content.....	45
§ 25607.22 Amusement Park Exposure Warnings - Method of Transmission	46
§ 25607.23 Amusement Park Exposure Warnings – Content .....	47
§ 25607.24 Petroleum Products Warnings (Environmental Exposures) – Methods of Transmission .....	47
§ 25607.25 Petroleum Products Warnings (Environmental Exposures) – Content.....	47
§ 25607.26 Service Station and Vehicle Repair Facilities Warnings (Environmental Exposures) – Methods of Transmission .....	48
§ 25607.27 Service Station and Vehicle Repair Facilities Warnings (Environmental Exposures) – Content.....	48
§ 25607.28 Designated Smoking Area Exposure Warnings (Environmental Exposures) – Method of Transmission .....	49
§ 25607.29 Designated Smoking Area Exposure Warnings (Environmental Exposures) – Content.....	49
Problems Being Addressed By This Proposed Rulemaking.....	49
Necessity.....	51
Benefits of the Proposed Regulation.....	51
Technical, Theoretical, and/or Empirical Study, Reports, or Documents Relied Upon.....	52

Reasonable Alternatives to the Regulation and the Agency’s Reasons for  
Rejecting Those Alternatives.....53

Reasonable Alternatives to the Proposed Regulatory Action That Would Lessen  
any Adverse Impact on Small Business.....54

Efforts to Avoid Unnecessary Duplication or Conflicts with Federal Regulations  
Contained in the Code of Federal Regulations Addressing the Same Issues...54

    Significant Statewide Adverse Economic Impact Directly Affecting Business,  
    Including Ability to Compete .....55

    Economic Impact Assessment Required by Gov. Code section 11346.3(b) ...55

Appendix A: Proposition 65 Clear and Reasonable Warnings Study.....58

Appendix B: Economic Impact Statement.....59

## Summary

Proposition 65<sup>1</sup> requires that businesses with 10 or more employees give a clear and reasonable warning to individuals before knowingly and intentionally exposing them to a chemical listed as known to cause cancer or reproductive toxicity. The Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency that implements Proposition 65. OEHHA maintains the list of chemicals known to the state to cause cancer or reproductive toxicity and has the authority to promulgate and amend regulations to further the purposes of the Act.<sup>2</sup> Existing regulations adopted by OEHHA's predecessor agency in 1988 (Title 27, Cal. Code of Regs., section 25601, et seq.) establish general criteria for providing "clear and reasonable" warnings.<sup>3</sup> These regulations also provide safe harbor<sup>4</sup>, non-mandatory guidance on general message content and warning methods for providing consumer product, occupational and environmental exposure warnings. The new regulations proposed for adoption into Article 6 retain the "safe harbor" concept by giving a business the opportunity to use warning methods and content that OEHHA has deemed "clear and reasonable", or a business may use any other warning method or content that is clear and reasonable under the Act.

Under the existing regulations, a warning is "clear" if it clearly communicates that the chemical in question is known to the State of California to cause cancer, birth defects or other reproductive harm. It is "reasonable" if the method employed to transmit the message is reasonably calculated to make the warning message available to the individual prior to exposure. However, the existing safe harbor warnings lack the specificity necessary to ensure that the public receives useful information about potential exposures. Further, the current regulations were adopted over 25 years ago and communication technology has progressed significantly during that time. It is therefore necessary to update the regulations to take advantage of current and future approaches to providing important health-related information to the public.

---

<sup>1</sup> 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".

<sup>2</sup> Health and Safety Code Section 25249.12(a).

<sup>3</sup> All further references are to sections of Title 27 of the California Code of Regulations, unless otherwise indicated.

<sup>4</sup> The term "safe harbor" is used throughout to refer to non-mandatory guidance provided by OEHHA for the methods and content of warnings the agency has deemed to meet the "clear and reasonable" standard required by Section 25249.6 of the Act.

The regulatory action OEHHA is proposing would repeal the current Article 6 regulations and adopt new regulations into Article 6. The new provisions in proposed Subarticle 1 would, among other things, set forth a new, mandatory regulation addressing the relative responsibility of product manufacturers and others in the chain of distribution, versus the product retail seller. It also contains the definitions relevant throughout Article 6. The regulations in proposed Subarticle 2 provide specific guidance on methods and content for safe harbor warnings. *Any express requirements under Subarticle 2 are requirements for safe harbor protection.* Failure to meet the requirements of Subarticle 2 is not a per se violation of the Act; rather, a person may provide warnings that differ from the safe harbor warnings, but that are nevertheless compliant with the Act. In that situation, the person would not have the benefit of a safe harbor defense to an enforcement action. It is the intent of OEHHA that safe harbor warnings under Subarticle 2 will provide more detailed information for the public, including a clear statement that a person “can be exposed” to a listed chemical, the names of one or more listed chemical that are the subject of the warning, and a link to a website maintained by OEHHA containing supplemental information.<sup>5</sup> These new regulations would further the “right-to-know” purposes of the statute and provide more specificity for the content of safe harbor warnings for a variety of exposure situations, and corresponding methods for providing those warnings. Businesses would continue to be assured that compliance with the safe harbor regulations will help them avoid litigation because the content and methods provided in the regulation are deemed “clear and reasonable” for purposes of complying with the Act.

## Background

Throughout the years, aspects of the “clear and reasonable” warning requirement of the Act<sup>6</sup> have been litigated, discussed and clarified in court decisions and settlements in enforcement cases. For example, in *Ingredient Communication Council (ICC) v. Lungren* (1992) 2 Cal. App. 4th 1480, the Court of Appeal

---

<sup>5</sup> OEHHA has separately proposed a regulation in Title 27, Cal. Code of Regs., Section 25205, which establishes the structure for an informational website to be developed and maintained by OEHHA that complements this regulation by providing the public with supplemental information regarding exposures to listed chemicals. The website regulation does not specify the content or methods for providing a clear and reasonable warning and is not intended to be a substitute for a clear and reasonable warning. Further, the website is not intended to be an extension of the requirements of Health and Safety Code Section 25249.6 and is *not* subject to private enforcement.

<sup>6</sup> Health and Safety Code Section 25249.6.

defined certain unacceptable methods for providing “clear and reasonable” warnings. In the *ICC* case, the court examined a method developed by consumer product and food companies for providing warnings. That system consisted of a general in-store sign and newspaper ads notifying customers that they could call a toll-free number for information on products that might require a Proposition 65 warning.

The court found that such a system was not clear and reasonable, saying that “*an invitation to inquire about possible warnings on products is not equivalent to providing the consumer a warning about a specific product.*” (Emphasis added) The court discussed the relative difficulties of calling a toll-free number in advance for every product the consumer plans to buy at the grocery store. It also quoted experts who stated that two-thirds of products are purchased on impulse while the consumer is at the store, which made it difficult for a consumer to access a warning before purchase. Finally, the court explained that “[An] effective 800 number system requires, as a first step, a *more complete in-store notification system which provides product-specific warnings.*” *Id.* at 1497. (Emphasis added)

In *Environmental Law Foundation v. Wykle Research, Inc.* (2005) 134 Cal. App. 4th 60, 66, the court found that the various safe harbor provisions established in Section 25601 were not intended to be hierarchical. In other words, no warning method is necessarily better than another. Any warning that fell into the established safe harbor provisions was adequate.

Since Section 25601 was adopted in 1988, there have been many requests for amendments to the regulation. Product manufacturers and retail groups, along with consumer representatives, enforcement and environmental groups, have asked OEHHA to adopt regulatory amendments that provide more guidance concerning acceptable methods for providing warnings to consumers and acceptable warning content. OEHHA has also been asked to clarify the relative responsibilities of product manufacturers and retail sellers in light of the statutory provision requiring that “regulations implementing [the Act] shall to the extent practicable place the obligation to provide any warning materials . . . on the producer or packager rather than on the retail seller . . . .”<sup>7</sup>

---

<sup>7</sup> Health & Safety Code Section 25249.11(f)

In addition, concerns have been voiced for many years about the lack of specificity in the current safe harbor warning language, which only requires a person to state that an area or a product “contains” a chemical that is known to the State of California to cause cancer, birth defects or other reproductive harm. The public currently has no simple process for obtaining information about the chemical(s) that are present, whether or how they are actually being exposed to a significant amount of the chemical, how the chemical(s) may cause harm (e.g. adverse effects on fetal development) or ways they can reduce or eliminate these exposures. A key objective of the proposed regulations is to provide consistent, understandable warnings for exposures to listed chemicals while referring interested individuals to the OEHHA website for more detailed, supplemental information regarding exposures to listed chemicals. The proposed regulations do this, in part, by integrating technology and methods for communication that were not available at the time the original regulations were adopted and by making the content of the warnings more clear. In order to assess the effectiveness of the current and proposed warnings OEHHA commissioned a study by researchers at the University of California Davis Extension Collaboration Center.<sup>8</sup> The study is referenced throughout this Initial Statement of Reasons and is included as Appendix A.

On May 7, 2013, Governor Brown proposed reforms to Proposition 65. One of Governor Brown’s proposed reforms involved “*improving how the public is warned about dangerous chemicals.*”<sup>9</sup> (Emphasis added). More specifically, this reform would “require more useful information to the public on what they are being exposed to and how they can protect themselves.” This proposed regulation is intended to implement the Administration’s vision concerning improving the quality of the warnings being given while providing compliance assistance to businesses subject to the warning requirements of the Act.

On July 30, 2013, OEHHA held a public workshop where concepts for possible amendments to the Proposition 65 warning were discussed, (<http://www.oehha.ca.gov/prop65/pdf/073013p65wkshp.pdf>). OEHHA presented ideas for potential changes to the current regulations and requested public

---

<sup>8</sup> Appendix A, UC Davis Extension Collaboration Center, Proposition 65 Clear and Reasonable Warning Regulations Study: Survey results assessing the effectiveness of existing and proposed Proposition 65 warning signs (2015).

<sup>9</sup> Press Release, Office of Governor Edmund G. Brown, Jr., Governor Brown Proposes to Reform Proposition 65. (May 7, 2013), available at <http://gov.ca.gov/news.php?id=18026>.



suggestions. Ten interested parties submitted comments in response to the workshop.<sup>10</sup>

On April 14, 2014, OEHHA held a pre-regulatory workshop on a draft potential regulation. Fifty-five written comments were submitted during the public comment period. OEHHA subsequently held dozens of meetings with various stakeholders to discuss the revamped proposal and modified the proposal to address their concerns to the extent feasible and consistent with the purposes and intent of the Act.

On January 16, 2015, OEHHA published a Notice of Proposed Repeal of Article 6 and Adoption of New Article 6. A public hearing was held on March 25, 2015 and the comment period closed on April 8, 2015. Sixty-one written comments were received during this comment period and OEHHA met with dozens of interested stakeholders over the course of several months. After reviewing written and oral public comments, OEHHA elected to further evaluate the potential economic impact of the regulations and the effectiveness of the existing and proposed warnings.

As noted above, OEHHA contracted with the UC Davis Extension Collaboration Center to conduct a study to better assess the effectiveness of the existing and proposed new warnings.<sup>11</sup> The purpose of the study was to assess whether the existing or proposed safe harbor warnings more clearly communicate that the chemical in question is known to the State of California to cause cancer, birth defects or other reproductive harm. The effectiveness of the warnings was assessed in terms of helpfulness. The results showed that over 75 percent of the participants selected the warnings based on the proposed regulations as being more helpful than the existing regulations. The participants also overwhelmingly supported the use of specific elements of the proposed regulations, such as the use of the warning symbol and inclusion of chemical names. The Proposition 65 Clear and Reasonable Warnings Regulations Study (“Warnings Regulations Study”) is included as Appendix A to this Initial Statement of Reasons (ISOR).<sup>12</sup>

---

<sup>10</sup> Public comments to OEHHA, Public Workshop on Concept for Regulation Addressing Proposition 65 Warnings (July 9, 2013), available at [http://oehha.ca.gov/prop65/public\\_meetings/wrksop070913.html](http://oehha.ca.gov/prop65/public_meetings/wrksop070913.html).

<sup>11</sup> Appendix A, UC Davis Extension Collaboration Center, Proposition 65 Clear and Reasonable Warning Regulations Study: Survey results assessing the effectiveness of existing and proposed Proposition 65 warning signs (2015).

<sup>12</sup> Id.

Based upon a thorough review of stakeholder input concerning the regulatory language proposed in January 2015, OEHHA made extensive revisions to the proposed regulation. Because of OEHHA's desire to ensure the public has a full opportunity to comment on the numerous changes to the regulation, OEHHA is filing a Notice of Decision Not to Proceed with the January 2015 rulemaking proposal concurrently with this new regulatory proposal that will open a new public comment period.<sup>13</sup>

In proposing this current regulatory action, OEHHA intends to address many of the issues that have surfaced since the original regulation was adopted in 1988 by clarifying the relative responsibilities of manufacturers and others in the chain of distribution for products that are eventually sold at retail, and making needed changes to the current requirements for a safe harbor warning, by integrating new technology, providing more useful information to Californians about their exposures to listed chemicals and by providing more compliance assistance for affected businesses, thereby furthering the purposes of the Act.

Each substantive provision of the proposed warning regulations is discussed below.

### **Subarticle 1: General**

Subarticle 1 of the regulation consists of mandatory general provisions applicable to all warnings. These provisions include definitions and specific rules regarding the allocation of responsibility among various businesses in the chain of commerce to provide consumer product exposure warnings.

#### **§ 25600 General**

Subsection (a) describes the general applicability of Subarticle 1 throughout Article 6 and briefly describes the contents of Subarticles 1 and 2. This subsection also explains that the proposed regulations do not address the determination by a business *whether* a warning is required under the Act. This determination is addressed by other provisions of the law and regulations. The proposed regulations only become relevant after a business determines that the

---

<sup>13</sup> As this is a new rulemaking record, the previous rulemaking record and activity will be considered pre-regulatory and referred to as such herein.

exposure to a listed chemical knowingly and intentionally caused by the business requires a warning.<sup>14</sup>

Subsection (b) provides a two-year delayed effective date for the new regulations. For two years following adoption of the regulations, businesses will have the option of using either the old safe harbor warnings or the newly adopted safe harbor warnings. OEHHA is aware that making significant changes to the existing regulations will require some retooling by businesses in order to take advantage of the new provisions. However, these effects should be short-term and will result in more effective warnings. To help provide for the transition to the new warning provisions, the regulation says it will become effective two years after the date of its adoption. Providing a two-year phase-in period will lessen any potential financial impacts for businesses that decide to take advantage of the new safe harbor provisions because these costs can be spread over a longer period. This provision allows for a “sell through” of products that may use the old warning language, and allows businesses time to replace existing signage or implement new technology.

OEHHA is sympathetic to the concerns expressed by some manufacturers regarding the change over from the old to the new safe harbor labels on durable goods. In order to avoid the difficulties involved for manufacturers and retailers to locate all products bearing the old warnings, the proposed regulation allows the old safe harbor to remain and be considered compliant if the product was manufactured prior to the effective date of the new regulation. Specifically, during the earlier phases of the development of this regulation, many stakeholders expressed concern over anticipated logistical and economic costs associated with changing the warnings on products already produced and distributed to the marketplace; this was of particular concern to businesses dealing in durable goods with compliant warnings and a long shelf-life. In order to address these concerns and mitigate potential cost impact on businesses, subsection (b) provides that a warning provided on products manufactured prior to the effective date of the revised Article 6 is deemed to be clear and reasonable if it complies with the September 2008 version of Article 6.

*It is important to note that a business retains the option of providing its own warnings that are compliant with the Act. A business which does not follow the*

---

<sup>14</sup> Health and Safety Code Sections 25249.6 and 25249.10; and Articles 5, 7 and 8 of Title 27, Cal. Code of Regs.

content and methods described in Subarticle 2, however, will not be able to assert a “safe harbor” defense on the basis of compliance with this subarticle.

Subsection (c) explains that any interested party can petition OEHHA to adopt additional regulations that are tailored to address exposures to listed chemicals in specific products or the environment that are not already sufficiently covered by the regulations. It is not possible for OEHHA to anticipate every situation in which a warning might be required for a given chemical exposure or the nuances of each exposure scenario. This provision is intended to encourage businesses to continue to work with OEHHA to develop a tailored warning method or message where the existing regulatory provisions are not sufficient to address a particular exposure scenario. In addition, this provision encourages interested parties to use other available options under existing regulations to request guidance concerning application of the Act to specific situations or products, including whether or not a warning is required.<sup>15</sup>

Subsection (d) allows the person giving a warning pursuant to Section 25249.6 of the Act to also provide information that is supplemental to the warning. Such information may be useful in allowing a potentially exposed person to make informed decisions. For example, a business may wish to provide information about the form and nature of the exposure to the listed chemical, other sources of exposure to the listed chemical, or ways a person can reduce or eliminate the exposure. However, this provision makes clear that any such supplemental information may not contradict the warning and is not a substitute for a warning. OEHHA is aware that some companies currently provide information to consumers about their Proposition 65 warnings that appear to be intended to reduce the effectiveness of the warnings by essentially contradicting it and providing other inaccurate information about the law. This type of information does not further the purposes of the Act and is not allowed under this regulation.<sup>16</sup>

---

<sup>15</sup> Specifically, Cal. Gov. Code Section 11340.6 et seq. (petition for rulemaking), Cal. Code of Regs., Title 27, Sections 25203 (Interpretive Guideline) and 25204 (Safe Use Determination).

<sup>16</sup> For example, one company recently provided the following information to a consumer:

**“UNDERSTANDING THE CALIFORNIA PROPOSITION 65 WARNING**

A small amount of wood dust, brass, PVC or other elements on furniture and household items might seem trivial to many. The state of California, however, has taken the issue of ingredients in consumer products to a whole new level with its Safe Drinking Water and Toxic Enforcement Act, known as “Proposition 65.”

Originally, the proposition was intended to protect drinking water sources from chemical contamination. Over the years, however, the scope of the law has exploded. As the Los Angeles Times

As described in subsection (e), a person is not required to provide separate warnings to each exposed individual. This provision is carried over from the existing regulations and essentially restates Section 25249.11(f) of the Act.

Finally, subsection (f) provides that the new requirements in the regulations do not apply to the parties<sup>17</sup> to court-ordered settlements or final judgments establishing methods or content for consumer products or environmental warnings. While this is simply a statement of existing law, many stakeholders requested that it be expressly included in the regulation. The provision was narrowly tailored in order to maintain consistency with the proposed regulations and avoid perpetuating potentially vague warnings.

Non-parties to settlements or final judgments wishing to use warning content or methods specific to a product, chemical or type of exposure, including warning

---

wrote recently, "Warnings (about Proposition 65) are everywhere: parking lots, hardware stores, hospitals and just about any decent-sized business."

Proposition 65 requires warning labels on products that may contain any of 800-plus chemicals or ingredients that the California Office of Environmental Health Hazard Assessment (OEHHA) lists as a carcinogen or a reproductive toxicant. These include wood dust, brass and a multitude of other everyday elements. A flame retardant upholstery chemical currently required by the state of California to be added to upholstered furniture foams is now included among chemicals that require a warning under Proposition 65.

Many of the elements listed under Proposition 65 are common everyday additives found in products such as jewelry, lamps, ceramic tableware, lead crystal glasses, electric cords, automobiles, beauty products and furniture.

Because there is always a chance that wood dust or some other of the hundreds of ingredients listed in Proposition 65 could potentially be on our furniture or packing materials, we must include Proposition 65 warnings on our products or risk large fines under this law in California. In addition, we are required to use the exact wording for this warning specified by California: "This product contains chemicals known to the state of California to cause cancer or birth defects or other reproductive harm."

We realize that this warning sounds very alarming. However, we want to reassure you based on the findings of reliable research. While there is research that supports health-related risks due to wood dust, this research also finds that the key factor in determining the health risk is the amount of exposure to wood dust. These hazardous exposure limits are generally found in the workplace when wood is being sawed or sanded, and have not been found to be present on [company name] furniture products being shipped to our retailers and customers.

Ideally, we would have placed these [company name] Furniture warnings only on our furniture products being shipped to California. However, [company name] Furniture, like most furniture companies, builds products in large quantities for stock. At the time of production, we rarely know where each item will ship. We have no alternative except to place these warnings on all of our furniture, whether it ends up in California or not. It is also important for all retailers to leave the warning on the furniture when they are shipping to people in California.

The safety of our customers and our employees is of highest priority for [company name] furniture. We want to assure you our commitment to offering among the highest quality and safest products in the industry. While there may be different opinions about California label requirements with this California law, [company name] Furniture must honor these compliance regulations. Most importantly, we promise to also honor the trust you have placed in us with your purchase or possible purchase of our products. We will honor your trust by offering furniture of enduring quality, lasting beauty and uncompromising safety to you and your family.

For more information go to <http://oehha.ca.gov/prop65/background/p65plain.html>."

<sup>17</sup> "Parties" are the persons or entities directly affected by a mandatory provision of a settlement that specifies the content of or methods for providing warnings under the Act.

methods or content contained in a court settlement, may petition the Agency under proposed Section 25600(c) to adopt the warning content or methods into the regulations.

## § 25600.1 Definitions

This regulatory proposal would readopt many of the existing definitions in Article 2 while making minor modifications for some terms, including “affected area,” “consumer product exposure,” “environmental exposure,” “label,” “labeling,” “occupational exposure” and “sign,” as well as adding definitions for the terms “authorized agent,” “food,” “knowingly” and “retail seller.” The modifications to the existing definitions included in this proposal are intended to clarify the definitions and in some cases to make them current with existing technology. New definitions are also included for purposes of clarity and consistency with other provisions of law.

Subdivision (b) adds a definition for “authorized agent” to the regulation to refer to the person or entity designated by a retail seller to receive notices on his or her behalf for purposes of Section 25600.2(b).

Subdivision (d), adds a definition for “food” that references the existing statutory definition of food found in Health and Safety Code Section 109935, which states:

“Food’ means either of the following:

(a) Any article used or intended for use for food, drink, confection, condiment, or chewing gum by man or other animal.

(b) Any article used or intended for use as a component of any article designated in subdivision (a).”

The regulation’s definition of “food” would also include dietary supplements as defined in Title 17 of the California Code of Regulations, Section 10200 as follows:

“(a) ‘Dietary supplement’

(1) Means an article (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) A vitamin,

- (B) A mineral,
- (C) An herb or other botanical,
- (D) An amino acid,
- (E) A dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or
- (F) A concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) Means a product that

- (A) Is labeled as a dietary supplement and
- (B) Is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form, or if not intended for ingestion in such a form
- (C) Is not represented for use as a conventional food, or as a sole item of a meal or the diet; and

(3) Does

(A) Include an article that is approved as a new drug in compliance with Health and Safety Code section 111550, subdivision (a) or (b), certified as an antibiotic under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. section 357, and/or licensed as a biologic under the Public Health and Safety Act, 42 U.S.C. section 262 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food, unless the article, when used as or in a dietary supplement under the conditions of use set forth in the labeling for such dietary supplement is adulterated under California Health and Safety Code section 110545, and

(B) Not include

1. An article that is approved as a new drug in compliance with Health and Safety Code section 111550, subdivision (a) or (b), certified as an antibiotic under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. section 357, and/or

licensed as a biologic under the Public Health and Safety Act, 42 U.S.C., section 262, or

2. An article authorized for investigation as a new drug, antibiotic, or biologic for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, and which was not, before its approval, certification, licensing, or authorization, marketed as a dietary supplement.

(b) A dietary supplement may be a food or a drug, or both a food and a drug, as these terms are defined in Health and Safety code sections 109935 and 109925.”

Incorporating these two definitions into the regulation’s definition of “food” is intended to clarify the types of products being referred to in the regulations using existing laws and regulations.

The definition of “consumer product exposure” in subsection (i) expressly states that food<sup>18</sup> is intended to be covered by the “product” definition. Questions about the scope of the definition have come up from time to time, including whether the safe harbor warnings could be used for foods and dietary supplements. Therefore, OEHHA believes such a clarification is necessary.

The minor changes to the definition of “environmental exposure” in subsection (c) simplify the language used in the definition, but are not intended to change the purpose or effect of the regulation.

The cross-reference to the existing definition of “knowingly” has been added in subsection (e) to assist readers of the regulation in locating the definition. Section 25102(n) provides as follows:

(n) “Knowingly” refers only to knowledge of the fact that a discharge of, release of, or exposure to a chemical listed pursuant to Section 25249.8(a) of the Act is occurring. No knowledge that the discharge, release or exposure is unlawful is required. However, a person in the course of doing business who, through misfortune or accident and without

---

<sup>18</sup> As noted in discussion of subsection (d), dietary supplements are included in the definition of “food.”



evil design, intention or negligence, commits an act or omits to do something which results in a discharge, release or exposure has not violated Sections 25249.5 or 25249.6 of the Act.

The cross-reference does not change the existing definition.

The definitions of “label” and “labeling” in subsections (f) and (g), respectively, have been updated to more specifically allow the use of newer technology to communicate the required warning.

The new definition of “retail seller” in subsection (j) is intended to clarify a term that is used throughout the Act and the regulation in regard to product exposures. A “retail seller” is a separate and distinct category of business that can cause exposures to listed chemicals. OEHHA has included specific provisions in the proposed regulation that only apply to retail sellers of foods and other products. Therefore a specific definition is needed.

The changes to the definition of “sign” in subsection (k) are similar to those made in the label and labeling definitions. OEHHA intends to clarify that signs can include graphics and other content and can be presented electronically. This reflects the technology that has developed in the quarter-century since the original regulation was adopted. In order to maximize the effectiveness of the warning message, this section requires that a sign be posted in a conspicuous manner that is associated with the exposure. The sign must be clearly visible under all lighting conditions normally encountered during business hours and under such conditions as to make it likely to be seen, read, and understood by an ordinary person.

## **§ 25600.2 Responsibility to Provide Consumer Product Exposure Warnings**

Over the years, many manufacturers and retail sellers have requested that OEHHA provide more clarity concerning the relative responsibility between manufacturers and retail sellers for providing warnings under Section 25249.11(f) of the Act.

Generally two concerns have been raised. First, many stakeholders have stated that the manufacturer, distributor, producer and packager are usually in a much better position than the retail seller to determine whether and for what a warning is required. Therefore, the manufacturer, distributor, producer and packager should have the primary responsibility for identifying products that require a warning. OEHHA agrees with that premise.

Second, some stakeholders have stated that the burden of complying with Proposition 65 and the commensurate burden of defending against enforcement of the law is disproportionately focused on relatively small retail facilities that may be accused of failing to warn even though they have no actual knowledge that a product can cause an exposure that requires a warning. When a business owner receives a 60-day notice of intent to sue,<sup>19</sup> he or she may choose to quickly settle with the person serving the notice to avoid paying potentially greater sums to litigate the matter, even though the violation was not knowing or intentional on the part of the retail seller.

Proposition 65 expressly addresses these concerns by instructing the lead agency as follows:

“In order to minimize the burden on retail sellers of consumer products including foods, regulations implementing Section 25249.6 shall to the extent practicable, place the obligation to provide any warning materials such as labels on the producer or packager rather than on the retail seller . . . .”<sup>20</sup>

Consistent with this section, the proposed language in Section 25600.2 is based on the premises that (1) the consumer must receive the warnings mandated by Section 25249.6 of the Act before being exposed to a chemical known to cause cancer or reproductive toxicity; and (2) the primary responsibility for providing the warning for products, including foods, is with the manufacturer, producer, packager, importer, or distributor of those products. The proposed regulation therefore recognizes that those parties are primarily responsible for providing warnings. The proposed regulation places retail sellers in a separate category. Retail sellers would only be responsible for providing warnings if certain specified conditions are present.

Under subsection (b) the manufacturer, producer, packager, importer or distributor of a product must affix a warning to the product; or provide specific written notice to the retail seller that contains a clear description of the product and either includes, or offers to provide, warning materials. The manufacturer, producer, packager, importer or distributor must obtain confirmation of receipt of this notice from the retail seller every 180 days for the first year during the period when the product is sold; thereafter, confirmation of receipt need be obtained

<sup>19</sup> Health and Safety Code Section 25249.7(d), Title 27, Cal. Code Regs., Section 25903.

<sup>20</sup> Health and Safety Code Section 25249.11(f).

only once per year. Such confirmation of receipt can be given via e-mail or other electronic method to the entity that provides the notice. It need not be provided in hard-copy form. Also, an additional notice is required within 90 days if a new listed chemical or endpoint is required to be included in the warning.

The manufacturer, producer, packager, importer and distributor do not need to obtain the retail seller's agreement to post the warning materials that are provided or made available under subsection (b)(3). As discussed below in connection with subsections (c) and (d)(4), once the retail seller receives a notice that complies with subsections (b)(1) through (3), the retail seller must, when selling the product, properly display those warning materials or give a warning of its own that complies with the Act.

Under subsection (c), it is the retail seller's responsibility to place and maintain any warning materials it receives from the manufacturer under subsection (b). With respect to labels affixed to the product, this means that the retail seller must ensure that it does not remove or obscure the warning label in some way, thereby thwarting the efforts of the product manufacturer, distributor, producer or packager that is providing the warning. Simply placing a product on a shelf in a manner that results in a printed warning on the product not being immediately visible is not "obscuring" the warning if the consumer will be able to see it upon picking up the product. With respect to shelf signs or tags that are not affixed to the product, the retail seller is required to post and maintain these materials in compliance with the requirements of Section 25600.2. If a manufacturer provides a shelf sign or tag to the retail seller and the retail seller covers it, fails to conspicuously post it, or intentionally removes it, the retail seller has not complied with Section 25600.2. If the retail seller loses or destroys the manufacturer's warning materials, the retail seller should request duplicate material from the manufacturer or other person in the chain of distribution. In the meantime the retail seller must still provide a warning that fully complies with the Act.

Subsection (d) sets forth the situations in which the retail seller is responsible for providing the warning. Under subsections (d)(1) through (3), the retail seller is also responsible for providing a warning if it is selling the product under its own brand name; if it has introduced the listed chemical or has caused the chemical to be created in the product (and is therefore directly responsible for the exposure), or where the retail seller has covered, altered, or obscured the warning label that has been affixed by the manufacturer, producer, packager, importer or distributor. Under subsection (d)(4), the retail seller is responsible for

providing a warning if it has received the notice described in subsection (b), whether or not it has provided a confirmation of receipt pursuant to subsection (b)(4) or (5). If the retail seller has received such a notice from the manufacturer, producer, packager, importer or distributor, then the retail seller has the responsibility to either pass on the warning or to provide a legally adequate warning of its own.

Finally, under subsection (d)(5) the retail seller has the duty to provide a warning if it has actual knowledge of the potential exposure (discussed in detail below) and either of the following two circumstances is present:

(A) There is no product manufacturer, producer, packager, importer or distributor of the product that is subject to Section 25249.6 of the Act. This will most often occur when the manufacturer, producer, packager, importer or distributor has fewer than 10 employees.

(B) Where the manufacturer, producer, packager, importer or distributor are foreign persons with no agent for service of process in the United States. Such foreign persons will usually have an obligation under the Act to provide a warning, but enforcing this obligation may be impractical because it would require the enforcing party to proceed in a foreign jurisdiction, for example, under the Hague Convention. Thus, the retail seller must provide the required warning in this situation.

The intent of subsections (d)(5)(A) and (B) is to require the retail seller to provide a warning when it has actual knowledge of the exposure and the manufacturer, producer, packager, importer or distributor cannot readily be compelled to provide it. This will ensure that the consumer will receive a warning as required by the Act. For example, if the product requiring a warning is produced and packaged by a foreign company with no agent for service of process in the United States, and it is distributed by an importer with fewer than ten employees, then it will be the responsibility of the retail seller to provide the warning.

There may be situations when the retail seller is unsure whether the manufacturer, producer, packager, importer and/or distributor are subject to the Act or are foreign corporations without agents for service of process in the United States. However, the retail seller will have a duty to inquire into these facts whenever the retail seller (1) has actual knowledge of the potential product exposure requiring the warning, and (2) has not received a notice from the

manufacturer, producer, packager, importer or distributor pursuant to subsection (b).

Subsection (d)(5)(c) defines “actual knowledge” of the exposure to include knowledge from “any reliable source”. For example, a retail seller may acquire knowledge of an exposure that requires a warning through news media, its customers or a trade association. However, if the retail seller’s only source of this knowledge is a 60-day notice that is served on the retail seller pursuant to Section 25249.7(d)(1) of the Act, then subsection (e) provides:

“The retail seller shall not be deemed to have actual knowledge of any product exposure that is alleged in the notice until two business days after the retail seller receives the notice.”

This provision focuses on those retail sellers who have no actual knowledge of a potential exposure prior to receiving a 60-day notice, and it provides them with a two business-day period after receipt of the notice in which to either post a warning or pull the product to avoid causing a knowing and intentional exposure. The two business-day period was selected as it is consistent with policies for recalls by the federal Food and Drug Administration and Consumer Product Safety Commission.<sup>21</sup> A retail seller whose only source of actual knowledge is from the 60-day notice, and who either provides the necessary warning or stops selling the product within the two business-day time period, is deemed to have complied with the Act.

For purposes of litigation to enforce the requirements of Proposition 65, when a product is sold without a warning, the enforcing party should generally proceed against the manufacturer, producer, packager, importer and/or distributor. An enforcement action against the retail seller will be appropriate only when one or more of the circumstances in subsection (d) exist.

---

<sup>21</sup> While neither of these agencies apply a two business day policy, they do require companies to “immediately cease distribution”, which is consistent with a 2 business day timeline. For example, “If the [FDA] Secretary determines . . . that there is a reasonable probability that an article of food is adulterated . . . and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals, the Secretary shall provide the responsible party with an opportunity to cease distribution and recall such article.” 21 U.S.C. § 350(a); “If the responsible party refuses to or does not voluntarily cease distribution or recall such article within the time and in the manner prescribed by the Secretary (if so prescribed), the Secretary may, by order require, as the Secretary deems necessary, such person to immediately cease distribution of such article.” 21 U.S.C. § 350(b)(1).

Subsection (f) is necessary because the retail seller may have important information regarding the identity of the manufacturer, producer, packager, importer and/or distributor who have the duty to warn under subsection (a), and it may be impossible for prosecutors to enforce the Act without obtaining this information. Subsection (f) therefore requires the retail seller to provide the name and contact information for such entities, upon written request, to the Lead Agency, Attorney General, a District Attorney, a City Attorney who has authority to proceed under Proposition 65, and to a person who has served a 60-day notice under Section 25249.7(d)(1) of the Act.

Subsection (g) requires the person or entity making a written request pursuant to subsection (f) to provide a description of the product with sufficient specificity for the retail seller to readily identify the product in accordance with Article 9, section 25903(b)(2)(D), which is the regulation governing the content of the 60-day Notice of Violation. This provision is needed in order to ensure that the retail seller can identify the product or products that are the subject of the Notice and take appropriate action within the two-business-day timeframe.

Subsection (h) allows the manufacturer, producer, packager, importer or distributor of a product to enter into an agreement with the retail seller that allocates warning responsibility between them in a manner that is different from the way in which the responsibility is allocated by the regulation. For example, the agreement might absolve the parties of the obligation to exchange annual notice and confirmation of receipt regarding the need to provide a warning after the first year as required by subsection (b)(5), on the condition that the retail seller provide continuing and adequate warnings of the exposure and that the manufacturer promptly inform the retail seller of any change in the formulation of the product that would require a different warning. Alternatively, a manufacturer may enter into an agreement with an importer or distributor or any other entity or entities in the supply chain to provide the required warning. Under subsection (h), an express condition for any such agreement is that “the warning provided to the purchaser of the product meets the requirements of Section 25249.6 of the Act.” Thus, no entity is released from its duty to warn through an agreement unless a clear and reasonable warning is provided prior to the exposure.

## **Subarticle 2: Safe Harbor Methods and Content**

Subarticle 2 provides *non-mandatory, safe harbor* methods and content for providing a warning that have been deemed to be “clear and reasonable” by the

lead agency. This subarticle does not address the question of *whether* a given exposure to a listed chemical requires a warning.

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

Subsection (a) establishes that a warning is “clear and reasonable” for purposes of the Act if the warning content and methods used comply with the requirements of this subarticle. Subsection (b) states that a person may use warnings other than those specified in this subarticle as long as the warning is compliant with the Act. Thus, the provisions of this subarticle are *voluntary* and *optional*. Any references made to *mandatory* requirements in this subarticle, i.e., “must include,” “at a minimum,” etc.; are directed towards the requirements for a “safe harbor” according to the lead agency’s interpretation of a “clear and reasonable” warning.

Subsection (c) provides that unless otherwise provided in the “short-form warning” provision of Section 25603(c), all warnings must include the name of one or more of the listed chemicals for which a warning is being provided. If a business is already providing a warning for a listed chemical, the identity of the chemical should already be known. If the warning is being provided with no knowledge of exposure to a listed chemical, then no warning is required and “over-warning” is occurring.

During the pre-regulatory process, many commenters expressed concern regarding the inclusion of chemical names in warnings. In order to fully evaluate the effectiveness of the inclusion of chemical names, OEHHA requested that the Warning Regulations Study conducted by UC Davis assess the inclusion of chemical names on the warning signs in relation to the existing warning signs with no chemical names. The results demonstrated that 66% of the people surveyed selected the sign with the specific chemical names as being more helpful than the sign that generally referred to chemicals. The survey also asked for respondents’ reactions to inclusion of the specific chemical(s) in the sign. The most frequent reaction was that the inclusion of the chemical names made people feel better able to make an informed choice. In addition, participants’ familiarity with specific chemicals (such as lead, mercury, and carbon monoxide) did not relate to their preference for the inclusion of chemical names on the signs. OEHHA has therefore determined that providing the name of a listed chemical in all warnings is consistent with and furthers the “right-to-know”

purposes of the statute and provides more specificity regarding the content of safe harbor warnings.<sup>22</sup>

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

Section 25602 describes *safe harbor methods* for providing a warning for an exposure to a listed chemical from a consumer product (as opposed to an occupational or environmental exposure). Warnings for exposures from foods, alcoholic beverages, food and non-alcoholic beverages served in restaurants, prescription drugs, dental care, passenger and off-road vehicles, diesel engines, raw wood products, furniture, amusement parks, petroleum products, service stations, vehicle repair facilities, smoking areas, parking facilities, and recreational vessels are treated separately in subsections of Section 25607, and are discussed later in this document.

A business that is subject to the requirements of Health and Safety Code Section 25249.6 may use one or more of the methods of transmission set out in subsections (a)-(d) to provide the warning. These include product-specific warnings on a shelf tag or shelf sign, on-product warnings, warnings provided via catalog for mail order purchases, warnings provided via the internet during online purchases, or warnings provided via other electronic means – so long as the person receiving the warning is not required to seek it out.

Subsection (a)(1) provides the option of providing a product-specific warning on a shelf tag or shelf sign at each point of display of the product. The previous regulatory proposal required that font size be no smaller than the largest font size used for other information. In response to stakeholder concerns regarding space limitations of shelf tags and signage, OEHHA is now proposing that the entire warning be provided in a type size no smaller than one half the largest type size used for other consumer information on the shelf tag or shelf sign for the same or similar consumer products. To ensure that the warning is visible, subsection (a)(1) states that the warning must not appear in a type size smaller than 8-point type.

The “catch-all” provision in subsection (a)(2) is intended to capture existing and future methods of communication, including currently available tools such as

---

<sup>22</sup> Appendix A, UC Davis Extension Collaboration Center, Proposition 65 Clear and Reasonable Warning Regulations Study: Survey results assessing the effectiveness of existing and proposed Proposition 65 warning signs, p. 16, (2015).



electronic shopping carts, smart phone applications, barcode scanners, self-checkout registers, pop-ups on Internet websites and any other electronic device that can immediately provide the consumer with the required warning. OEHHA does not intend for this provision to be read in such a way that a business may rely exclusively on a website or other device to provide a warning where the individual must seek out the warning. For example, a general reference to a website would not comply with this provision or the Act. Similarly, an invitation to go to a website to determine which products within a given facility require a warning would not comply with the Act.<sup>23</sup>

Subsection (a)(3) provides the safe harbor warning methods for labels and follows the content requirements of Section 25603(a). Additionally, to ensure the warning is readable and legible, the type size of the entire warning must be no smaller than the largest type size used for other consumer information on the product, but in no case may the type size be smaller than 8-point type.

Subsection (a)(4) addresses on-product labels and follows the content requirements of Section 25603(b). Additionally, to ensure the warning is readable and legible the type size of the entire warning must be no smaller than the largest type size used for other consumer information on the product, but in no case may the type size be smaller than 6-point type.

Subsection (b) sets forth safe harbor warning methods for internet purchases. In order to ensure the warning is seen at or during purchase of the product, the warning must be provided using a clearly marked hyperlink including the signal word "**WARNING**" on the product display page, or otherwise be prominently displayed to the purchaser before the purchaser completes his or her purchase of the product. To ensure the warning is readable and legible, the warning must be provided in a type size no smaller than the largest type size used for other consumer information on the page. A warning is not considered to be prominently displayed if the purchaser must search for it in the general content of the website.

Subsection (c) establishes safe harbor warning methods for catalog purchases. The warning must be provided in the catalog in a manner that clearly associates it with the item being purchased and to ensure the warning is readable and legible, must be provided in a type size no smaller than the largest type size used

---

<sup>23</sup> See *Ingredient Communication Council, Inc. v. Lungren* (1992), 2 Cal. App. 4th 1480.(1992).

for other consumer information in the catalog for the same or similar consumer products.

Under subsection (d) product exposure warnings must be provided in the same language or languages used for providing consumer information such as directions or ingredient lists on a label, labeling or sign accompanying a product in order to qualify for a safe harbor. OEHHA does not intend for this provision to apply where only the name of the product is provided in a language other than English. This was determined to be the most feasible method to ensure that a warning is likely to be understood by non-English speaking members of the public without burdening a business with language requirements beyond those already provided with a product. This provision will allow people to read and understand the warning and should not create a significant hardship for businesses, since it only applies where the business is already providing consumer information in an alternate language. Given California's linguistic diversity,<sup>24</sup> OEHHA believes this safe harbor requirement in the proposed regulation will further the purposes of the statute by expanding the number of individuals who can understand the warning, thus ensuring it is "clear and reasonable". Further, more than 25 percent of those individuals who participated in the UC Davis Extension Collaboration Center Study reported speaking a language other than English at home and over 15 percent chose to complete the survey in Spanish, thus reflecting a need for the information to be provided in alternative languages in some situations.<sup>25</sup>

OEHHA has determined that the methods for delivering the warning message set out in this section will provide effective warnings that comply with Section 25249.6 of the Act. The methods described in the proposed regulation are likely to provide an individual with the required warning in a manner that is easily understood and is associated with the product or service that can cause an exposure to a listed chemical. The identified methods also ensure that the individual will not have to seek out the warning. Other methods of transmitting

---

<sup>24</sup> "According to the most recent U.S. Census Bureau's 2007-2011 American Community Survey (ACS), nearly 43% of Californians speak a language at home other than English, about 20% of the state's population speaks English 'not well' or 'not at all,' and 10% of all households in California are linguistically isolated." Office of Environmental Health Hazard Assessment, *California Communities Environmental Health Screening Tool, Version 1.1* (September 2013), available at <http://www.oehha.ca.gov/ej/ces11.html>.

<sup>25</sup> Appendix A, UC Davis Extension Collaboration Center, Proposition 65 Clear and Reasonable Warning Regulations Study: Survey results assessing the effectiveness of existing and proposed Proposition 65 warning signs, p. 9, (2015).

the warning message that satisfy these objectives may be developed and adopted into the regulations in the future.

## § 25603 Consumer Product Exposure Warnings – Content

Section 25603 sets out the *safe harbor* requirements for providing a warning for an exposure to a listed chemical from a product, other than products that are covered in Section 25607 et seq. of the regulations. In order for a warning to meet the requirements for a safe harbor under this subarticle, the warning must include all the elements set forth in Section 25603 or the relevant provisions of Section 25607 et seq., as applicable.

### Warning Symbol

Subsection (a)(1) establishes a warning symbol to be used on all Proposition 65 product warnings, except where otherwise stated in Section 25607 et seq. The first pre-regulatory draft of the proposed regulation required the use of a pictogram developed under the Globally Harmonized System (GHS) for chemical health hazard warnings<sup>26</sup> because it has been adopted by numerous federal, state and international governments to identify toxic chemicals, including chemicals that cause cancer or reproductive toxicity.<sup>27</sup> However, several stakeholders were concerned that the GHS symbol would not be recognizable to most individuals outside the occupational context and would result in confusion and unnecessary alarm. In response, OEHHA considered potential alternatives and selected a symbol in general use that is presently more familiar to the general public.

The symbol proposed is similar to the warning symbol in widespread use by businesses in the United States and internationally for general warnings and notifications, and is currently in use by many businesses for existing Proposition

---

<sup>26</sup> U.S. Occupational Safety & Health Administration, Modification of the Hazard Communication Standard (HCS) to conform with the United Nations' (UN) Globally Harmonized System of Classification and Labeling of Chemicals (GHS), available at <https://www.osha.gov/dsg/hazcom/hazcom-faq.html>.

<sup>27</sup> U.S. Occupational Safety & Health Administration, "Hazard Communication Standard Pictogram" (2014) available at [https://www.osha.gov/Publications/HazComm\\_QuickCard\\_Pictogram.html](https://www.osha.gov/Publications/HazComm_QuickCard_Pictogram.html). As noted on the page, the symbol is required to be used for health hazard warnings including carcinogenicity, mutagenicity, reproductive toxicity, respiratory sensitizer, target organ toxicity and aspiration toxicity.

65 warnings.<sup>28</sup> Variations of the symbol are used by the American National Standards Institute (ANSI). The symbol selected for use by OEHHA consists of a black exclamation point in a yellow equilateral triangle with a bold black outline. In order to minimize potential economic impact from printing costs, the regulation provides that if the relevant signage or labeling on a product does not utilize yellow, the symbol may be printed in black and white. Figure 1 is an example of the symbol. The symbol in Figure 1 is provided solely for illustration purposes and should not be considered a scale representation. According to the proposed regulation, the symbol size must be no smaller than the height of the signal word “**WARNING**” as described further below and in subsection (a)(2). Using a graphic symbol that is familiar to consumers on both a domestic and international level is likely to enhance the effectiveness of the warnings, particularly for non-English speaking or low literacy populations.



**Figure 1. Warning symbol**  
**(Not to Scale)**

Several commenters voiced concern during the development of the prior proposal that the proposed warning symbol was confusing, alarming, and meaningless. The UC Davis Warning Regulations Study tested participant’s reaction to the proposed warning symbol both in yellow and black and white. The most frequent reaction was that the symbol meant “warning.” Few people expressed confusion or fear when viewing the symbol.<sup>29</sup>

#### Signal Word “**WARNING**”

Subsection (a)(2) retains the existing safe harbor requirement that all warnings contain the signal word “**WARNING**.” Including this word in capital letters and bold print ensures that consumers will immediately know the information being provided is important and not just informational in nature. Given that the Act

---

<sup>28</sup> Additional background information and FAQs can be found on the ANSI website located at [http://www.ansi.org/about\\_ansi/faqs/faqs.aspx?menuid=1#overview](http://www.ansi.org/about_ansi/faqs/faqs.aspx?menuid=1#overview).

<sup>29</sup> Appendix A, UC Davis Extension Collaboration Center, Proposition 65 Clear and Reasonable Warning Regulations Study: Survey results assessing the effectiveness of existing and proposed Proposition 65 warning signs, p. 36, (2015).

specifically requires a clear and reasonable *warning* to be given,<sup>30</sup> including this signal word is fully consistent with the Act and furthers its purposes.

#### Change in Language from “Contains” to “Can Expose”

Subsections (a)(2)(A)-(C) set out the message that must be provided in each warning in order to qualify for a safe harbor. The most significant change to the content of the message in this proposed regulation versus the existing safe harbor regulations is the use of the phrase “can expose you to”, rather than the word “contains”. Since the existing regulations were adopted over 25 years ago, it has become clear that using the word “contains” does not communicate the fact that individuals can actually be exposed to a chemical if they use a given product or enter an affected area. The statute clearly states that warnings are required for *knowing and intentional exposures* to listed chemicals. Warnings are not required where a product simply “contains” a listed chemical but may not actually have the potential to cause an exposure. Using the word “contains” in the warning is confusing for both businesses and the individuals receiving the warning. For example, under the existing regulation it is not clear to many businesses that a warning is not required for a chemical that is contained in a product in such a way that it cannot foreseeably cause an exposure (e.g. where the chemical is bound in a matrix such as titanium dioxide in paper, or sealed inside the product like a battery that contains lead, but is inaccessible to the average user of the product). On the other hand, individuals who see a warning for the content of a product often will not know if they actually can be exposed to a listed chemical and might not take such a warning seriously. Therefore, OEHHA has determined that the phrase “can expose you to” provides greater clarity and consistency with the requirements of the Act than the “contains” language in the existing regulations.

Some stakeholders have objected to the use of the word “expose” in product warnings because they are concerned that it will cause unnecessary alarm and because they allege that an exposure may not actually occur. These concerns are anecdotal and are contrary to the data generated in the UC Davis Warnings Regulations Study. Further, Proposition 65 is a right-to-know law. The purpose of the statute is to provide people with notice concerning their *exposures* to listed chemicals. The preamble to the law states in part that:

---

<sup>30</sup> Health and Safety Code Section 25249.6.

“Section 1. The people of California find that hazardous chemicals pose a serious threat to their health and well-being . . . .

The people therefore declare their *rights*: . . . .

(b) To be informed about *exposures* to chemicals that cause cancer, birth defects, or other reproductive harm . . . .” (Emphasis added)<sup>31</sup>

Clearly, the citizens who voted for the law wanted to be informed about actual *exposures* to carcinogens and reproductive toxicants. They did not anticipate that they would receive vague warnings about the *content* of the products they purchase and use without providing any context for that information. Such general warnings generate confusion and encourage businesses to provide a warning even when none is required, precisely because they are so vague and meaningless. Requiring that the warnings include more specific, relevant information will further the right-to-know purposes of the law and reduce the likelihood that businesses will provide unnecessary warnings for non-existent or insignificant exposures.

A prior draft of the proposed regulation used the term “will expose” you to X chemical. Some stakeholders expressed concerns that some products might or might not expose the public to a listed chemical, depending on how they are used. There were also concerns because some products contain varying levels of a listed chemical, so any individual sample of the product may or may not actually expose the consumer. For these reasons OEHHA chose the term “can expose” rather than “will expose”.

#### OEHHA URL

The regulation would also require the inclusion of a Uniform Resource Locator (URL) in all warnings so that the information on OEHHA’s website can be accessed easily by most consumers.<sup>32</sup> The Internet did not exist when voters approved Proposition 65 in 1986, but most modern-day Californians expect that important or meaningful information will be accessible on the Internet. The UC Davis Warning Regulations Study assessed how likely participants would be to

---

<sup>31</sup> Ballot Pamphlet, Proposed Law, Gen. Elec. (Nov. 4, 1986) p. 53.  
[http://www.oehha.ca.gov/prop65/law/pdf\\_zip/Prop65Ballot1986.pdf](http://www.oehha.ca.gov/prop65/law/pdf_zip/Prop65Ballot1986.pdf)

<sup>32</sup> OEHHA is separately, but concurrently, proposing a regulation in Title 27, Cal. Code of Regs., Section 25205 that establishes the structure for an informational website to be developed and maintained by OEHHA that complements this regulation by providing the public with supplemental information regarding exposures to listed chemicals.

visit the Proposition 65 website if they wanted additional information. Over half of the respondents said they are “very likely” or “somewhat likely” to visit the website.<sup>33</sup> Having the OEHHA website URL available on the warnings will allow individuals who receive warnings to easily access additional information regarding the potential exposure. As noted earlier in the document, many current warnings incorporate a URL. OEHHA believes that this approach will allow businesses to continue to provide a short warning message that complies with the Act, while pointing interested persons to a location where they can obtain more information. A companion regulation provides for the website and the general kind of content it would provide.

Subsection (b) sets out a specific short version of the warning that may only be used for on-product warnings. This provision proposes a very limited level of content to be included in an on-product warning to accommodate some product manufacturers’ stated concern that a longer warning message will simply not fit on the labeling or packaging of some small products. OEHHA is proposing a label that strikes a balance between this concern and the requirement in the statute that a person receive a warning prior to exposure. OEHHA believes that this approach will provide useful information to individuals while avoiding unwieldy on-product warnings. Further, the warning is clearer and more direct than the existing safe harbor warnings being used by many businesses. Recognizing the potentially limited space available for a warning, under subsection (c) the name of the listed chemical being warned for is not required.

#### **§ 25604 Environmental Exposure Warnings – Methods of Transmission**

Section 25604 is similar to the existing regulation for general environmental exposures. The provisions have been updated to remove obsolete citations, to reflect changes in communication technology that have occurred since the original regulation was adopted, and to ensure the warnings are sufficiently detailed to provide adequate notice of the exposure, while recognizing that some individuals may not have access to current technology. The proposed regulation has also been updated to account for non-English speaking persons who are in the affected area.

---

<sup>33</sup> Appendix A, UC Davis Extension Collaboration Center, Proposition 65 Clear and Reasonable Warning Regulations Study: Survey results assessing the effectiveness of existing and proposed Proposition 65 warning signs, p. 45, (2015).

Specifically, subsection (a)(1) requires signage to be posted at all public entrances to the affected area in no smaller than 72-point type that clearly identifies the area for which a warning is being provided. The warning must be provided in a conspicuous manner to ensure the warning is seen, read, and understood. The warning must clearly identify the area for which the warning is being provided and the location and source of the exposure. The warning must be provided in English and in any other language used in signage in the affected area. Subsection (a)(2) requires the business to provide a warning notice mailed or electronically delivered to each occupant in the affected area at least once every three months and in any language ordinarily used by the business to communicate with the public. The reason for this provision is the same as discussed above for the analogous provision for product warnings in Section 25602(d).

Subsection (a)(3) provides more detail concerning safe harbor requirements for warnings published in newspapers, including minimum warning size, concurrent publication in the electronic version of the newspaper, and publication in languages other than English if such a newspaper is circulated in the affected area. This requirement is intended to refer to local and regional newspapers that serve the affected area, including local and regional foreign language newspapers where the affected area contains a significant number of non-English speaking households. It is not intended to refer to general-circulation newspapers with a state-wide or national audience in English or other languages. Further, the warning must also contain a map showing the area in which an individual can be exposed. These provisions are consistent with guidance from the Attorney General's office regarding settlements of cases alleging environmental exposures<sup>34</sup>, and are intended to make it more likely that individuals who are or can be exposed to a listed chemical actually receive and understand the warning prior to exposure.

### **§ 25605 Environmental Exposure Warnings – Content**

Section 25605 closely tracks the safe harbor content requirements used for other required warnings. The message content has been slightly modified to tailor it to environmental exposures versus other types of exposures to listed chemicals. For all environmental exposure warnings, the affected area must be clearly described in the warning message.

---

<sup>34</sup> Title 11, Cal. Code of Regs., Section 3202(d)(3), available at <https://oag.ca.gov/prop65/regulations> .



## § 25606 Occupational Exposure Warnings

Given that warnings for occupational exposures are also regulated by federal and state entities, including the federal Occupational Safety and Health Administration, several stakeholders expressed concern over the possibility of federal preemption of Proposition 65 warnings for occupational exposures. To address these concerns, the proposed regulation incorporates by reference existing federal and state law and regulatory requirements related to warnings for occupational exposures. The requirements of the proposed regulation thus harmonize with existing federal and state laws and regulations in this area and pose no preemption concern.

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

After considering stakeholder input, OEHHA has determined that certain product, chemical and environmental exposure scenarios would benefit from exposure-specific methods of transmission and content in order to provide certainty to businesses subject to the warning requirements of the Act, while ensuring that the public receive consistent warnings about the exposures that can occur through these products or facilities. In most cases, OEHHA has adopted, with modifications for consistency, methods of warning and content for warnings that are currently in use by the affected industries.

Under Section 25607(a), where OEHHA has adopted warning methods and content for a specific type of exposure (“tailored warnings”), a person must provide a warning using those methods and content *in order to benefit from the safe harbor of this subarticle*. Providing more specific warning methods and content for certain types of exposure scenarios will facilitate the public’s understanding of the warnings in the context in which they occur and ensure clarity and consistency.

The tailored warning methods described in Section 25607, et seq. require the names of listed chemicals for which a warning has been required within certain industries. Under subsection (b) if a listed chemical that is required to be included in the tailored warning is not present at a level requiring a warning, a person is not required to include that chemical in the warning; however, the name of at least one chemical for which a warning is being provided must be included in all warnings. If a business does not knowingly and intentionally cause an exposure to at least one listed chemical, no warning is required at all.

## § 25607.1 Food Exposure Warnings – Methods of Transmission

While the general provisions of the proposed regulations that apply to other products equally apply to foods, OEHHA recognizes that providing warnings for exposures that occur through foods poses special issues that should be addressed differently. Further, based on comments from stakeholders, dietary supplements have been specifically included within this section and are included in the definition of “food” in Section 25600.1(d).

Subsection (a) clarifies that all methods of transmitting the warning for other consumer products under Section 25602 are equally available to businesses that manufacture or sell foods. The content of the warning is set forth in Section 25607.2. Additionally, to ensure the warning is readable and legible, the type size must be no smaller than the largest type size used for other consumer information on the product, however, in no case shall the warning appear in a type size smaller than 8-point.

Subsection (b) follows the safe harbor content requirements for on-product warnings but additionally requires that the warning be set off from other surrounding information by enclosing it in a box to ensure that the warning is likely to be seen and understood prior to exposure. Requiring the warning to be enclosed in a box is proposed in this section because food product labeling does not generally include warning symbols. A warning enclosed in a box along with the signal word “**WARNING**” should effectively alert the consumer that important information follows.

Subsection (c) requires that a warning be provided in the same language or languages other than English that are already used for other consumer information on a label, labeling, or sign for a food. This provision will increase the ability of people to read and understand the warning consistent with the purposes of the Act. Consumer information includes ingredients or preparation instructions, but does not include foreign words that identify the product brand or the type of food, such as “salsa,” “ravioli,” “chow mein,” etc.

## § 25607.2 Food Exposure Warnings – Content

It should be noted at the outset that the content of some food warnings may need to be more nuanced than warnings for other products. OEHHA has adopted

regulations dealing with naturally-occurring chemicals in foods<sup>35</sup> and has issued several Interpretive Guideline documents specific to potential exposures to listed chemicals in foods that do not require warnings.<sup>36</sup> Perhaps for this reason, very few food products currently carry Proposition 65 warnings.<sup>37</sup> Those that do sometimes include additional information about the origin of the chemical in the food,<sup>38</sup> the target audience, such as pregnant women and children,<sup>39</sup> types of foods affected,<sup>40</sup> and a URL for more information.<sup>41</sup> These warnings were developed in response to litigation and are not universally accepted by all businesses or specifically approved by OEHHA. All existing warnings being given by companies that were parties to litigation that resulted in warning methods or content approved by the courts would be deemed compliant with the proposed regulation and would not need to be changed. Because OEHHA does not enforce Proposition 65 and is not involved in private litigation, it is frequently unaware that a settlement has been entered that requires a certain type of warning. By proposing more specific methods and content for warnings in these regulations, OEHHA intends to ensure that warnings that are not mandated by court orders are consistent, accurate and understandable and that approved warnings and methods are available to all businesses, not just those who are parties to litigation, when appropriate. To the extent that existing warnings meet

---

<sup>35</sup> Title 27, Cal Code Regs, Section 25501; *Nicolle-Wagner v. Deukmejian*, (1991) 230 Cal. App. 3d 652. (Ct. App. 1991).

<sup>36</sup> See, e.g., OEHHA, Interpretive Guideline No. 2012-02, Consumption of Sulfur Dioxide in Dried Fruits (June 28, 2012), available at [http://oehha.ca.gov/prop65/law/pdf\\_zip/SO2driedfruitIG.pdf](http://oehha.ca.gov/prop65/law/pdf_zip/SO2driedfruitIG.pdf).

<sup>37</sup> Examples: certain balsamic vinegars, some potato chips, fresh fish, coffee and baked goods.

<sup>38</sup> For example, the current warning for acrylamide in snack foods states, "Warning: this product contains acrylamide, a chemical known to the State of California to cause cancer and reproductive toxicity. Acrylamide is not added to the products, but is created by browning potatoes. The FDA does not recommend that people stop eating potatoes. For more information, see the FDA's website at [www.fda.gov](http://www.fda.gov);" *People v. Snyder's*, No. RG-09-455286 (Alameda Cnty. Super. Ct.) (Consent Judgment, filed August 31, 2011), available at <http://oag.ca.gov/system/files/prop65/judgments/2009-00181J1401.pdf>.

<sup>39</sup> See, e.g., *Proposition 65 Fish Cases*, No. CGC 03419292 and BC 293749 (San Francisco Cnty. Super. Ct.) (Consent Judgment, filed February 4, 2005), available at [http://oag.ca.gov/system/files/attachments/press\\_releases/05-011.pdf](http://oag.ca.gov/system/files/attachments/press_releases/05-011.pdf). ("Pregnant and nursing women, women who may become pregnant, and young children should not eat the following fish....")

<sup>40</sup> See, e.g., warning at restaurants, warning that "Cooked potatoes that have been browned, such as French fries, baked potatoes, and potato chips, contain acrylamide, a chemical known to the State of California to cause cancer.... It is created in fried and baked potatoes made at all restaurants, by other companies, and even when you bake or fry potatoes at home...." *State of California v. Frito-Lay Inc., et al.* No. BC 338956 (Los Angeles Cnty. Super. Ct.) (Consent Judgment, filed Aug. 26, 2005), available at [http://oag.ca.gov/system/files/attachments/press\\_releases/2007-04-24\\_KFC\\_docs.pdf](http://oag.ca.gov/system/files/attachments/press_releases/2007-04-24_KFC_docs.pdf).

<sup>41</sup> For example, the warning label posted at Starbucks coffee establishments refers patrons to OEHHA's website, <http://oehha.ca.gov/prop65/acrylamide.html>.

the minimum safe harbor requirements of this section, OEHHA will consider adopting them into the regulations. No such food-specific warnings have been proposed in this regulatory action because none have been requested. Most of the existing warnings are being provided pursuant to court orders or settlements and would, therefore, not be affected by the proposed regulations.

Subsection (a) of the proposed regulation closely tracks the consumer product warning provisions of Section 25603, with two main exceptions. First, the warning symbol is not required for food product warnings. OEHHA has not included the warning symbol as a safe harbor requirement for food exposure warnings because food product labeling does not generally include warning symbols. Use of the signal word “**WARNING**,” and setting off the warning in a box should sufficiently alert the consumer that important information follows.

Second, the required content of the warning message set out in subsections (a)(2)-(4) is tailored to describe exposures that occur through consumption of a food product. Thus the warning message states, “Consuming this product can expose you to . . . .” This phrase is consistent with the obvious route of exposure to the listed chemical in a food and is more descriptive than the existing safe harbor message that simply says the product “contains” a listed chemical. As provided in Section 25600(d), a business may include additional contextual information to supplement the warning, as long as it does not contradict the warning. To the extent feasible, OEHHA encourages businesses to include information such as ways to reduce exposure (e.g. washing fruit or vegetables before eating, avoiding over-browning, controlling portion size or frequency of consumption),<sup>42</sup> in the warning. At a minimum, OEHHA intends to include general information of this type on its website, some of which may be provided by food product manufacturers or producers.

### § 25607.3 Alcoholic Beverage Exposure Warnings – Methods of Transmission

The safe harbor alcoholic beverage warnings are the most comprehensive provisions in the regulations that are being repealed as part of this regulatory

---

<sup>42</sup> As one example of this practice, the Attorney General’s settlement regarding warnings for fish and shellfish provides information about the health benefits of eating fish and shellfish, and provides specific portion and fish-choice information for women who are or plan to become pregnant. *Proposition 65 Fish Cases*, No. CGC 03419292 and BC 293749 (San Francisco Cnty. Super. Ct.) (Consent Judgment, filed February 4, 2005), available at [http://oag.ca.gov/system/files/attachments/press\\_releases/05-011.pdf](http://oag.ca.gov/system/files/attachments/press_releases/05-011.pdf).

proposal. They contain very detailed safe harbor requirements for the size, font, and placement of warnings for exposures from alcoholic beverages. All these warnings are off-product as the federal requirements for on-label warnings are mandatory and are also generally consistent with the requirements of Proposition 65, except that there is no specific federal warning for carcinogenicity.<sup>43</sup>

A warning may be provided using one or more of the methods outlined in subsection (a). Signs must be displayed so they are readable and conspicuous to customers as they enter areas where alcohol may be served. A warning may be provided under subsection (a)(1) with an 8 ½ by 11 inch sign in no smaller than 22-point type. Warnings may also be provided consistent with subsection (a)(2), by using a 5 by 5 inch sign placed at each retail point of sale or display. The warning text must be no smaller than 20-point type and be enclosed in a box. The sign sizes of 8 ½ by 11 inch and 5 by 5 inch were proposed because these sizes can easily be printed out from a computer template, thus making it easier for businesses to comply with the regulation using existing technology. The proposed regulations would provide more flexibility for businesses that manufacture, distribute or sell alcoholic beverages, while at the same time maintaining sufficient specificity to ensure industry compliance and certainty. The existing provision explaining the relative responsibilities of the manufacturer, distributor and retail seller has been moved to Section 25600.2 which now covers all product warnings, including those for alcoholic beverages. It was modified to fit this wider application.

Subsection (a)(3) provides that warnings for alcoholic beverages served by food or beverage persons or by over-the-counter service may be provided on a menu or list identifying the alcoholic beverages served on the premises in a type size no smaller than the largest type size used for other consumer information on the food, but no smaller than 8-point. If there is no alcoholic beverage list or menu then the warning may be provided on a food or non-alcoholic beverage menu or list in a type size no smaller than the largest type size for other consumer information on the product but no smaller than 8-point.

---

<sup>43</sup> OEHHA is aware that there is an existing warning program managed by trade groups representing the beer and wine industry for alcoholic beverages that was established via a court settlement. While that settlement generally tracks the existing regulations fairly closely, it does not incorporate the basic elements of the new proposed warning regulations. Specifically it does not incorporate the OEHHA URL and does not include alternative language requirements. While the majority of the market is covered by that settlement, many mid-to small size producers and retailers are not covered and may use the safe harbor regulations. The proposed regulations will not impact the existing settlement.

Subsection (a)(4) provides that warnings for alcoholic beverages sold or distributed to purchasers within California through package delivery services must incorporate or place the warning message on or in the shipping container or delivery package in a type size no smaller than the largest type size used for other consumer information on the product but no smaller than 8-point type. The warning message must be readable and conspicuous to the recipient prior to consumption of the alcoholic beverages.

Subsection (b) provides that alcoholic beverage exposure warnings must be provided in English and any other language used for labeling or advertising on the premises.

#### **§ 25607.4 Alcoholic Beverage Exposure Warnings – Content**

Subsection (a) includes the safe harbor requirements for providing a warning that have been described in Section 25607.3. The language in subsection (a)(2) is tailored to exposures that occur through consumption of alcohol and closely tracks the warning language in the existing regulation with the exception of the OEHHA URL which is now included in the warning language.<sup>44</sup>

#### **§ 25607.5 Food and Non-Alcoholic Beverage Exposure Warnings for Restaurants – Methods of Transmission**

Subsection (a) provides safe harbor methods for food and non-alcoholic beverage exposure warnings for restaurants. A business may choose to display an 8 ½ by 11 inch sign with no smaller than 28-point type at each public entrance, a 5 by 5 inch sign at each point of sale in a minimum 20-point type, or in a menu or list in a type size no smaller than the largest type size used for the names of general menu items. Subsection (b) repeats the safe harbor requirement for a warning to be in English and any other language used on other signage on the premises. These methods are intended to ensure that warnings are seen and understood.

---

<sup>44</sup> A 2005 press release states, in part, “U.S. Surgeon General Richard H. Carmona today warned pregnant women and women who may become pregnant to abstain from alcohol consumption in order to eliminate the chance of giving birth to a baby with any of the harmful effects of the Fetal Alcohol Spectrum Disorders (FASD)... Alcohol-related birth defects are completely preventable.” Press Release, U.S. Surgeon General, U.S. Surgeon General Releases Advisory on Alcohol Use in Pregnancy (Feb. 21, 2005), available at <http://www.lhvpn.net/hhspress.html>.

## **§ 25607.6 Food and Non-Alcoholic Beverage Exposure Warnings for Restaurants – Content**

Subsection (a)(2) sets forth the safe harbor content requirements for restaurants. As with food warnings, this section does not require the warning symbol. The warning language specifically identifies the chemicals acrylamide and mercury because these types of exposures commonly occur through foods such as coffee and fish which are sold at many restaurants. The safe harbor warning also contains a link to the OEHHA URL related to food and beverage exposures for supplemental information.

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

During the pre-regulatory period, OEHHA met with members of the California Medical Association and California Hospital Association. After consideration of issues arising during the provision of health care, OEHHA substantially retained the existing prescription drug exposure provisions. Given that drugs are very closely regulated by the federal Food and Drug Administration, and that federal law may prohibit businesses from deviating in any way from an approved label or related materials, labeling approved or provided under federal law has been determined by OEHHA to satisfy the requirements of this Article.<sup>45</sup> Similarly, a prescriber's accepted practice of obtaining informed consent meets the Article's requirements and is consistent with existing duties of health care providers under state and federal law.

Subsection (b) of the proposed regulation substantially maintains the existing regulatory language concerning emergency or urgent medical or dental care. It is intended to incorporate existing informed consent practices for emergency or urgent medical care.

## **§ 25607.8 Dental Care Exposure Warnings – Methods of Transmission**

OEHHA is proposing this section in order to provide consistency in the format, size and placement of warnings for exposures to listed chemicals from dental care services. While the target audience for dental care warnings includes

---

<sup>45</sup> *Dowhal v. SmithKline Beecham Consumer Healthcare* (2004), 32 Cal. App. 4th 910, 934-35 (2004) (“In most cases FDA warnings and Proposition 65 warnings would serve the same purpose—informing the consumer of the risks involved in use of the product—and differences in wording would not call for federal preemption.”)

employees, the proposed warnings are primarily focused on patients. Setting these safe harbor requirements out in the regulation will also provide certainty for a business providing dental care services that it is compliant with the Act if it meets the safe harbor requirements of the regulation. Subsections (a)(1) and (a)(2) set out two alternatives for providing the warning that may be used singly or in combination, depending on the needs of the individual dental care provider.

During the pre-regulatory phase of this proposed regulation OEHHA met with representatives from the California Dental Association to consider dental industry-specific issues. This section and the safe harbor warning content requirements in Section 25607.9 are intended to cover exposure scenarios that may occur during the receipt and delivery of dental care, including exposures related to dental appliances and prescriptions from a dental care provider. The term “dental appliances” is intended to cover all fixed and removable appliances used in dentistry, including, for example, inlays/onlays, veneers, bridges, partial and full dentures, dental implant prosthesis, mouthguards, splints, trays, stents, and TMJ and sleep apnea devices.

#### **§ 25607.9 Dental Care Exposure Warnings – Content**

This section tailors the warning message content to address the specific types of exposures that may occur from dental care services. As with food and beverage warnings, this section does not require the warning symbol. The safe harbor warning language advises that exposure to a listed chemical may occur during dental procedures. Procedures can include sedation with nitrous oxide, root canals, placement or removal of crowns, bridges, and restorations such as mercury-containing fillings. The warning content advises a person to consult with their dental care provider about these exposures and appropriate materials for treatment. The safe harbor warning also contains a link to the OEHHA URL related to dental exposures for supplemental information.

The warning language ensures the warning is clear to the person being exposed, since it explains that exposure can occur through the receipt of dental care and the placement of dental appliances, and it provides an avenue for getting more information that is specific to the chemicals and types of exposures that can occur. Referring the individual to the dental care provider is consistent with advice given in other medical settings<sup>46</sup> and dental offices.<sup>47</sup> It is also consistent

---

<sup>46</sup> For example, the FDA requires a Medication Guide for hundreds of drugs, including the prescription drug Ritalin, but notes that the guide “does not take the place of talking to your doctor



with the duty that dental care providers already have to their patients under state and federal informed consent laws. The warning text does not contain an exhaustive list of the types of care or devices that can cause exposures because it would be unwieldy, and therefore, the patient is referred to the care provider for specific information. OEHHA intends to include supplemental information on its website about common exposures from dental care and dental appliances.

### **§ 25607.10 Raw Wood Product Exposure Warnings – Methods of Transmission**

The tailored warning for wood dust is derived from language currently used in the industry for warnings related to exposures to wood dust from raw wood products. Subsection (a)(1) specifies that a warning can be displayed at the point of sale or display of the product causing the exposure provided the sign is no smaller than 8 ½ by 11 inches, printed no smaller than 20-point type and placed where it is likely to be seen by the purchaser.

For raw wood products sold in bulk, subsection (a)(2) allows a business to provide a warning via a receipt or invoice in no smaller than 12-point type since the material may be delivered or otherwise transferred to the purchaser in a manner that precludes the posting of a warning. These methods of transmission make it likely that a warning will be seen by the individual when purchasing wood products and prior to exposure.

For purposes of clarity, subsection (b) provides a definition for “raw wood products” based on input provided by the wood product industry.

### **§ 25607.11 Raw Wood Product Exposure Warnings - Content**

The warning consists of language similar to existing warnings already being provided by the raw wood product industry. However, the warning content has been adjusted for consistency with the other warnings in this proposed

---

about your or your child’s treatment.” U.S. Food & Drug Administration, Medication Guide: Ritalin (2013), available at <http://www.fda.gov/downloads/Drugs/DrugSafety/ucm089090.pdf>.

Additionally, the Proposition 65 warning provided by retailer Amazon.com advises would-be purchasers of products that contain progesterone, a listed chemical, to “Consult with your physician before using this product.” Amazon.com, About California Proposition 65 (accessed January 2014), available at

<http://www.amazon.com/gp/help/customer/display.html?nodeId=3234041>.

<sup>47</sup> [http://www.dbc.ca.gov/formspubs/pub\\_dmf2004.pdf](http://www.dbc.ca.gov/formspubs/pub_dmf2004.pdf), Fact sheet prepared by the Dental Board of California discussing dental fillings which includes a discussion of Proposition 65 related to mercury in certain types of fillings.

regulation. The tailored warning thus includes the warning symbol described in Section 25603(a)(1), the signal word “**WARNING**” in bold, and a link to the OEHHA website for information regarding raw wood product exposures.

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

Within the furniture industry, warnings and other consumer information are generally provided on labels affixed to the bottom of upholstered furniture, or on the external packaging for other large furniture products where it may not be readily observed by a consumer. To ensure that the consumer is warned about potential exposure to listed chemicals, OEHHA has developed safe harbor methods for exposure to listed chemicals in furniture products.

Under subsection (a)(1), OEHHA has incorporated the warning method of affixing a warning to the furniture product in the same manner as other consumer information or warning materials provided on the product. To ensure the warning is readable and legible, the warning must be in a type size no smaller than the largest used for other consumer or warning information on the product, but in no case may the warning be provided in smaller than 12-point type. Because the warning may not be readily seen by a consumer, it is important to point the consumer to the correct location of the warnings in order to make the warning clear and reasonable. Therefore under subsection (a)(1)(A)-(B), in addition to the on-product warning, a business must provide a notice on a sign no smaller than 8 ½ by 11 inches displayed at each public entrance or point of display, using no smaller than 28-point type; or provide such a notice by stamping it on each receipt in no smaller than 12-point type. This notice serves as the “pointer” for consumers so they can find the warning and ensures that the consumer receives a clear and reasonable warning prior to exposure to a listed chemical.

### § 25607.13 Furniture Product Exposure Warnings – Content

The safe harbor content for furniture product warnings incorporates several of the general product exposure warning safe harbor content requirements of Section 25603, but also incorporates content requirements consistent with current industry warnings.

Subsection (a)(1) requires that an on-product warning affixed to the furniture pursuant to Section 25607.12(a)(1) use the warning symbol in Section 25603(a)(1), the signal word “**WARNING,**” in capital letters and bold print, and warning language tailored specifically to furniture products that includes the name of one or more listed chemicals.

The notice that must be displayed pursuant to Section 25607.12(a)(1)(A) or stamped on a receipt pursuant to Section 25607.12(a)(1)(B) must contain the word “**NOTICE**” in all capital letters and bold print, and the safe harbor warning language directing a person to check the on-product warning language.

#### § 25607.14 Diesel Engine Exposure Warnings (Except Passenger Vehicle Engines) – Methods of Transmission

The safe harbor method for providing a warning for diesel engines draws on processes currently used by the diesel truck and engine industry pursuant to court settlements. The combination of methods proposed in this section is likely to result in the warning being seen and understood by the operator prior to exposure.

Subsection (a) requires the warning to be printed in the owner’s manual in no smaller than 12-point type, and enclosed in a box. The warning must also be provided on a separate, permanently attached warning label placed on the product itself in a type size no smaller than the largest type size used for other consumer information on the product; to ensure the warning is readable and legible however, the warning must be provided in a type size no smaller than 8-point. Given that diesel engines can be found in many applications ranging from stationary generators to heavy outdoor equipment, this method helps ensure the warning will be received by the operator prior to exposure. In addition, if other warnings or operator instructions are provided in an on-screen display, the warning is also to be provided in that manner, however, to ensure the warning is readable and legible in no case shall the warning appear in a smaller than 8-point type size. As noted, this combination of warning methods has been used by the industry for some time pursuant to court settlements, so most businesses should be familiar with it.

#### § 25607.15 Diesel Engine Exposure Warnings (Except Passenger Vehicle Engines) – Content

The warning language currently in use for diesel engines by members of that industry has been retained but slightly adjusted to conform to the content and format proposed for other product exposures in these regulations. The tailored warning thus includes the warning symbol described in Section 25603(a)(1), the signal word “**WARNING**” in bold, and a URL for the OEHHA website for supplemental information. The warning message includes language currently used for precautions to reduce exposure to diesel engine exhaust such as operating the engine in a well-ventilated area or venting exhaust to the outside

and a warning not to tamper with the exhaust system, which could result in increased exposure. Including such information furthers the purposes of the Act by providing the operator product user with specific ways to reduce or avoid exposure to diesel engine exhaust.

#### **§ 25607.16 Vehicle Exposure Warnings – Methods of Transmission**

This section is intended to cover “passenger vehicles” as defined in California Vehicle Code Section 465 as well as “off-road vehicles” as defined in California Vehicle Code Section 38012(b). It is patterned after existing warning programs developed by California retail sellers of passenger vehicles, though the methods and content requirements have been simplified. The safe harbor method requires the warning to be provided in the owner’s manual in no smaller than 12-point type and enclosed in a box. A label must also be attached to the front window on the driver’s side of the vehicle in a type size no smaller than the largest type size used for other consumer information affixed to the vehicle. To ensure the warning is readable and legible, it must be provided in no smaller than 8-point type. This section takes into account stakeholder concerns that some vehicles may not have driver’s side windows or rear view mirrors, by allowing a warning to be provided in another location, so long as the warning is placed in another prominent location. Using this combination of methods is intended to ensure that the warning will likely be seen and understood prior to exposure.

#### **§ 25607.17 Vehicle Exposure Warnings – Content**

The content for the warning message was developed based on discussions with industry stakeholders and a review of the warning language currently in use and is consistent with the warning requirements in Section 25603. The warning is intended to highlight common exposures to listed chemicals resulting from the operation, servicing and maintenance of passenger vehicles, includes precautionary measures an individual can take to minimize or avoid those exposures and provides the URL to the OEHHA website for supplemental information related to exposures to listed chemicals from passenger vehicles.

#### **§ 25607.18 Recreational Vessel Exposure Warnings – Method of Transmission**

The safe harbor warning provisions for exposures to listed chemicals resulting from recreational vessels were developed in conjunction with industry stakeholders. The term “recreational vessel” is defined by reference in California Harbors and Navigation Code Section 651(t) as “a vessel that is being used only

for pleasure.” A warning must be provided in the owner’s manual in no smaller than 12-point type enclosed in a box and either printed or affixed to the inside or outside of the front or back cover of the manual, or on the first page of text. Additionally, the warning must be provided on a hang tag readily visible from the helm of the recreational vessel and to ensure the warning is readable and legible, must be printed in no smaller than 12-point type.

#### § 25607.19 Recreational Vessel Exposure Warnings – Content

In terms of content, a warning must include the warning symbol described in Section 25603(a)(1), the word “**WARNING**” in capital letters and bold print, and the OEHHA URL for recreational vessel warnings. The warning language includes listed chemicals for which warnings are likely required and includes precautionary measures to minimize exposure to listed chemicals from recreational vessels.

#### § 25607.20 Enclosed Parking Facility Exposure Warnings – Method of Transmission

This section provides specific requirements for the size and location of warnings to be used in parking facilities that are intended to ensure that individuals will see and understand the warning before the exposure occurs. Currently, many parking structure warnings are provided within the structure, which presumably would be seen only after the exposures have already occurred. This section requires the notice to be posted in at least 72-point type on a 20 by 20 inch sign at each public entrance to the parking facility so that the warning is likely to be seen and understood prior to exposure. Further, the warning is being proposed only for enclosed parking structures since it is likely that exposures that require a warning would most likely occur in an enclosed facility. To increase the likelihood that the warning is understood by visitors to an enclosed parking facility, a warning must be provided in English and any other language in which entrance signage is being provided at the facility.

#### § 25607.21 Enclosed Parking Facility Exposure Warnings– Content

The content requirements in this section continue the use of the warning symbol and signal word required for other warnings in these proposed regulations. The content of the warning itself has been tailored to include the likely route of exposure (inhalation) and the most common listed chemicals or mixtures of chemicals that occur in this setting. It also includes advice about how to reduce the person’s exposure to those chemicals. This message is more clear and

informative than existing warnings that merely state the area “contains” listed chemicals. The requirement to include a location-specific URL for the OEHHA website is also repeated here.

### **§ 25607.22 Amusement Park Exposure Warnings - Method of Transmission**

Amusement and theme parks present another example of the types of facilities that need specific method and content regulations as these facilities can present many different exposure scenarios. While not all amusement parks need to provide warnings for exposures other than via restaurants or enclosed parking garages, which must be provided separately, some parks currently provide general warnings. This section provides the method and content for providing general area warnings when there are exposures that require them. Thus, as with other safe harbor warnings, the general amusement park warning must include the name of at least one listed chemical it is intended to cover.

Subsections (a) and (b) define the term “amusement parks” as used in 25607.22 and 25607.23. As there is no current definition of the term in California state law, the definition is derived from current Nevada state law.<sup>48</sup> To increase the visibility of the warnings so they are likely to be seen and understood prior to exposure to a listed chemical, this section requires signs to be posted at each public entrance to the facility in a minimum 72-point type. Because some facilities have multiple public access points, signs must be posted at the most common areas used by the public to access the facility. This requirement is intended to ensure a park patron receives a warning prior to exposure regardless of which entrance he or she uses to access the facility.

Subsection (c) requires warnings to be provided both in English and in the same language(s) as other permanent signage provided by the amusement park. Amusement park industry stakeholders have expressed concern that temporary signage such as banners related to special events may be presented in multiple languages and would thus require warnings to be provided in those languages.

---

<sup>48</sup> NRS 455B.010 provides:

- “1. “Amusement park” means any permanent facility or park where amusement rides are available for use by the public.
2. “Amusement ride” or “ride” means any type of ride, including, without limitation, any mechanical or aquatic device which carries passengers over a fixed or restricted route primarily for the passengers’ amusement. The terms include any ride propelled by its passengers or gravity if it is located in an amusement park,” available at <https://www.leg.state.nv.us/nrs/NRS-455B.html>.

To address this concern, OEHHA has specified in subsection (c) that the language requirement applies only to “permanent signage”.

The provision in subsection (d) is intended to clarify that these facilities must also use the warning methods and content proposed elsewhere in the regulation for certain exposures that occur at the facility (such as exposures to listed chemicals from consumer products, foods and alcoholic beverages and enclosed parking structures.) This ensures that warnings are provided in a manner and location that allows an individual to associate the warning with the source of the exposure and maintains consistency for warnings throughout California for these types of exposures. Consistent with the language of the other applicable sections, the location-specific warnings may be provided at the entrances to those themed areas that provide food or alcoholic beverages where warnings are required.

#### § 25607.23 Amusement Park Exposure Warnings – Content

The content requirements for the amusement park warning closely track the general environmental exposure warning content requirements in Section 25605. It includes the warning symbol described in Section 25603(a)(1), the signal word “**WARNING**” in bold, and a link to the OEHHA website URL for information regarding amusement park exposures.

#### § 25607.24 Petroleum Products Warnings (Environmental Exposures) – Methods of Transmission

This section applies to exposures to petroleum products from industrial operations. Method and content requirements for service stations and vehicle repair facilities are set forth in Sections 25607.26 and 25607.27, respectively. OEHHA developed this section of the regulations using samples of current warnings being provided by the industry. This section incorporates the method of transmission requirements for environmental exposure warnings found in Section 25604 and requires in subsection (b) that the warning be provided in both English and other languages used on other signage at the facility.

#### § 25607.25 Petroleum Products Warnings (Environmental Exposures) – Content

The warning includes the symbol described in Section 25603(a)(1), the signal word “**WARNING**” in bold, and a link to the OEHHA website URL for information regarding exposures to listed chemicals from petroleum products. The warning language advises of the risk of environmental exposure to chemicals such as

toluene and benzene through contact with and inhalation of crude oil, gasoline, diesel fuel and other petroleum products that are common types of exposures in and around these facilities. The warning additionally describes locations where these exposures may occur so that individuals receiving the warning can reduce or eliminate their exposures where possible.

#### § 25607.26 Service Station and Vehicle Repair Facilities Warnings (Environmental Exposures) – Methods of Transmission

A warning for environmental exposures to listed chemicals at service stations must be provided at the most common location for exposures to listed chemicals. OEHHA has determined that these are most likely to occur at or near the gas pumps; therefore a warning must be provided at each gas pump. This process is consistent with existing industry practices. The sign must be printed in no smaller than 22-point type and be enclosed in a box so that it is set off from other warnings and information posted on the pumps.

A warning for environmental exposures to listed chemicals at vehicle repair facilities must be posted at each public entrance to the repair facility. The sign must be printed in no smaller than 32-point type and be enclosed in a box.

Signage for a service station or a vehicle repair facility must be provided in English and any language used on other signage at the facility. Using these methods of providing a warning will ensure that it is likely to be seen and understood prior to exposures occurring at these types of facilities.

#### § 25607.27 Service Station and Vehicle Repair Facilities Warnings (Environmental Exposures) – Content

Warnings for service stations must include the symbol described in Section 25603(a)(1), the signal word “**WARNING**” in bold, and a link to the OEHHA website URL related to supplemental information about service station exposures. In order to comply with the requirements of this section, a warning must use the required language regarding exposures to benzene, motor vehicle exhaust and carbon monoxide. These listed chemicals were selected because they are commonly encountered at these facilities.

Warnings for vehicle repair facilities must include the symbol described in Section 25603(a)(1), the signal word “**WARNING**” in bold, and a link to the OEHHA website URL related to supplemental information about vehicle repair facilities exposures. A safe harbor warning under this section must use the



required language regarding exposures to benzene, motor vehicle exhaust, and carbon monoxide. These listed chemicals were selected to correspond with the types of exposures for which warnings are being provided at these facilities.

#### **§ 25607.28 Designated Smoking Area Exposure Warnings (Environmental Exposures) – Method of Transmission**

To meet the safe harbor requirements for exposures to listed chemicals from designated smoking areas, a warning must be posted on a sign no smaller than 8 ½ by 11 inches both at the entrance to and within the designated smoking area. The warning language must be printed in no smaller than 22-point type and enclosed in a box.

#### **§ 25607.29 Designated Smoking Area Exposure Warnings (Environmental Exposures) – Content**

Under this section, the warning must include the symbol described in Section 25603(a)(1), the word “**WARNING**” in capital letters and bold print, and a link to the OEHHA website URL regarding exposure to listed chemicals from designated smoking areas. The warning language advises of potential exposures to chemicals such as tobacco smoke and nicotine through breathing the air in the smoking area and advises persons to minimize time in the area in order to reduce their exposure. OEHHA intends for this warning to provide consistency of form and content for these areas.

#### **Problems Being Addressed By This Proposed Rulemaking**

Since Article 6 was adopted in 1988, the public has voiced concerns about the lack of specificity in the current safe harbor warnings, which merely state that a product or area “contains” a chemical that is known to the State of California to cause cancer, birth defects or other reproductive harm. Members of the public currently have no simple process for obtaining information about the chemical(s) that are present, whether or how they are actually being exposed to a significant amount of the chemical, which health effects among the three listed are actually relevant, or ways that they can reduce or eliminate these exposures when possible. A key objective of these proposed regulations is to provide the public with consistent, understandable information concerning exposures to listed chemicals. The proposed regulations do this by modifying the warning content to add more specificity to the warning and integrating technology and methods for

communication that were not available at the time the original regulations were adopted.

In addition, product manufacturers and retail sellers, along with consumer representatives, enforcement and environmental groups, have asked OEHHA to adopt regulatory amendments that provide more guidance concerning acceptable methods for providing warnings to individuals. OEHHA has also specifically been asked to clarify the relative responsibilities of product manufacturers and others in the chain of product distribution and sale in light of the statutory provision requiring that “regulations implementing [the Act] shall to the extent practicable place the obligation to provide any warning materials . . . on the producer or packager rather than on the retail seller . . . .”<sup>49</sup> Similar comments and requests were expressed in the pre-regulatory phase of this proposal.

On May 7, 2013, Governor Brown proposed reforms to Proposition 65. One of Governor Brown’s proposed reforms involved “*improving how the public is warned about dangerous chemicals.*”<sup>50</sup> (Emphasis added). More specifically, this reform would “require more useful information to the public on what they are being exposed to and how they can protect themselves.” This proposed regulation is intended to implement the Administration’s vision concerning improving the quality of the warnings being given while providing compliance assistance to businesses subject to the warning requirements of the Act.

This proposed regulatory action is intended to address all of these concerns.

## Purpose

1. OEHHA intends to address many of the issues that have surfaced since the original regulation was adopted in 1988 by clarifying the relative responsibilities of manufacturers and others in the chain of distribution for providing warnings for products that are eventually sold at retail.
2. The proposed regulations will provide more useful information to Californians about their exposures to listed chemicals and by providing more compliance assistance for affected businesses, thereby furthering the purposes of the Act.

---

<sup>49</sup> Health and Safety Code Section 25249.11(f).

<sup>50</sup> Press Release, Office of Governor Edmund G. Brown, Jr., Governor Brown Proposes to Reform Proposition 65. (May 7, 2013), available at <http://gov.ca.gov/news.php?id=18026>.

3. The proposed regulations would make needed changes to the current requirements for “safe harbor” warning methods and content through the integration of new technology.

## **Necessity**

The existing regulations were adopted more than 25 years ago shortly after Proposition 65 was passed. Much has changed during that time. The regulations are in need of updating and reform to ensure that they take advantage of newer communications processes and provide more useful, informative warnings for individuals who may be exposed to listed chemicals. Many stakeholders have requested modifications to the regulations throughout the years to reduce the number of unnecessary warnings, make the warnings more informative, and provide certainty for businesses who must comply with the warning requirements of the Act.

## **Benefits of the Proposed Regulation**

These proposed regulations would repeal the current Article 6 and adopt a new Article 6 that includes two subarticles that better serve the public by requiring more detailed information in Proposition 65 warnings including how to avoid or reduce their exposure to listed chemicals. This furthers the “right-to-know” purposes of the statute. This access to more detailed information would further promote public health and safety.

The regulatory proposal also provides more clarity to the warning requirements and more specificity regarding the minimum safe harbor elements for providing a “clear and reasonable” warning for exposures that occur from products, including foods, and exposures that occur in various environmental settings. The proposed regulation will benefit Californians by:

- Making warnings more visible (due to the use of the familiar exclamation point symbol for most warnings)
- Stating that the product or the location can expose them to a listed chemical (as opposed to the current general practice of simply warning of the presence of a chemical)
- Identifying at least one listed chemical to which they would be exposed
- Providing the URL for an OEHHA web site which will provide general information about listed chemicals, products or locations commonly associated with those chemicals, and general advice for how to reduce or avoid exposures to those chemicals.

- Providing for warnings in non-English languages in instances where product labeling contains information in alternative languages or at locations where signs are posted in those languages.

Because businesses are given the option to use warning methods adopted by the lead agency, a business will enjoy more certainty and confidence that it is in compliance with the regulations while retaining the right to provide other non-safe harbor warnings they believe are compliant with the Act.

The implicit net benefit of Proposition 65 and the proposed regulation is based on the stated desire of Californians to be informed of exposures to chemicals that are known to cause cancer or reproductive effects, as evidenced by the passage of Proposition 65 by the voters in 1986 by a vote of 63%-37%. In addition, a public-opinion survey conducted for OEHHA by the University of California, Davis and its contractor found that clear majorities of those surveyed found the “safe harbor” warnings in the proposed regulation to be more informative than current Proposition 65 warnings.

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

As noted above, OEHHA reviewed public records from cases filed under Proposition 65 including:

- *Ingredient Communication Council (ICC) v. Lungren* (1992) 2 Cal. App. 4th 1480.
- *Environmental Law Foundation v. Wykle Research, Inc.* (2005) 134 Cal. App. 4th 60.
- *Dowhal v. SmithKline Beecham Consumer Healthcare*, (2004) 32 Cal. App. 4th 910, 934-35.
- *Nicolle-Wagner v. Deukmejian*, (1991) 230 Cal. App. 3d 652.

OEHHA also commissioned a study by researchers at the UC Davis Extension Collaboration Center to assess the effectiveness of the current and proposed warnings. The Proposition 65 Clear and Reasonable Warning Study report was relied upon in the development of this regulatory proposal and is included as Appendix A to this Initial Statement of Reasons.

OEHHA further considered the economic impacts of the proposed regulation and prepared an assessment of the economic impact of this proposed regulatory action. This is included as Appendix B to this Initial Statement of Reasons.

OEHHA additionally relied upon the US Census Bureau's 2007-2011 American Community Survey (ACS). OEHHA also relied upon Title 11, Cal. Code of Regs., Section 3202(d)(3), which is available at the Attorney General's website at <https://oag.ca.gov/prop65/regulations>. These documents are included in the rulemaking record and are available for public inspection by contacting Monet Vela of the OEHHA Legal Office at (916) 323-2517.

Finally, OEHHA reviewed but did not rely upon oral and written public comments from interested parties that were offered as part of two pre-regulatory workshops, the comments received during the prior rulemaking process and other written and oral communications from interested parties that were received during the development of this proposal.

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

Pursuant to Government Code section 11346.5(a)(13), OEHHA has initially determined that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to the attention of OEHHA, would be more effective in carrying out the purpose for which Proposition 65 is proposed, or would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The warning regulation proposal has been developed over the course of more than two years. OEHHA has received many comments and suggestions via oral and written comments on prior proposals and through dozens of meetings with interested stakeholders and groups. Alternatives were offered by these stakeholders in the comment letters and in the meetings. OEHHA carefully considered each alternative and OEHHA incorporated both substantive and non-substantive input offered by stakeholders into this regulatory proposal. However, OEHHA was also mindful of its statutory responsibility to ensure that this regulatory effort remains consistent with the purpose of the statute.<sup>51</sup> Some of the suggested alternatives would not accomplish that goal and were therefore not

---

<sup>51</sup> Health and Safety Code Section 25249.12(a).

included in this proposal. The now-withdrawn January 2015 regulatory proposal identified 12 listed chemicals or chemical groups that would have been required to be named in the warning if exposures to those chemicals were the reason for the warning. This alternative, it was argued, would result in costs for testing products or locations to determine if their warnings would need to name some of those chemicals. The current proposed regulation would require only that one or more chemicals be named in the warning. The choice of which chemical is named is left to the discretion of the business providing the warning. This should not trigger the need for any additional testing as businesses providing warnings already have ascertained that they are causing an exposure to at least one chemical and should know the identity of that chemical.

### **Reasonable Alternatives to the Proposed Regulatory Action That Would Lessen any Adverse Impact on Small Business**

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 employees<sup>52</sup> from the warning requirement of the law. In addition, certain provisions such as Subarticle 1, section 25600.2 are specifically designed to lessen the existing burdens on small retail businesses that are subject to the warning requirements of the Act.

### **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. There are federal regulations addressing warnings for prescription drugs and certain workplace exposures. OEHHA has determined that the regulations do not duplicate and will not conflict with federal regulations. In fact, the statute specifically provides that warnings are only required to the extent they do not conflict with federal law.<sup>53</sup> The regulation incorporates federal and state regulations defining terms and specifically those that apply to occupational and prescription drug warnings in order to avoid duplication or inconsistency with federal and state laws and regulations.

---

<sup>52</sup> Health and Safety Code section 25249.11(b).

<sup>53</sup> Health and Safety Code Section 25249.10(a) (Exempting warnings governed by federal law). Refer also to Sections 25606 and 25607.7 of these proposed regulations.

## Significant Statewide Adverse Economic Impact Directly Affecting Business, Including Ability to Compete

OEHHA has made an initial determination that the adoption of the proposed amendments to the regulation will have an impact on some business sectors. OEHHA has, however, determined that the proposed regulation will not have a significant *statewide* adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. Proposition 65 and this regulation apply equally to California and all out-of-state businesses that sell products in California. Impacts on facility operation costs are minor. **Additional detailed information regarding the estimated economic impact of these regulations can be found in the Economic Impact Statement, which is included in the Initial Statement of Reasons as Appendix B.**

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

Upon review of the Economic Impact Statement, OEHHA has determined that the adoption of the proposed amendments to the regulation will have an impact on some business sectors. OEHHA estimates that the economic impact of the proposed regulation to be between 15 to 30 million dollars per year in the two years before full implementation of the regulation. The regulation is thus below the threshold for a major regulation, and no Standardized Regulatory Impact Assessment (SRIA) is required. **Detailed information regarding the estimated economic impact of these regulations can be found in the Economic Impact Statement, which is included in the Initial Statement of Reasons as Appendix B.**

The mandatory provisions in Subarticle 1 of the proposed regulation are related to the responsibility to provide warnings, and provide guidance on determining which party has the responsibility of providing warnings that must already be provided under the Act for exposure to a listed chemical. Subarticle 2 of the proposed regulation does not impose any new requirements upon private persons or business because it provides non-mandatory guidance and a voluntary safe harbor process for providing warnings already required under the Act that businesses can choose to follow. A business may continue to provide the warnings required by Section 25249.6 of the Act in any manner and with any content they can show is “clear and reasonable” under the law. Businesses that decide to convert from the current safe harbor warning to the safe harbor warning described in the proposed regulation will incur costs, primarily for relabeling

products or purchasing new warning signs. The regulation includes a two-year phase-in period that would allow businesses time to convert to the new warnings. Additionally, the proposed regulations provide that a warning for a consumer product manufactured prior to the effective date of the regulation is deemed to be clear and reasonable if it complies with the September 2008 revision of regulation. Many business costs frequently attributed to Proposition 65 such as defending lawsuits, paying attorney's fees and penalties, determining the chemical exposures from products, reformulating products to avoid the need to provide warnings, etc., fall outside the scope of this regulation.

OEHHA concludes that it is:

- (A) Unlikely that the proposal will have a major impact on the creation or elimination of jobs within California
- (B) Unlikely that the proposal will have a major impact on the creation of new businesses or the elimination of existing businesses within California
- (C) Unlikely that the proposal will have a major impact on the expansion or elimination of existing businesses within California
- (D) Likely that the proposal will benefit the health, safety and welfare of California residents.

### **Creation or Elimination of Jobs within the State of California**

This regulatory action will not likely have a major impact on the creation or elimination of jobs within the State of California. Total employment is projected to decline by 263 jobs (high-cost scenario) or 164 jobs (low-cost scenario) in the first 12 months, and 312 jobs (high-cost scenario) or 195 jobs (low-cost scenario) in the second 12 month period after its adoption. No specific types of jobs or occupations would be impacted. No jobs are projected to be created by the regulatory action.

### **Creation of New Businesses or Elimination of Existing Businesses within the State of California**

This regulatory action will not likely have a major impact on the creation of new businesses or the elimination of existing businesses within the State of California. The economic impact of the proposed regulation is very small relative to any one establishment's typical cost of operation and the need for business to be created or eliminated as a result of the proposed regulation does not exist.



## **The Expansion of Businesses Currently Doing Business within the State**

OEHHA does not anticipate any major impact on the expansion of businesses currently doing business within the state because the proposed regulations will not change whether warnings are required by a business. The proposed regulations focus on the manner in which the warnings are being provided, i.e., the content and methods for warnings. While businesses can download and print signs on their own, vendors of Proposition 65 warning signs may experience increased activity during the implementation period due to purchase of new warning signs.

## **Benefits of the Proposed Regulation**

The health and welfare of California residents will likely benefit from the increased information regarding exposures to listed chemicals and the clarity provided to businesses complying with the clear and reasonable warning requirements of the Act. More informative warnings will further the purposes of Proposition 65 by increasing the public's ability to make informed decisions regarding the products they choose to purchase and the places they frequent based on information about their exposures to chemicals that cause cancer or reproductive effects. Because businesses are given the option to use warning methods adopted by the lead agency, a business will have more certainty and confidence that it is in compliance with the statute while retaining the right to provide other non-safe harbor warnings they believe are compliant with the Act.

**Appendix A: Proposition 65 Clear and Reasonable Warnings Study**

## Appendix B: Economic Impact Statement