

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

January 16, 2015

SUMMARY

Proposition 65¹ requires that persons in the course of doing business 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.² 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.³ These regulations also provide safe harbor⁴, 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

¹ Health and Safety Code Section 25249.5 *et seq.*, The Safe Drinking water and Toxic Enforcement Act of 1986, commonly known as "Proposition 65". Hereafter referred to as "Proposition 65" or "the Act".

² Health and Safety Code Section 25249.12(a)

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

⁴ 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.

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.

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, establish a new, mandatory regulation addressing the relative responsibility of product manufacturers and others in the chain of distribution, versus the product retailer. It also contains the definitions relevant to Article 6. The regulations in proposed Subarticle 2 provide specific guidance on methods and content for safe harbor warnings that 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 certain chemicals and a link to a website maintained by OEHHA containing supplemental information.⁵ 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 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 Act⁶ 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 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.

⁵ OEHHA is separately, but concurrently, proposing 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.

⁶ Health and Safety Code Section 25249.6.

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 retailers 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....”⁷

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. 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.

⁷ Health & Safety Code Section 25249.11(f)

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.*"⁸ (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 suggestions. Ten interested parties submitted comments in response to the workshop.⁹

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.

In proposing this 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

⁸ 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>.

⁹ 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/wrkshop070913.html.

the allocation of responsibility among various businesses in the chain of commerce to provide 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 or not a warning is required under the Act. This decision is addressed by other provisions of the law and regulations. The proposed regulations only become relevant after a business determines that the exposure to a listed chemical it knowingly and intentionally causes requires a warning.¹⁰

Subsection (b) provides a two-year delayed effective date for the new regulations. This will allow businesses to use either the old safe harbor warnings or the newly adopted safe harbor warnings for two years following adoption of the regulations. This will provide businesses with a transition period to “sell through” products that may use the old warning language and allow time to replace existing signage or implement new technology. 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. Providing a two year phase-in period will also 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.

Subsection (c) explains that any interested party can petition OEHHA to adopt additional regulations that address exposures to listed chemicals in 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 a warning is required at all.¹¹

¹⁰ Health and Safety Code Sections 25249.6 and 25249.10; and Articles 5, 7 and 8 of Title 27, Cal. Code of Regs.

¹¹ 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).

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. However, this provision makes clear that any such supplemental information may not contradict, dilute or diminish the warning and is not a substitute for a warning.

Finally, 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.

§ 25600.1 Definitions

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

For example, a definition for “food” was added 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.

OEHHA changed the definition in subsection (h) from “Consumer Product Exposure” to “Product Exposures,” and this new term is used throughout the regulation. OEHHA intends this change to clarify that a warning for an exposure to a listed chemical from any product, or component of a product, whether it is sold directly to a consumer or not, may be provided using the methods and content described in the regulation. The definition of “products exposure” in subsection (h), expressly states that food and dietary supplements are 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 component parts. Therefore, OEHHA believes such a clarification is necessary.

The changes to the definition of “environmental exposure” in subsection (b) 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 (d) 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 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 (e) and (f), respectively, have been updated to more specifically allow the use of newer technology to communicate the required warning.

The new definition of “retailer” in subsection (i) is intended to clarify a term that is used throughout the regulation in regard to product exposures. A “retailer” 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 retailers of foods and other products.

The changes to the definition of “sign” in subsection (j) 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.

§ 25600.2 Responsibility to Provide 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 retailers 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 retailer 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,¹² 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 retailer.

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

¹² Health and Safety Code Section 25249.7(d), Title 27, Cal. Code Regs., Section 25903

“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...”¹³

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 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 retailers in a separate category. Retailers are responsible for providing warnings only if certain specified conditions are present.

Under subsection (b) the manufacturer, producer, packager, importer or distributor of a product may comply with the Act by affixing a warning to the product; or providing specific notice to the retailer 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 written acknowledgement of this notice from the retailer every 180 days during the period when the product is sold. Such acknowledgement 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.

The manufacturer, producer, packager, importer and distributor do not need to obtain the retailer’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 retailer receives a notice that complies with subsections (b)(1) through (3), the retailer 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 retailer’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 retailer 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 retailer is required to post these materials in compliance with the

¹³ Health and Safety Code Section 25249.11(f)

requirements of section 25603. If a manufacturer provides a shelf sign or tag to the retailer and the retailer covers it, fails to conspicuously post it, or intentionally removes it, the retailer has not complied with Section 25603. If the retailer loses or destroys the manufacturer's warning materials, the retailer should request duplicate material from the manufacturer or other person in the chain of distribution. In the meantime the retailer must still provide a warning that fully complies with the Act.

Subsection (d) sets forth the situations in which the retailer is responsible for providing the warning. Under subsections (d)(1) through (3), the retailer 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 retailer 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 retailer is responsible for providing a warning if it has received the notice described in subsection (b), whether or not it has provided an acknowledgement pursuant to subsection (b)(4) or (5). If the retailer has received such a notice from the manufacturer, producer, packager, importer or distributor, then the retailer has the responsibility to either pass on the warning or to provide a legally adequate warning of its own

Finally, under subsection (d)(4) the retailer 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 distributors 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 retailer must provide the required warning in this situation.

The intent of subsection (d)(5)(A) and (B) is to require the retailer 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 retailer to provide the warning.

There may be situations when the retailer 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 retailer will have a duty to inquire into these facts whenever the retailer (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).

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

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

This provision focuses on those retailers 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.. A retailer 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 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 will generally need to proceed against the manufacturer, producer, packager, importer and/or distributor. An enforcement action against the retailer will be appropriate only when one or more of the circumstances in subsection (d) exist.

Subsection (e) is necessary because the retailer 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 (e) therefore requires the retailer to provide the name and contact information for such entities, upon written request, to the 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 (f) allows the manufacturer, producer, packager, importer or distributor of a product to enter into an agreement with the retailer 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 notice and acknowledgement of the exposure every 180 days as required by subsection (b)(5), on the condition that the retailer provide continuing and adequate warnings of the exposure and that the manufacturer promptly inform the retailer 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 (f), 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.

Court Approved Settlements

The pre-regulatory draft of these regulations released by OEHHA for comment in April 2014 contained a provision stating that the new requirements in the regulations would not apply to the parties to settlements that have been approved by a court prior to January 1, 2015.¹⁴ This “grandfathering” provision is not, however, incorporated in this formal regulatory proposal.

The Agency agreed with comments from stakeholders questioning the need for a grandfathering provision in light of the non-mandatory, safe harbor approach in the proposed regulation and the fact that businesses who are parties to a settlement or judgment must comply with the provisions of the court’s order, regardless of whether this regulation states that fact. Further, under proposed Section 25600(c), a non-party has the option of petitioning the Agency to adopt warning content or methods specific to a product, chemical or type of exposure pursuant to Government Code Section 11340.6 et seq., including warning methods or content contained in a court settlement.

Subarticle 2: Safe Harbor Methods and Content

Subarticle 2 provides non-mandatory, safe harbor guidance for the methods and content for providing a warning that are 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.

¹⁴ “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.

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

This section describes the availability of a safe harbor to a business if the business complies with the requirements of this Subarticle. The safe harbor consists of warning methods and content that OEHHA has determined to be “clear and reasonable” for the purposes of the Act.

§ 25602 Chemicals Included in the Text of a Warning

Section 25602 of the proposed regulation is intended to provide the public with more information directly in the warning concerning exposures to certain listed chemicals. Exposures to the chemicals identified in Section 25602 are commonplace through a variety of product or environmental scenarios. By proposing this section, OEHHA does not intend to extend, limit, or modify the names or scope of the existing chemical listings contained in Title 27, California Code Regulations, section 27001. Including the more technical chemical names, or all the individual chemicals within a chemical class or mixture in the text of a warning could defeat the purpose of providing understandable and useful information to individuals on the warning itself. OEHHA has therefore determined that in some cases including the simplified names of the chemicals in the warning will enhance the effectiveness of the warning and make it more understandable to the reader.

When selecting chemicals to be included in Section 25602, OEHHA considered the following criteria. (Note that some chemicals may not have information available for all of the criteria.)

- Widespread prevalence of the listed chemical in products and/or locations beyond those that are covered by specific warning language in Section 25608;
- Potential for significant exposure to the listed chemical through human interactions with products, including food, or at locations frequented by the public;
- Recent Proposition 65 enforcement activity;
- Recognizability of the chemical name among the general public;
- The general availability of additional authoritative information and resources for the public on the toxicity and exposure to the chemical, doses of concern, and ways to prevent or reduce exposure.

A list of scientific references relied upon by OEHHA in the selection of chemicals to be included in this section is attached to this document.

Subsection (a) provides that the general chemical name includes all listed chemicals in the same category or group. Most of the chemicals in this section of

the proposed regulation are listed in Section 27001 in a more technical form. For example, the general term “mercury” in Section 25602 covers the Proposition 65 listings for mercury, mercury compounds, methyl mercury and methyl mercury compounds. Similarly, the family of chemicals identified as “phthalates” in Section 25602 covers several listed phthalates with names that may not be recognizable to many members of the public, including di(2-ethylhexyl)phthalate, di-n-butyl phthalate and di-isodecyl phthalate. It should be noted that not all phthalates are listed under Proposition 65. However, using the term “phthalates” will cover exposures to any or all of the phthalates that are listed currently or in the future.

The chemicals identified in subsection (a) are organized alphabetically. OEHHA does not intend for an inference to be drawn as to relative health risks from individual chemicals or chemical groups based on numerical order within the regulation. Similarly, it is not OEHHA’s intent to imply that any or all of these chemicals pose greater health risks to the public than other listed chemicals not included in Section 25602. As stated above, these chemicals were selected using the above-mentioned criteria with the intent of making Proposition 65 warnings more informative and meaningful to the public.

Following is specific information concerning each of the twelve chemicals or chemical groups included in this section.

(1) Acrylamide. Acrylamide is a carcinogen and reproductive toxicant found in many starchy and plant-based foods cooked at high-temperatures such as frying or baking. Given the popularity of acrylamide-containing foods, including French fries, pretzels, peanut butter, roasted almonds, potato chips, ready-to-eat grain-based cereals, breads and coffee, the potential for regular exposure to acrylamide is significant.

Occupational exposures to acrylamide can occur as a result of its use as a polymerizing agent in grouts and cement, as a flocculating agent in water treatment processes, and to make polyacrylamide, which is used in biological laboratories to make chromatographic gels. Acrylamide is also used as a polymerizing agent in various manufacturing processes.

Due to significant media attention to the issue of acrylamide in foods in recent years, and the fact that some businesses have warnings posted that already name acrylamide, this chemical is considered fairly recognizable by the public. The Food and Drug Administration and the World Health Organization both have significant information available for the public on their web pages on acrylamide.

During the past 5 years, about 17 60-day notices were filed regarding exposures to acrylamide, resulting in 5 complaints, 12 settlements, and 1 judgment. These settlements and judgments involved acrylamide

exposures from potato chips, coffee, breakfast cereals and baby food products.

(2) Arsenic. Arsenic is listed as both a carcinogen and reproductive toxicant. This commonly known element is present in food, air, water, soil, and tobacco smoke. Dietary sources of inorganic arsenic include rice and rice products, wheat and some vegetables and fruits. Arsenic was extensively used as a wood treatment. Exposure risk from treated wood is elevated with direct skin contact with or inhaled dust from these products. Occupational exposures are due to airborne arsenic generated by metal and coal mining, metal smelters and other production processes, production and application of arsenical pesticides, energy generation from the burning of fossil fuels, glass manufacture, cement manufacture, semiconductor manufacture, and other industrial processes. Nearby residents may also be exposed as a result of these activities. The general public is most familiar with arsenic as a potential drinking water contaminant; however, identification of arsenic exposures through other products can provide valuable information.

During the past 5 years, 109 60-day notices were filed regarding arsenic, resulting in 19 complaints, 39 settlements, and 19 judgments. These settlements and judgments involved exposures to arsenic in dried seaweed, concrete and cement-based products, dietary supplements, water filtration systems and Halloween costumes and accessories.

(3) Benzene. Benzene is a carcinogen and reproductive toxicant that is present in natural gas, crude oil, and petroleum products such as gasoline, diesel, and other petroleum-based fuels. Benzene is in tobacco smoke and wood smoke. Benzene is used as an organic solvent, to synthesize intermediates (e.g., ethylbenzene, cumene) used in the production of plastics, elastomers, phenolic and nylon resins, and other organic compounds, and to produce acetone. Occupational exposures can occur during manufacturing processes like plastic and pesticide production or inhaling fossil fuel emissions, such as from oil refineries. Tobacco smoke and motor vehicle and industrial emissions are likely the most common sources of benzene exposures for the general public. Proximity to industrial sites, gas stations, and vehicle exhaust, are common ways the public can be exposed to benzene.

During the past 5 years, there have been approximately 23 60-day notices filed regarding benzene exposures, resulting in 3 complaints, 6 settlements, and 2 judgments. These settlements and judgments were related to benzene exposures from flame cooked ground beef products, printers, copiers and toner.

(4) Cadmium. Cadmium is a metal identified as a reproductive toxicant and carcinogen. Cadmium is present in food, air, water, soil, and tobacco smoke. Dietary sources of cadmium include organ meats (e.g., liver, kidney), shellfish, and some vegetables, beans, and nuts. Cadmium is used in the production of rechargeable nickel-cadmium batteries found in a multitude of personal and commercial electronics, as a stabilizer in polyvinylchloride (PVC), as a pigment in paints, glass, plastics, and ceramics, as an anticorrosive coating on steel, in welding, silver solder, steel alloys, and solar cells. Additional sources include metal plating, jewelry, combustion of coal and other fossil fuels, and cement production. The general public can be exposed to cadmium from a variety of sources, particularly from costume jewelry, household and craft products, thereby increasing the risk of levels accumulating within the body. Specific identification of a potential cadmium exposure can inform individuals about their particular exposure potential based on the products they buy or use in common activities, including jewelry and art crafts.

There has been extensive media attention in recent years to cadmium exposures, especially from children's jewelry. There have been numerous product recalls due to this issue, and the Consumer Product Safety Commission has resources and information for consumers on its website related to cadmium products.

During the past 5 years, about 107 60-day notices were filed alleging exposures to cadmium, resulting in 61 complaints, 47 settlements, and 37 judgments. Settlements and judgments during this period involved cadmium exposures from cocoa/cacao, dietary supplements, Halloween costumes, accessories, and decorations, jewelry, fertilizer and glassware.

(5) Carbon Monoxide. Carbon monoxide is a gas byproduct of combustion and is identified as a reproductive toxicant. Sources include industrial and vehicle emissions, tobacco smoke and non-electric heating sources. Members of the general public are widely familiar with the immediate toxic effects of carbon monoxide exposure in the context of a malfunctioning furnace or engine exhaust in an enclosed space. However, the general public may be unaware of the potential health risks associated with common, lower-level exposures to carbon monoxide associated with parking garages, areas of concentrated industrial or vehicle emissions, and tobacco smoke.

During the past 5 years, there have been approximately 7 60-day notices filed regarding carbon monoxide, resulting in 2 complaints and 5 settlements. Carbon monoxide emissions from heater fuel and propane tanks were the subject of the complaints and settlements during this period.

(6) Chlorinated Tris. Chlorinated Tris (TDCPP); tris (1,3-dichloro-2-propyl) phosphate) is identified as a carcinogen. It is a high production volume chemical used as an additive flame retardant in flexible and rigid polyurethane foams, and in resins, plastics, textile coatings and rubber. It is commonly found in polyurethane foam-containing furniture, and in automobile seat cushions and headrests. TDCPP is present in dust in residential and commercial settings due to its pervasive use as a flame retardant in upholstered furniture, including automotive seat cushions and head rests, and other materials. Identification of TDCPP exposures from individual product use can notify individuals about potential sources of exposure in residential or other indoor environments. There has been extensive media attention to flame retardant chemicals in recent years, and California legislation requires furniture to be labeled if it contains flame retardant chemicals, effective January 1, 2015. For these reasons, members of the public are reasonably likely to recognize the name "chlorinated tris".

During the past 5 years, there have been approximately 301 60-day notices filed for alleged exposures to chlorinated tris, resulting in 120 complaints, 167 settlements, and 119 judgments. Examples of settlements and judgments involving chlorinated tris during this period include exposures to the chemical from children's furniture, nursing pillows, pregnancy pillows/cushions, upholstered furniture including children's car seats, foam cushioned pads for infants and children, sleepers with padding, seat cushions, massaging pillows, changing pads and acoustic/soundproofing foam.

(7) Formaldehyde. Formaldehyde is a carcinogen present in air, soil, food, water, vehicle exhaust, and tobacco and wood smoke. Sources of exposure to the general public include combustion sources such as motor vehicles, power plants, incinerators, refineries, off-gassing from building and home-furnishing materials such as reconstituted wood products, carpeting and other consumer goods such as laundry detergents, wall paper adhesives, sanitizer, clothing and linens treated with formaldehyde as a mildewcide, and use of cosmetics and other products that contain formaldehyde or formaldehyde-releasing compounds as preservatives, anti-microbial and fungicide soaps, shampoos, cleaning agents, paints, lacquers and cutting fluids.

Occupational exposures occur in a number of industries, including the production of formaldehyde, formaldehyde-based resins, plastic products, fiberglass, abrasives, and rubber, the finishing of textiles, in biology teaching and pathology autopsy laboratories, in the embalming, funeral services and crematory industries, in the reconstituted wood products, lumber, and wood products industries, and in the varnishing of furniture and wooden floors. The potential for exposure can be elevated in areas of

high industrial or vehicle emissions or when working with treated wood or wood byproducts during construction-related activities, such as during home improvement projects.

During the past 5 years, there have been approximately 19 60-day notices filed regarding formaldehyde exposures, resulting in 5 complaints, 2 settlements, and 1 judgment. The settlements and judgment during this five year period involved formaldehyde exposures from hair relaxer and Halloween costumes and decorations.

(8) Hexavalent Chromium. Hexavalent chromium (chromium VI) is the hexavalent ionic form of the metal chromium, and is a carcinogen and reproductive toxicant. Hexavalent chromium may be present in air, water, soil and foods. Hexavalent chromium was extensively used as a wood treatment. Exposure risk from treated wood is elevated with direct skin contact with or inhaled dust from these products. Hexavalent chromium is used to harden steel, as a corrosion inhibitor in various paints and coatings, in production of chromate and chromate pigments, in tanning processes, metal finishing and chrome plating. It is present in Portland cement, welding fumes, tobacco smoke, and vehicle emissions. Industrial emissions, including fly ash from power plants, kiln discharges from Portland cement processing, and chrome plating facilities are some of the more common sources of exposure for members of the general public. Environmental exposures can be significant when hexavalent chromium breaches a work or storage site and leaches into the ground water or when airborne particles drift into areas where personal protective equipment is not used, such as outside a manufacturing plant. Specific warnings to the general public can mitigate risk to individuals in or near the affected area.

Hexavalent chromium contamination in water supplies has received extensive public attention, in part due to a major motion picture about water contamination in Hinckley, California. For this reason, and due to ongoing media attention in some parts of the state to water contamination with this chemical, the chemical name is considered to be reasonably recognizable to the public.

During the past 5 years, there have been approximately 31 60-day notices filed alleging exposures to hexavalent chromium, resulting in 12 complaints, 22 settlements and 12 judgments. The judgments and settlements during this period involved exposures to hexavalent chromium in concrete and cement products.

(9) Lead. Lead is a metal identified as a reproductive toxicant and carcinogen. Lead may be present in dust, air, water, food, soil, and tobacco smoke. Historically, lead has been used as a fuel additive and is

still used in certain aviation fuel. Lead is a component of many household products, including some made of polyvinyl chloride (PVC), such as electrical cords and holiday lights, items made of brass, including water fixtures lead crystal, lead-glazed ceramics, some hair dyes, cosmetics, toys, art supplies costume jewelry and imitation leather. Lead exposures can occur through some foods, such as balsamic vinegar, certain candy, spices from Asia and Mexican chili and in some herbal and traditional medicines. Lead is also present in some artificial turf. Lead remains pervasive in older homes and other buildings as a result of its use in paint prior to 1978, and plumbing pipes, fittings and solder. Lead can be released to the water or air during manufacturing, lead battery recycling, metallurgic and combustion processes, building demolitions, and from lead wheel weights that fall on roadways and become pulverized by traffic. The general public has widespread familiarity with lead due to the ongoing issue of lead in old paint and because most children are screened for lead exposure. Potentially unsafe levels of lead in products such as jewelry and fashion accessories imported into the U.S. still pose a significant concern. It is less well known that lead is a significant toxic air pollutant, particularly in areas with high industrial emissions or in areas where lead batteries are recycled. Specific warnings for potential lead exposures, particularly near high combustion emission discharges, can help individuals to identify exposure sources in affected areas. There are extensive authoritative resources on the Internet related to lead.

During the past 5 years, there have been approximately 533 60-day notices filed regarding lead and lead compounds, resulting in 252 complaints, 235 settlements, and 113 judgments. Examples of settlements and judgments regarding lead exposures during this timeframe include dietary supplements, ceramic ware, jewelry, water heater valves, brass components of tools, valves, plumbing products, kitchen products, flashlights, vinyl or imitation leather such as wallets, handbags, purses, belts, footwear, foods (ginger and fruit snacks, honey licorice, vinegar, soy sauce, kombucha), aviation fuel (AVGAS) and earphones.

(10) Mercury. Mercury and mercury compounds are reproductive toxicants, and methylmercury compounds are also listed carcinogens. Historically, mercury has been used in the manufacturing of fluorescent light bulbs and measurement devices, including thermometers. Mercury emissions are most commonly the results of mining practices and combustion from certain industrial sources such as coal-fired power plants, incinerators, and cement kilns. Mercury in the environment can be converted by bacteria to methyl mercury and enter the food chain, particularly in aquatic environments, resulting in contamination of fish. Mercury can accumulate in the body and regular consumption of mercury-contaminated fish can pose a significant health

risk, particularly in children and pregnant women. The general public has widespread familiarity with mercury as a potential contaminant in certain fish. Specific warnings for mercury-containing products or emissions can reduce the risk of exposure in the general population and the sensitive human subpopulations such as pregnant women. Extensive authoritative resources are available on the Internet from the Food and Drug Administration, the U.S. EPA and other agencies related to mercury.

During the past 5 years, there were 3 60-day notices filed regarding exposures to mercury and mercury compounds, resulting in 2 complaints and 1 settlement. The complaints and settlement during this period involved exposures to mercury in dietary supplements and discharges into drinking water.

(11) Methylene Chloride. Methylene chloride (dichloromethane) is a carcinogen and high volume production chemical in paint removers/strippers and degreasers, in addition to metal cleaning and fat/oil extraction processes. Methylene chloride is also a component of some household products including furniture strippers, lubricants, rust removers, water repellants, and in electronic device coatings. Occupational exposures and exposures to the public can occur through dermal contact or inhalation of methylene chloride vapors. Exposures outside of the occupational setting pose a significant concern, as individuals working with products that contain methylene chloride may not know to utilize personal protective equipment that may be a standard practice in an occupational setting, and may not use the product under conditions with adequate ventilation. Specific warnings for these exposures can potentially mitigate risk.

Although methylene chloride is less well-known to the general public than some other chemicals in this section, there have been some well-publicized deaths in California in recent years due to methylene chloride exposure. In addition, existing warnings on furniture strippers specifically identify methylene chloride.

During the past 5 years, there were 2 60-day notices filed regarding methylene chloride with no reported complaints or settlements. Alleged sources of exposure to methylene chloride include a landfill site and a potential discharge into drinking water.

(12) Phthalates. Phthalates comprise a class of chemicals with individual compounds identified as reproductive toxicants or carcinogens, depending on the specific chemical. These chemicals are heavily utilized in the production of plastics and a number of other products, including solvents, coatings, plasticizers, inks and sealants. Examples of polyvinyl chloride (PVC) products containing phthalates include PVC pipe, wire and cable

insulation, vinyl flooring, carpet backing, coated fabrics, artificial leather, garden hoses, auto under-coatings, disposable gloves and medical products. Non-PVC products that may contain phthalates include cosmetics, perfume and other personal care products such as nail polish, lotions, soap, shampoos, conditioners, hair spray, and fragrances, air fresheners, paints, lacquers, adhesives, pesticides¹⁵, food packaging, children's toys and art supplies. Levels of occupational and environmental exposures to phthalates by inhalation, dermal or ingestion routes vary depending on the interaction of individuals with the products. Given the extensive use of plastic products for personal care, and for the processing, cooking, and storing of food; the level of cumulative exposure risk from multiple sources and regular daily exposures is of significant concern, especially for children.

There has been significant media attention concerning various phthalates in cosmetics and other products in recent years, making it reasonably likely that members of the public will be familiar with this chemical group. The Consumer Product Safety Commission has published extensive information on these chemicals, including resources for consumers.

During the past 5 years, there have been approximately 2351 60-day notices filed regarding alleged exposures to phthalates, resulting in 554 complaints, 891 settlements, and 237 judgments. Examples of products that have been the subject of settlements and judgments involving exposures to phthalates during this period include vinyl/PVC products (mats, grips, tape/table tops, beverage insulators, toiletry bags, cord protectors, and book covers), cookware, sunglasses, eyewear, eyewear cases, tile flooring, pet accessories, automobile accessories, storage cases, wallets and footwear.

The chemical names required to be included in a warning under this section is not intended to be exhaustive and may be changed over time as the public becomes familiar with the improved warning format. Some stakeholders have voiced concern that OEHHA will frequently change the list of chemicals in this section, forcing businesses to continually incur expenses in order to comply with the removal or addition of a listed chemical in this section. However, the addition or removal of a listed chemical from this section will require the adoption of an amended regulation and can only occur after a formal regulatory process that includes a public notice, hearing and opportunity to comment. Businesses will have adequate time to modify warnings to include the relevant chemical names if they choose to provide the safe harbor warning.

¹⁵ "Pesticide carriers" are liquid or solid chemicals, such as certain phthalates, that are added to a pesticide product to aid in the delivery of the active ingredient.

Several businesses have objected to the general idea of including chemical names in the warning text for two primary reasons: first, chemical names could be long and difficult for the members of the general public to understand; and second, some warnings would be inordinately long and cumbersome if the names of several chemicals were included. On the other hand, many public interest organizations asked that all listed chemicals intended to be covered by the warning be disclosed in the warning. After careful review of these concerns, OEHHA determined that the approach presented in proposed Section 25602, in which only certain chemical names must be included in the basic warning message, would better inform the public concerning common chemical exposures than the current regulation without excessively burdening businesses.

It should be noted that certain chemicals, including some that are listed in this section are named in the content requirements for some of the product and area-specific warnings adopted in Section 25608. Those specific warnings need not list additional chemicals in this section unless there is an express requirement for a business to do so in Section 25608.

Because these 12 individual chemicals or groups of chemicals vary in their uses and prevalence in commerce, OEHHA anticipates that most warnings will not contain more than one or two of the chemicals included in this section. However, businesses that believe a given warning would be unwieldy or infeasible due to Section 25602 would have at least two alternatives. In Section 25604(b) of the proposed regulations, OEHHA has provided an alternative “short form” warning that does not include the chemical name. Further, businesses could request that OEHHA adopt a product or exposure-specific warning in Section 25608. This would enable OEHHA to consider the specific circumstances that might make a particular warning’s compliance with Section 25602 to be difficult, and to provide regulatory guidance as appropriate for a clear and reasonable warning. Lastly, a business may use its own warning as long as such a warning is “clear and reasonable” for purposes of the Act. For these reasons, OEHHA does not anticipate that Section 25602 will have an adverse impact on businesses that is not offset by the benefit to the public of obtaining more specific information concerning exposures to these 12 chemicals/chemical groups.

§ 25603 Product Exposure Warnings – Methods of Transmission

Section 25603 describes methods for providing a warning for an exposure to a listed chemical from a product (as opposed to an occupational or environmental exposure). Warnings for exposures from foods, alcoholic beverages, prescription drugs, dental care, passenger vehicles, diesel engines, raw wood products, and furniture are treated separately in subsections of 25608, and are discussed later in this document.

A business that is subject to the requirements of Health and Safety Code Section 25249.6 may choose 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 the internet during on-line purchases, or warnings provided via other electronic means – so long as the person receiving the warning is not required to seek it out.

The “catch-all” provision in subsection (a)(2) is intended to capture existing methods of communication, including currently available tools such as electronic shopping carts, QR Codes, 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.¹⁶

Under subsection (d) product exposure warnings must be provided in the same language or languages as any other label, labeling or sign accompanying a product. 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 information in an alternate language. Given California’s linguistic diversity,¹⁷ OEHHA believes this requirement in the proposed regulation will further the purposes of the statute by expanding the number of individuals who can easily access and understand the warning, thus ensuring it is “clear and reasonable”.

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. While other methods of transmitting the warning message may be developed, the methods described in the proposed regulation are likely to provide an individual with the required warning in a manner that is easily

¹⁶ See *Ingredient Communication Council, Inc. v. Lungren*, 2 Cal. App. 4th 1480 (1992).

¹⁷ “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>.

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.

§ 25604 Product Exposure Warnings – Content

Section 25604 sets out the requirements for providing a warning for an exposure to a listed chemical from a product, other than products that are covered in Section 25608 of the regulations. A business that is subject to the requirements of Section 25249.6 of the Act must include all the mandatory elements set out in Section 25604 or the relevant provisions of Section 25608, in order for the warning to be considered clear and reasonable under this Article.

Subsection (a)(1) establishes a warning symbol to be used on all Proposition 65 product warnings, except where otherwise stated in Section 25608. 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 warnings¹⁸ because it has been adopted by numerous federal, state and international governments to identify toxic chemicals, including chemicals that cause cancer or reproductive toxicity.¹⁹ 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 is similar to the warning symbol used by the American National Standards Institute (ANSI), is used extensively by businesses in the United States and internationally, and is currently in use by many businesses for existing Proposition 65 warnings.²⁰ The symbol consists of a black exclamation point in a yellow equilateral triangle with a bold black outline. 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

¹⁸ 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>.

¹⁹ U.S. Occupational Safety & Health Administration, “Hazard Communication Standard Pictogram” (2014) available at 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.

²⁰ 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.

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

Subsection (a)(2) carries over the requirement in the existing regulations that all warnings contain the signal word “WARNING”. Including this word in bold and capital letters ensures that consumers will immediately know the information being provided is important and not just informational in nature. Given that the Act specifically requires a clear and reasonable *warning* to be given,²¹ including this signal word is fully consistent with the Act and furthers its purposes.

Subsections (a)(2)(A-D) set out the message that must be provided in each warning. 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 as seriously. Therefore, OEHHA has determined that the phrase “can expose you to” is more clear and consistent 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. Proposition 65 is a right-to-know law. The purpose of the statute is to provide people with notice

²¹ Health and Safety Code Section 25249.6

concerning their *exposures* to listed chemicals. The preamble to the law states in part that:

“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)²²

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 expose the public to a listed chemical, or not, 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”.

The proposal also includes the use of a Uniform Resource Locator (URL) so that the information on OEHHA’s website can be accessed easily by most consumers.²³

Subsection (b) sets out a specific 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

²² Ballot Pamphlet, Proposed Law, Gen. Elec. (Nov. 4, 1986) p. 53.
http://www.oehha.ca.gov/prop65/law/pdf_zip/Prop65Ballot1986.pdf

²³ 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.

provide useful information to individuals while avoiding unwieldy on-product warnings. Further, the warning is more clear and direct than the existing safe harbor warnings being used by many businesses.

§ 25605 Environmental Exposure Warnings – Methods of Transmission

Section 25605 is similar to the existing regulation for general environmental exposures. The provisions have been updated to remove obsolete citations and to reflect changes in communication technology that have occurred since the original regulation was adopted, 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. Subsection (a)(1) requires signage to 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 in any language ordinarily used by the business to communicate with the public, in addition to English. The reason for this provision is the same as discussed above for the analogous provision for product warnings in Section 25603(d).

Subsection (a)(3) provides more detail concerning 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. Further, the warning must also contain a map showing the area in which an individual can be exposed. These provisions 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.

§ 25606 Environmental Exposure Warnings – Content

Section 25606 closely tracks the 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.

§ 25607 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.

§ 25608 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 is properly warned about the exposures that can occur through these products or facilities.

Section 25608 requires a person to provide a warning in a specific way and with specific content where a warning covering that exposure has been adopted by OEHHA. 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.

§ 25608.1 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(c).

Subsection (a) clarifies that all methods of transmitting the warning for other products under Section 25603 are equally available to businesses that manufacture or sell foods. The content of the warning is set forth in Section 25608.2.

Subsection (b) requires that a warning be provided in the same language or languages other than English that are already included on a label, labeling, or sign for a food.

§ 25608.2 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 foods²⁴ and has issued several Interpretive Guideline documents specific to potential exposures to listed

²⁴ Title 27, Cal Code Regs, Section 25501. *Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652 (Ct. App. 1991).

chemicals in foods that do not require warnings.²⁵ Perhaps for this reason, very few food products currently carry Proposition 65 warnings.²⁶ Those that do sometimes include additional information about the origin of the chemical in the food,²⁷ the target audience, such as pregnant women and children,²⁸ types of foods affected,²⁹ and a URL for more information.³⁰ These warnings were developed in response to litigation and are not universally accepted by all businesses or specifically approved by OEHHA. 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 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 the minimum 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.

Subsection (a) of the proposed regulation closely tracks the product warning provisions of Section 25600(d), with two main exceptions. First the warning symbol is not required for food product warnings. OEHHA has not included the warning symbol as a mandatory requirement for food exposure warnings because food product labeling does not generally include warning symbols. Use

²⁵ 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.

²⁶ Examples: certain balsamic vinegars, some potato chips, fresh fish, coffee and baked goods.

²⁷ 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." *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>.

²⁸ 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. ("Pregnant and nursing women, women who may become pregnant, and young children should not eat the following fish....")

²⁹ 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.

³⁰ For example, the warning label posted at Starbucks coffee establishments refers patrons to OEHHA's website, <http://oehha.ca.gov/prop65/acrylamide.html>.

of the signal word WARNING, should sufficiently alert the consumer that important information follows.

Second, the required content of the warning message set out in subsections (a)(2-5) 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.

Consistent with the proposed content for warnings for other products, this provision provides the option for a very limited level of content to be included in an on-product warning based on product manufacturers’ concerns that a longer warning message will not fit on the labeling or packaging of some products. Subsection (b) follows the content requirements for on-product warnings but additionally requires that the label 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.

As provided in Section 25601(d), a business may include additional contextual information to supplement the warning, as long as it does not contradict, dilute or diminish 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),³¹ 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.

§ 25608.3 Alcoholic Beverage Exposure Warnings – Methods of Transmission

The existing regulations addressing alcoholic beverage warnings are the most comprehensive provisions in the current regulations. They contain very detailed 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.

³¹ 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.

Subsection (a) requires signs to be displayed so they are clearly visible under all lighting conditions normally encountered during business hours. Subsection (a)(1) requires the use of an 8 1/2-by-11 inch sign in no smaller than 28-point type. The sign sizes of 8 1/2-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.

§ 25608.4 Alcoholic Beverage Exposure Warnings – Content

Subsection (a) includes the mandatory requirements for providing a warning that have been described in Section 25608.3. 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.³²

§ 25608.5 Non-Alcoholic Beverage and Food Exposure Warnings for Restaurants – Methods of Transmission

Subsection (a) provides options for signs or notices to be displayed at restaurants. A business may choose to display an 8 1/2 by 11 inch sign with no smaller than 28-point type or a 5 by 5 inch sign at each point of sale in a minimum 20-point type. Subsection (b) repeats the 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.

§ 25608.6 Food and Non-Alcoholic Beverage Exposure Warnings for Restaurants – Content

Subsection (a)(2) sets forth a tailored warning for restaurants. This section does not require the warning symbol as part of the warning. The warning language specifically identifies the chemicals lead, mercury and acrylamide because food

³² 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>.

supplied or served in restaurants is a common source of exposure to these listed chemicals.

§ 25608.7 Prescription Drug 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.³³ 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 maintains the existing regulatory language concerning emergency medical care. It is intended to incorporate existing informed consent practices for emergency medical care.

§ 25608.8 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 employees, the proposed warnings are primarily focused on patients. Setting these 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 requirements of the regulation. Subsections (a)(1-2) 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 warning content requirements in Section 25608.9 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

³³ *Dowhal v. SmithKline Beecham Consumer Healthcare*, 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.")

dentures, dental implant prosthesis, mouthguards, splints, trays, stents, TMJ, and sleep apnea devices.

§ 25608.9 Dental Care Exposure Warnings – Content

This section tailors the warning message to address the specific types of exposures that may occur from dental care services. The warning language required under this section 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 further advises a person to consult with their dental care provider about these exposures and appropriate materials for treatment. The warning also requires 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 settings³⁴ and dental offices.³⁵ It is also consistent 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 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.

§ 25608.10 Raw Wood Product Exposure Warnings – Methods of Transmission

The tailored warning for wood dust is derived from existing language for exposures to wood dust from wood products. For wood products sold in bulk, subsection (b) allows a business to provide a warning via a receipt or invoice

³⁴ 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 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>.

³⁵ http://www.dbc.ca.gov/formspubs/pub_dmfs2004.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.

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.

§ 25608.11 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 regulation. The tailored warning thus includes the warning symbol described in 25604(a)(1), the word “WARNING”, and a link to the OEHHA website for supplemental information.

§ 25608.12 Furniture Product Exposure Warnings – Methods of Transmission

The regulation requires the following process for providing a warning for exposures to listed chemicals from furniture:

1. A notice is displayed at a public entrance or point of display advising the potential purchaser that a Proposition 65 warning may be required for a given product and the location where a warning can be found; and
2. A similar notice on the receipt or invoice with information regarding the existence and location of a Proposition 65 warning; and
3. A warning message affixed to the furniture product. OEHHA has determined that this three-part process is appropriate to ensure that the warning is seen and understood prior to exposure.

Generally, warning messages and other information are 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. Therefore, it is important to point the consumer to the correct location of the warnings in order to make the warning clear and reasonable in the context of a furniture purchase. These methods of transmission for furniture warnings were developed to ensure that the consumer is warned about potential exposure to listed chemicals prior to those exposures.

§ 25608.13 Furniture Product Exposure Warnings – Content

This section incorporates by reference the general product exposure warning content requirements of Section 25604. The only deviation is the requirement for the use of a URL that is specific to furniture products. OEHHA has determined

that the product exposure content requirements will provide a warning that meets the requirements of Subarticle 6.2.

§ 25608.14 Diesel Engine Exposure Warnings (Except Passenger Vehicle Engines) – Methods of Transmission

The method for providing a warning for diesel engines draws on processes currently used by the diesel truck and engine industry pursuant to court settlements. Subsection (a) requires the warning to be printed in the owner's manual and a separate, permanently attached warning label be placed on the product itself. If other warnings or operator instructions are provided in an on-screen display, the warning is also to be provided in that manner. Using this combination of methods is likely to result in the warning being seen and understood by the operator prior to exposure.

§ 25608.15 Diesel Engine Exposure Warnings (Except Passenger Vehicle Engines) – Content

The warning language currently in use for diesel engines 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 25604(a)(1), the word "WARNING", and a link to the OEHHA website for supplemental information. The warning message includes existing language 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 product user with specific ways to reduce or avoid exposure to diesel engine exhaust.

§ 25608.16 Passenger Vehicle Exposure Warnings – Method of Transmission

This section is intended to cover passenger vehicles as defined in California Vehicle Code section 465. It is patterned after existing warning programs developed by the retail sellers of passenger vehicles, though the methods and content requirements have been simplified. The regulation requires the warning to be provided in the owner's manual and on a label attached to the front window on the driver's side of the vehicle. Using this combination of methods is intended to ensure that the warning will likely be seen and understood prior to exposure.

§ 25608.17 Passenger 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. The warning is intended to highlight common exposures to listed chemicals resulting

from the operation, servicing and maintenance of passenger vehicles and includes precautionary measures an individual can take to minimize or avoid those exposures.

§ 25608.18 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 font 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.

§ 25608.19 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.

§ 25608.20 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. This section is intended to cover commercially operated parks having various devices for entertainment (such as a merry-go-round or roller coaster) and usually booths for the sale of products, food and drink.

The amusement and theme park industry currently provides many warnings for potential exposure at their facilities that may be unnecessary because the exposures are too low, or that could be combined and discussed in supplemental warning materials such as a pamphlet that is provided to each patron before they enter the facility.

Subsection (a) requires signs to be posted at each public entrance to the facility

in a minimum font size of 72-point type. Because some facilities have multiple 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 they use to access the facility. Subsection (b) 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. To address this concern, OEHHA has specified in subsection (b) that the language requirement applies only to “permanent signage”.

The provision in subsection (c) 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 product, food, restaurant and alcoholic beverage exposures and parking structure exposures). 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. Pursuant to 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 that require a warning.

§ 25608.21 Amusement Park Exposure Warnings – Content

The content requirements for the amusement park warning closely track the general environmental exposure warning content requirements in Section 25600. It includes the warning symbol described in subsection 25604(a)(1), the word “WARNING”, and a link to the OEHHA website URL for supplemental information regarding amusement park exposures. Subsection (a)(3) provides additional language for warnings when chemicals must be identified under Section 25602.

§ 25608.22 Petroleum Products Warnings (Environmental Exposures) – Method 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 25608.26 and 25608.27, 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 25605 and requires in subsection (b) that the warning be provided in both English and other languages where signage at the facility is provided in any language other than English.

§ 25608.23 Petroleum Products Warnings (Environmental Exposures) – Content

The warning includes the symbol described in subsection 25604(a)(1), the word “WARNING”, and a link to the OEHHA website URL for supplemental information regarding 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.

§ 25608.24 Service Station and Vehicle Repair Facilities Warnings (Environmental Exposures) – Method 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 the 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. Warnings for vehicle repair facilities must be posted at each public entrance to the repair facility. Signage for a service station or a vehicle repair facility must be provided in English and any language other than English used on other signage at the facility. Using these two methods of providing the warning will ensure that it is likely to be seen and understood prior to exposures occurring at these types of facilities.

§ 25608.25 Service Station and Vehicle Repair Facilities Warnings (Environmental Exposures) – Content

Warnings for service station and vehicle repair facilities must include the symbol described in subsection 25604(a)(1), and the word “WARNING” in bold, and a link to the OEHHA website URL related to service stations and vehicle repair facilities. In order to comply with the requirements of Subarticle 2, 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.

§ 25608.26 Designated Smoking Area Exposure Warnings – Method of Transmission

This section is intended to provide a conspicuous and consistent warning for potential exposures to tobacco smoke and nicotine that are reasonably

calculated to occur within or near designated smoking areas. To fall under the safe harbor of this Subarticle, 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.

§ 25608.27 Designated Smoking Area Exposure Warnings (Environmental Exposures) – Content

Under this section, the warning must include the symbol described in 25604(a)(1) and the word “WARNING” and a link to the OEHHA website URL for supplemental information regarding 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. OEHHA intends for this warning to provide consistency of form and of content for these areas.

PROBLEMS BEING ADDRESSED BY THIS PROPOSED RULEMAKING

Since Article 6 was adopted in 1988, concerns have been voiced 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 and integrating technology and methods for communication that were not available at the time the original regulations were adopted.

In addition, product manufacturers and retailers, 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 and improved warning content. OEHHA has 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...”³⁶

³⁶ Health and Safety Code Section 25249.11(f)

Similar comments and requests were expressed in the pre-regulatory phase of this proposal. This proposed regulatory action is intended to address all of these concerns.

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 REGULATIONS

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 elements for providing a “clear and reasonable” warning for exposures that occur from products, including foods, and exposures that occur in various occupational or environmental settings. 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. Litigation concerning the adequacy of warnings should also be reduced as a result of the increased clarity provided by the proposed changes to the regulations.

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 reviewed oral and written public comments from interested parties that were offered as part of two pre-regulatory workshops, and other written and oral communications from interested parties that were received during the development of this proposal. A list of scientific references relied upon by OEHHA in the selection of chemicals to be included pursuant to Section 25602 is attached to this document.

REASONABLE ALTERNATIVES TO THE REGULATION AND THE AGENCY’S REASONS FOR REJECTING THOSE ALTERNATIVES

OEHHA received over 50 comment letters in response to the pre-regulatory workshop and pre-regulatory draft regulation. OEHHA also participated in over 30 meetings with a wide range of stakeholders. 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.³⁷ Some of the suggested alternatives would not accomplish that goal and were therefore not included in this proposal.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESS

The proposed regulatory action will not adversely impact very small businesses because Proposition 65 is limited by its terms to businesses with 10 or more employees (Health and Safety Code Sections 25249.5, 25249.6, and 25249.11(b)). 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.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON ANY BUSINESS

The proposed regulatory action 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. The proposed regulation does not impose any new requirements upon private persons or business because it primarily provides non-mandatory guidance and a voluntary safe

³⁷ Health and Safety Code Section 25249.12(a)

harbor process for providing warnings already required under the Act that businesses can choose to follow. A business is still free 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.

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, as drafted, 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.³⁸ 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.

ECONOMIC IMPACT ASSESSMENT

Gov. Code section 11346.3(b)

OEHHA finds there will be no significant economic impact related to this proposed regulatory action. The proposed regulations would not impose any significant costs because businesses are already subject to the warning requirements of Proposition 65. The proposed regulations do not impose any mandatory requirements that would significantly increase costs for businesses. The proposed regulations interpret and make specific certain provisions of the Act and provide guidance for safe harbor warnings that a business may use. A business may also choose not to take advantage of the safe harbor provisions and provide an otherwise “clear and reasonable” warning that complies with the Act.

Creation or Elimination of Jobs within the State of California

This regulatory action will not impact the creation or elimination of jobs within the State of California. The regulation interprets and makes specific certain aspects of the Act and provides more specific and detailed guidance for safe harbor

³⁸ Health and Safety Code Section 25249.10(a) (Exempting warnings governed by federal law). Refer also to Sections 25607.2, 25607.4, 25607.5, 25607.12, and 25607.13 of these proposed regulations.

warning methods and content for businesses that decide to take advantage of this guidance.

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

This regulatory action will not impact the creation of new businesses or the elimination of existing businesses within the State of California. The regulation interprets and makes specific certain aspects of the Act and provides more specific and detailed guidance for safe harbor warning methods and content for businesses that decide to take advantage of this guidance.

Expansion of Businesses within the State of California

This regulatory action will not impact the expansion of businesses within the State of California. The regulation interprets and clarifies certain aspects of the Act and provides more specific and detailed guidance for safe harbor warning methods and content for businesses that choose to take advantage of this guidance.

Benefits of the Proposed Regulation

The proposed regulations will further the purposes of Proposition 65 by providing more informative warnings to the public and reduced uncertainty for businesses who must comply with the warning requirements of the Act. These proposed changes will benefit the health and welfare of California residents and improve worker safety by providing more information to the public and facilitating industry's compliance with the Act.

REFERENCES FOR SECTION 25602

General references

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