PRE-REGULATORY DRAFT- FOR DISCUSSION PURPOSES ONLY

INITIAL STATEMENT OF REASONS

TITLE 27, CALIFORNIA CODE OF REGULATIONS

POTENTIAL AMENDMENTS TO ARTICLE 6

CLEAR AND REASONABLE WARNINGS

MARCH 7, 2014

PLEASE NOTE: This is a pre-regulatory proposal. The potential regulation may change substantially prior to the eventual initiation of a formal regulatory proceeding. If OEHHA decides to formally propose changes to Section 25601, additional opportunities for public input will be provided during the formal process.

SUMMARY

Proposition 65 and Title 27, California Code of Regulations, section 25601, require that persons in the course of doing business give clear and reasonable warnings to individuals before knowingly and intentionally exposing them to chemicals known to cause cancer or reproductive toxicity. The Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency that implements Proposition 65 and has the authority to promulgate and amend regulations to further the purposes of the Act.[1] Existing regulations adopted by OEHHA establish general criteria for providing "clear and reasonable" warnings.[2] These regulations also provide general message content and approved warning methods for providing certain consumer product, occupational and environmental exposure warnings. Persons using these "safe harbor" messages and methods are assured that such warnings are deemed clear and reasonable by OEHHA. The existing regulations are considered "safe harbor" guidance since they allow businesses to use any warning method or content that the business determines is "clear and reasonable."

[1] Health and Safety Code section 25249.12 (a)
[2] Cal. Code of Regs., Title 27, section 25601, *et seq*. All further references are to sections of Title 27 unless otherwise indicated.

Under the existing regulations, a warning is “clear” if it clearly communicates that the individual will be exposed to a chemical known to the State to cause cancer, and/or 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.

The regulatory amendments OEHHA is proposing would repeal the current Article 6 and adopt a new Article 6 that provides for warnings containing more detailed information for the public, including the names of the chemicals covered by individual warnings, the ways that individuals are exposed to these chemicals, and how individuals can avoid or reduce their exposure to these chemicals. These new provisions further the “right-to-know” purposes of the statute. The proposed regulations would accomplish this in part by establishing a website operated by OEHHA that would provide much of this more-detailed information to the public At the same time, the regulatory amendments provide more clarity to the Proposition 65 warning requirements and more specificity regarding the minimum elements for providing a “clear and reasonable” warning for exposures that occur from a consumer product, including foods and exposures that occur in occupational or environmental settings. Since the regulations would create mandatory minimum content for the warnings and also prescribe acceptable warning methods, businesses would be able to rely on their compliance with the regulations and litigation concerning the adequacy of warnings should be reduced.

Background

Throughout the years, aspects of Section 25601 have been litigated and discussed or clarified in court decisions and settlements. For example, in the *Ingredient Communication Council (ICC) v. Lungren* (1992) 2 Cal. App. 4th 1480, the court of appeal defined 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 consisted of a general in-store sign and newspaper ads notifying customers of a toll-free number where information could be found on products that might require a Proposition 65 warning.

The court found that such a system was not clear and reasonable, saying that “*an invitation to inquire about possible warnings on products is not equivalent to providing the consumer a warning about a specific product*” (emphasis added). The court discussed the relative difficulties of calling a toll-free number in advance for every product the consumer plans to buy at the grocery store. It also

quoted experts who stated that two-thirds of products are purchased on impulse while the consumer is at the store, which made it difficult for a consumer to access a warning before purchase. Finally, the court explained that "[An] effective 800 number system requires, as a first step, a *more complete in-store notification system which provides product-specific warnings*." *Id*. at 1497. (Emphasis added)

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

Since Section 25601 was adopted in 1988, there have been many requests for amendments. Manufacturer and retailer 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 versus 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…."[3]

In addition, concerns have been voiced for many years about the lack of specificity in the current safe harbor warning language, which merely says 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. 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, the specific toxic hazard (cancer or birth defects or other reproductive harm how the chemical(s) may cause harm (e.g. adverse effects on fetal development or ways that they can reduce or eliminate these exposures. A key objective of the proposed regulation is to provide consistent, understandable information concerning exposures to listed chemicals. It does this by integrating technology and methods for communication that were not available at the time the original regulations were adopted.

[3] Health & Safety Code section 25249.11(f)

On May 7, 2013, Governor Brown proposed reforms to Proposition 65. This reform would "revamp Proposition 65 by ending frivolous 'shake-down' lawsuits, *improving how the public is warned about dangerous chemicals* and strengthening the scientific basis for warning levels."[4] (Emphasis added). One aspect of this proposed reform was to "require more useful information to the public on what they are being exposed to and how they can protect themselves." This regulatory proposal is intended to implement the Administration's vision concerning improving the quality of the warnings being given and providing certainty for businesses subject to 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.[5]

On October 5, 2013, Governor Brown signed into law Assembly Bill (AB) 227,[6] which amended Proposition 65 to provide a 14-day opportunity to cure specified violations of the warning requirements of the Act for certain businesses that sell alcoholic beverages, restaurants that sell foods and beverages that contain chemicals formed during preparation of the food and beverages on the premises, and certain businesses that cause exposures to environmental tobacco smoke and vehicle exhaust. The bill was passed as "urgency" legislation in order to address what the law describes as an urgent need to "…avoid unnecessary litigation and to facilitate compliance with [the Act]…" The author stated in a press release that:

> "Unfortunately, a small number of attorneys have recently used Proposition 65 technical violations to target small businesses, which lack resources for a legal defense, with the goal of reaching quick settlements to avoid costly litigation. Since 2012, more than two-dozen brick-and-mortar businesses in Southern California, including restaurants and cafés in Burbank, Glendale, Pasadena, and Los Angeles, have been threatened

[4] 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.
[5] 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.
[6] AB 227 (Gatto), Chapter 581, Stat. of 2013. Codified at Section 25249.7, Health and Safety Code.

> with Prop. 65 lawsuits for simply neglecting to have posted signs (or signs of the right size), that warn about beer, wine, or chemicals that result from the natural process of cooking food. Some businesses have paid settlements of $5,000 or more, for failure to post a $20 sign or for posting a sign that was one inch too small…."[7]

OEHHA's proposal includes a somewhat broader opportunity to cure that applies to all small businesses with less than 25 employees and mirrors many of the provisions of AB 227.

In proposing this regulation, OEHHA is attempting to address the issues that have arisen since the original regulations were adopted, by making needed changes to the requirements for a "clear and reasonable" warning and integrating new technology, in order to provide more useful information to Californians about their exposures to listed chemicals, more certainty for affected businesses and thereby further the purposes of the statute.

PROPOSED REGULATION

The regulation being proposed by OEHHA is designed to provide more meaningful information for individuals in Proposition 65 warnings, facilitate the public's understanding of these warnings and make the warnings more consistent. These regulations would provide more certainty for businesses by specifying minimum requirements for both the content of and methods for providing warnings for exposures to listed chemicals, where warnings are required under Health and Safety Code section 25249.6.[8] The proposed regulation also would provide a limited opportunity for small retail sellers to cure certain minor warning violations within 14 days.

The proposed regulation would create a warning program with two components, a basic pre-exposure warning that includes certain mandatory elements and a web-based process for providing additional relevant information to the public in a

---

[7] Press Release, Office of Assemblyman Mike Gatto. Mike Gatto's Bill to Protect Small Businesses Unanimously Passes Assembly (May 24, 2013), available at: http://www.asmdc.org/members/a43/press-releases/mike-gatto-s-bill-to-protect-small-businesses-unanimously-passes-assembly.

[8] Health and Safety Code section 25249.10 provides three exemptions from the warning requirement for exposures to listed chemicals, including (1) exemptions for warnings governed by federal law, (2) exemptions for exposures that occur within 12 months of a chemical's listing, and (3) exemptions for chemical exposures below the safe harbor level. OEHHA has adopted related regulations in Articles 5, 7 and 8 of Title 27, Cal. Code of Regs. to assist businesses in determining when a warning is required under the Act.

consistent, understandable format. The two-part warning program would apply to all warnings for exposures to listed chemicals, whether from consumer products (including foods, alcoholic beverages, drugs and medical devices), environmental sources, or in occupational settings. In order to assure that all the relevant information for a clear and reasonable warning is provided to the public, this regulatory proposal establishes new requirements for businesses to provide the Lead Agency with certain information that the Agency will make available to the public on its website along with chemical and exposure specific materials that are developed by the Agency.

In the event this proposed regulation is adopted, OEHHA intends to adopt specific warning methods and content for common types of exposures that frequently occur in California. Examples of these warnings are included in this proposal and others will be developed through stakeholder input and may be added to this proposal or adopted through a separate regulatory process. OEHHA strongly encourages stakeholders to submit tailored warnings for possible inclusion in the initial version of the regulation.

Each provision of the proposed regulation is discussed below.

Section 25601 - Clear and Reasonable Warnings

This section has been modified to reflect the mandatory nature of the requirements of the Article, rather than the previous approach that styled the regulation as a “safe harbor” that was completely optional. In practice, many businesses and even certain courts treated the regulations as mandatory minimum requirements for reasonable warnings and most warnings are currently provided with the suggested content and format. However, some plaintiffs argued that “safe harbor” warnings were insufficient in certain situations, such as where exposures occur from foods, and where a given exposure is particularly harmful to certain subpopulations such as children or women of child-bearing age, including exposures to mercury or lead.

Subsection (a) makes the warning regulations mandatory for all businesses. Making the regulations mandatory will ensure that the warnings being provided to Californians will be more consistently presented, clear, understandable and informative and, at the same time will provide clarity and certainty for businesses who must comply with the law, thus furthering the purposes of the Act.

OEHHA is aware that making significant changes to the regulations will require some retooling by businesses in order to comply with the new provisions and

some education for members of the public. However, these effects should be short-term and will result in more effective warnings and more certainty for affected businesses.

Subsection (b) explains that any interested party can petition OEHHA to adopt additional regulatory provisions that address exposures to listed chemicals in products or in an occupational or environmental setting that are not already sufficiently covered by the regulation. It is not possible for OEHHA to anticipate every situation in which a warning might be required for a given chemical exposure. This provision is intended to encourage business to work with OEHHA to develop a tailored warning method or message where the existing regulatory provisions are not sufficient.

In addition, this provision encourages interested parties to use other available options under existing regulations[9] to request guidance concerning application of this regulation to specific situations or products, including whether a warning is required at all.

Subsection (c) clarifies that the regulation does 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 regulation becomes effective only after a business determines that the exposure to a listed chemical it knowingly and intentionally causes requires a warning.[10]

Section 25602 - Definitions

This regulatory proposal would readopt many of the existing definitions in the regulations while making minor modifications for some terms, including "consumer products exposure," "environmental exposure," "label and labeling", "occupational exposure," and "sign," as well as adding a definition for the new term "Retail seller." The modifications to the existing definitions included in this proposal are intended to clarify, rather than change, the meaning of the definitions.

Specifically, the change to the definition of "consumer products exposure" in subsection 25602(b), clarifies that food is considered a consumer product, but does not change the purpose or effect of the existing regulation.

[9] 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).
[10] Health and Safety Code sections 25249.6 and 25249.10; and Articles 5, 7 and 8 of Title 27, Cal. Code of Regs.

The changes to the definition of “environmental exposure” in subsection 25602(c), simplifies the language used in the definition, but does not change the purpose or effect of the regulation.

In subsection (d) the existing definitions for “Label” and “Labeling” have been combined for clarity and to avoid redundancy since there is little functional difference between the two definitions.

The change to the definition of “occupational exposure” in subsection 25602(e), clarifies that exposures that occur to an employee include those that may result from the performance of his or her duties.

The new definition of “Retail seller” in subsection 25602(f) is intended to clarify a term that is used in the regulations related to consumer products and foods. Retail sellers are a separate and distinct category of businesses that can cause exposures to listed chemicals. The retail seller typically sells a product directly to a consumer either in a brick-and-mortar store, via the Internet, or via some other similar transaction but is likely not aware of the chemical exposures that may occur through the use or consumption of those consumer products. A food or consumer product manufacturer generally is in a much better position to know what chemicals are in a product that may cause an exposure that triggers the warning requirement. Therefore, OEHHA has included specific provisions in the proposed regulation that only apply to retail sellers of foods and other consumer products.

The change to the definition of “sign” in subsection 25602(g), clarifies that the components displayed in the sign must conform to the requirements of the proposed regulations.

Section 25603 - Court Approved Settlements

This section has been added to clarify that the new requirements in the regulation do not apply to the parties[11] to settlements that have been approved by a court prior to January 1, 2015. This provision is limited to the parties to the settlement so that any provisions in the original settlement that are not consistent with the new regulations do not carry over to the whole industry in perpetuity. Most warnings that have been agreed to in Proposition 65 cases substantially comply with the terms of these proposed regulations. This provision will provide

[11] The persons or entities directly affect by a mandatory provision of the settlement related to the content of or methods of providing warnings under the Act.

certainty for those parties to litigation that have agreed on a given method or content for warnings, and provide deference to the courts that have approved those settlements.

Some stakeholders have argued that the better approach would be to adopt all warnings that are currently being provided pursuant to informal opinions provided by the Attorney General's Office or OEHHA, and all current warnings in compliance with the existing regulations so that there would be minimal costs incurred by California businesses who are already providing warnings. OEHHA has determined that incorporating such a provision into this proposal would essentially result in little change in the content and methods of delivery for the warnings for many, many years, since the proposed regulations would only affect situations in which a warning is not currently being provided. OEHHA has determined that this would be inconsistent with the intent of the proposed regulatory changes and would not further the purposes of the Act.

Section 25604 - Lead Agency Website

As noted above, warnings are only required under Proposition 65 for knowing and intentional exposures to listed chemicals. Therefore, where a business provides such a warning, subsection (a) requires the business to provide the Lead Agency with certain information within 30 days. This section requires businesses that provide warnings to individuals to also give OEHHA essential information concerning the exposures for which they are providing warnings. With few exceptions, this additional information is not now being provided to OEHHA or the individuals who are or may be exposed to chemicals that are listed under Proposition 65 as known to cause cancer or reproductive toxicity.

OEHHA believes that this requirement is essential so that interested individuals are adequately informed of the chemicals involved in the exposure, how they may be exposed to those chemicals, and any steps they may be able to take to reduce or eliminate the exposure. This will further the purposes of the Act by improving the quality of the information conveyed by Proposition 65 warnings.

OEHHA also believes this requirement is needed in order to reduce the number of warnings that are being provided for non-existent exposures or in situations where a chemical could be present, but not at a level that requires a warning. This provision clarifies that a business should have a good-faith belief that a warning is required for a given exposure when it provides a warning, thereby reducing the warnings that are provided where businesses have no reasonable belief that one is required. This will further the purposes of the Act by avoiding

the existing problem of over-warning that dilutes the impact of warnings for real exposures and ensuring that accurate information is being provided to those individuals that may actually be exposed to a listed chemical so they can make informed decisions about those exposures.

In order to reduce the burden on individual businesses and encourage cooperation within an industry, subsection (a) expressly allows a business to report the required information through an authorized agent. This provision is intended to encourage businesses to coordinate reporting through their trade groups or other organizations since many exposures to listed chemicals occur throughout an industry, not from a single product or occupational or environmental scenario. For example, in recent years, trade groups representing the wood product, [12] apartment,[13] hotel[14] and automobile[15] industries have jointly developed and distributed warning materials for their members. Businesses are encouraged to collaborate with each other as they provide information to OEHHA for use on its website in order to make the process efficient and cost effective for both the businesses and the state.

Subsection (b) of the proposed regulation allows a business to provide all the information required in subsection (a)(1-10) directly to an individual on or with the warning. In that case, the business need not provide any information to the Lead Agency. However, the business is encouraged to provide the information so that the Lead Agency's website can be as comprehensive as possible.

Subsection (c) requires businesses to update the information they initially provide to OEHHA when they become aware of additional chemical exposure(s) for an already reported product, occupational or environmental warning, or other required information changes within 30 days. This provision is needed to ensure that the information on the OEHHA website is as accurate and up-to-date as possible.

---

[12] See, e.g., the Western Wood Products Association's "Required notification of potential health hazard from wood dust and chemicals associated with wood products," available at http://www2.wwpa.org/SPECIESPRODUCTS/WoodDust/tabid/1006/Default.aspx.

[13] See, e.g., the San Francisco Apartment Association's "Legal Corner Q&A," available at http://www.sfaa.org/0505legalqa.html.

[14] See, e.g., the California Hotel & Lodging Association's "Complying with Proposition 65's Warning Requirements," available at www.calodging.com/images/uploads/general/Prop65Guidelines-Revised2013.pdf.

[15] See, e.g., the California New Car Dealers Association's "Proposition 65 Compliance Handbook," available at www.cncda.org/secure/GetFile.aspx?ID=2195.

Subsection (d) requires the Lead Agency to develop a website for the purpose of collecting the information required under subsection (a) and to provide that information in a clear and reasonable manner to individuals who receive a warning and subsequently access the website. The Agency may also develop additional information concerning the chemicals and common routes or pathways of exposure, the relevant toxic effects (i.e. cancer, birth defects or other reproductive harm) and strategies for avoiding or reducing exposures in order to supplement the specific information provided by businesses.

The purpose of the website is to take advantage of technology that was unavailable at the time the original regulations were adopted. In the intervening years electronic methods of communication have become ubiquitous. Tools such as computers, smart phones and the Internet offer most Californians instant access to a wealth of information. OEHHA intends to tap into these new communication methods to provide information concerning potential exposures to listed chemicals through consumer products, foods, drugs, work and the environment. Substantially more information can be provided through a website than on a label or sign. Immediate access to more detailed information concerning chemicals, exposures, and potential ways to reduce or avoid exposure will further the purposes of the Act by allowing individuals to make more informed choices, while encouraging businesses to reduce or eliminate exposures when feasible and to avoid providing unnecessary warnings.

Additionally, OEHHA's website can provide links to authoritative entities such as the U.S. Food and Drug Administration, U.S. Environmental Protection Agency, the Surgeon General and other sources that an individual may wish to consult for more detailed information concerning a given chemical or exposure.

Some stakeholders suggested that each business providing a warning should be allowed to provide the required information on its own website. However, OEHHA determined that requiring the website to be developed and managed by OEHHA will ensure that the warning information will be provided in a consistent format in a way that is easily accessible to the public, is accurate and does not contain information that negates or reduces the effectiveness of the warnings. Further, as a governmental entity, OEHHA is required to ensure that information provided on its website is accessible to persons with disabilities. There is no commensurate requirement for private websites. Thus, hosting the information on the OEHHA website will ensure access to warning information for persons with disabilities.

Section 25605 - Chemicals, Substances or Mixtures that must be Disclosed in Warnings

OEHHA discussed the concept of requiring warnings to include the names of the listed chemicals that the warning is intended to cover with stakeholders in workshops and other meetings. Many businesses objected to the idea of including chemical names (or the names of each of the chemicals in a mixture such as exhaust or tobacco smoke) for two primary reasons: first, chemical names could be long and difficult for the average person 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 on the warning itself. After careful review of these concerns, OEHHA is proposing that only certain chemical names be included in the basic warning message. All the additional chemicals the business intends to be covered by the warning will be disclosed via the OEHHA website based on the information the business provides.

Section 25605 identifies twelve currently listed chemicals that are commonly found in consumer products, including foods, and those that commonly are involved in occupational or environmental exposures. The list of chemicals is not intended to be exhaustive and may be changed over time as the public becomes more familiar with the improved warning format. Further, OEHHA does not anticipate that warnings will contain more than one or two of the listed chemicals. The list is consolidated in this section in order to avoid duplication and the potential confusion that could occur if it was divided in some way in the other sections of the regulation.

Section 25605 of the proposed regulation is intended to provide the public with more information directly on the warning concerning exposures to chemicals with names that are commonly understood. Some of the named chemicals are listed under Proposition 65 in a more technical form, such as “mercury.” The term “mercury” in this section includes mercury, mercury compounds, methyl mercury and methyl mercury compounds; similarly, the category of chemicals known as “phthalates” include several listed chemicals with names that may or may not be recognizable to the public including, for example Di(2-ethylhexyl)phthalate, Diisononyl phthalate and Di-isodecyl phthalate.

By adopting this section, OEHHA does not intend to extend, limit or modify the names or scope of the existing chemical listings contained in Title 27, Cal. Code Regs., section 27001. However, including the longer more technical chemical

names or all the individual chemicals within a chemical class or mixture in the text of the warning would defeat the purpose of providing understandable and useful information to individuals on the warning itself. The technical names and discussion of the scope of the listing can be better explained in the information that will be made available on OEHHA's website.

This section is also not intended to provide businesses with guidance concerning when a given exposure requires a warning. Other provisions of the existing law and regulations provide guidance in this regard.[16] This provision, and as noted previously, the entire warning regulation is only applicable where a business has determined a given exposure requires a warning.

Section 25606 - Consumer Product and Food Warnings

Subsections (a) and (b) of the proposed regulation are intended to provide clarity concerning the relative responsibilities of a product manufacturer or distributor versus a retail seller of a given product as provided in the statute.[17]

> "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…"

Consistent with this statutory provision, the proposed regulation clarifies that the primary responsibility for providing warnings for consumer products, including foods, is with the manufacturer, distributor, producer or packager of those products. However, the proposed regulation further provides that the retail seller must cooperate with the manufacturer, distributor, producer or packager in order to ensure that the required warning is provided.

This provision is included in the existing regulations, but is currently limited to warnings for alcoholic beverages. Over the years, many manufacturers and retail sellers have requested that OEHHA provide more guidance concerning the relative responsibility between manufacturers and retailers for providing warnings. The proposed regulation is intended to address the fact that retail sellers seldom know when a warning is required for a given product. The manufacturer, distributor, producer or packager is in a much better position to

[16] Health and Safety Code section 25249.10, Cal. Code of Regs., Title. 27, Articles 5, 7 and 8.
[17] Health and Safety Code section 25249.11(f)

determine when the warning is required and the best method for providing it. Once that determination has been made, this regulation clarifies that the retail seller must cooperate with the product's manufacturer, distributor, producer or packager to ensure that the warning is in fact provided.

OEHHA believes that this division of costs and responsibility is consistent with and furthers the purposes of the Act. The regulation is not stated in absolute terms because provision of the warnings may require the participation of the retail seller when the warning is not provided directly on the product. Even when it is, the retail seller must ensure that it does not remove or obscure the warning in some way, thereby thwarting the efforts of the product manufacturer, distributor, producer or packager that is providing the warning. Essentially, the retail seller will generally serve as a "pass through" for consumer product warnings in most situations.

Stakeholders have provided anecdotal evidence that in some cases, alcoholic beverage manufacturers or distributors have provided and posted warning materials only to have the retail seller remove or obscure them. This proposed regulation is intended to rectify that situation. Under this proposed regulation, responsibility for posting and maintaining the warnings would be the primary responsibility of the retail seller so long as the manufacturer or distributor has made a good faith effort to provide the warning materials.

Subsection (c) of the proposed regulation requires that a warning also be provided in languages other than English when labeling or other materials provided with the product are provided in those languages. This provision will better allow consumers 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,[18] OEHHA believes this provision of the proposed regulation will further the purposes of the statute by expanding the number of individuals who can easily access and understand the warning.

Section 25607- Opportunity to Cure

[18] "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.

This section of the proposed regulation is intended to build on the recent additions to Section 25249.7 of the Act.[19] These new statutory provisions provide a limited opportunity to cure certain relatively minor violations of the warning requirements of the Act for a small subset of businesses in California; specifically sellers of alcoholic beverages for onsite consumption, sellers of specified foods sold in restaurants, second-hand smoke exposures for businesses that allow smoking and exposures to engine exhaust that occur in parking structures. As noted previously, the author's stated purpose for the amendments to the Act was to protect small businesses from frivolous litigation.

Consistent with these goals, subsection (a) of the proposed regulation would provide all small retail sellers with a limited opportunity to cure minor violations of the warning requirements of the Act. It only applies to the following:

- Retail sellers with less than 25 employees; who have made minor deviations from the warning requirements such as:
    - The short-term absence of a sign or other warning materials,
    - Interruption of an electronic device such as software problems or Internet connectivity issues,
    - Inadvertent obstruction of a warning label or sign, that is:
        - Not the result of intentional neglect or disregard for the requirements of this Article
        - Not avoidable using normal and customary quality control or maintenance
        - Corrected within 24 hours of discovery or notification, or within 14 days if software or equipment must be repaired or replaced
        - Not recurrent

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 small retail facilities that may commit relatively minor, inadvertent violations. When a small-business owner receives a 60-day notice of intent to sue,[20] he or she may choose to quickly settle with the person

[19] AB 227 (Gatto), Chapter 581, Stat. of 2013. Codified at Section 25249.7, Health and Safety Code.
[20] Health and Safety Code section 25249.7(d), Title 27, Cal. Code Regs., section 25903

serving the notice to avoid paying potentially greater sums to litigate the matter, even though the alleged violation was inadvertent or is easily corrected, as where a warning sign was unintentionally obscured, fell down, was slightly larger or smaller than the regulation specifies, or an electronic system failure disrupts the person's ability to provide a warning.

By providing this limited opportunity to cure for small retail businesses, OEHHA does not intend to encourage or condone repeated, intentional or negligent violations of the warning requirements of the Act. Instead, OEHHA intends to encourage businesses to correct violations as soon as they are made aware of them and reduce the number of lawsuits that may be brought for such minor violations. This narrow and targeted opportunity to cure will further the purposes of the law by ensuring that timely corrections of minor violations are made so the public receives the required warnings, while avoiding expensive or protracted litigation for small retail sellers over minor, unintentional violations of the Act.

Subsection (b) clarifies that small retail sellers that correct the minor, unintentional violation of the Act as required in this section shall not be liable for violating the warning requirement of the Act.

Subsection (c) states that the Attorney General and local prosecutors in whose jurisdiction an alleged violation has occurred retain the ability to file an enforcement action. This provision provides an important "backstop" by allowing enforcement actions by public prosecutors to ensure that businesses do not take advantage of the limited opportunity to cure to avoid compliance with the Act.

NOTE: The following provisions of the proposed regulations are organized by type of exposure (e.g. consumer product, occupational, environmental) and within those three areas, by the permissible methods for transmitting the warnings and the required minimum content for the warnings. The methods and content provisions necessarily rely on each other and should be considered together.

Section 25607.1 - Consumer Products Exposure Warnings – Methods of Transmission for Consumer Products Other Than Food

Section 25607.1 sets out the mandatory minimum requirements for providing a warning for an exposure to a listed chemical from a consumer product other than a food. Warnings for exposures to foods, prescription drugs, medical devices

and dental care are treated separately in subsequent subsections of 25607, which 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 the regulation to provide the warning. These include on-product warnings, warnings provided with or on an invoice or other materials that are given to the individual prior to exposure, warnings provided on a shelf-tag or shelf sign, or warnings provided via electronic means – so long as the person receiving the warning is not required to seek it out.

OEHHA has determined that these methods for delivering the warning message, coupled with the information available on the OEHHA website, will provide effective warnings that comply with Section 25249.6 of the Act. While other methods of transmitting the warning message may be developed, OEHHA believes that each of the methods described in the proposed regulation are likely to provide a consumer with the required warning in a manner that will ensure that it is easily understood and is associated with the product or service that will cause an exposure to a listed chemical and the consumer will not have to seek out the warning.

The "catch-all" provision in subsection (5) is intended to capture existing methods of communication, including currently available tools such as electronic shopping carts, smart phone applications, barcode scanners, self-checkout registers, pop-ups on Internet websites and any other electronic device that can immediately provide the consumer with the required warning would be covered by this provision.

OEHHA does not intend for this provision to be read in such a way that a business relies exclusively on a website or other device to provide a warning where the consumer must seek out the mandatory minimum information required in Section 25607.2. For example, a general reference to a website that is not associated with a specific product would not comply with this provision or the Act. Similarly, an invitation to determine which products within a retail facility require a warning would not comply with the Act.[21]

Subsection (b) expressly allows a business to provide additional information concerning an exposure to a consumer as long as that information does not dilute or negate the required warning.

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

Section 25607.2 - Consumer Products Exposure Warnings for Consumer Products Other than Food, Drugs, Medical Devices or Dental Care – Content

Section 25607.2 sets out the mandatory minimum content requirements for providing a warning for an exposure to a listed chemical in a consumer product, other than foods, drugs, medical devices or dental services which are covered by more specific subsections of the regulations. A business that is subject to the requirements of Section 25249.6 of the Act must include all the mandatory minimum elements set out in this section in order for the warning to be considered clear and reasonable under Health and Safety Code section 25249.6.

Subsection (a)(1) establishes a symbol or pictogram to be used on all Proposition 65 consumer product warnings, other than those provided for foods, drugs, medical devices and dental care services. The symbol is taken from the standard graphics used under the Globally Harmonized System (GHS) for chemical health hazard warnings.[22] According to the federal Occupational Safety and Health Administration (OSHA):

> "The Globally Harmonized System (GHS) is an international approach to hazard communication, providing agreed criteria for classification of chemical hazards, and a standardized approach to label elements and safety data sheets. The GHS was negotiated in a multi-year process by hazard communication experts from many different countries, international organizations, and stakeholder groups. It is based on major existing systems around the world, including OSHA's Hazard Communication Standard and the chemical classification and labeling systems of other US agencies."[23]

The pictogram required in the proposed regulation has been adopted by numerous federal, state and international governments to identify toxic chemicals, including chemicals that cause cancer or reproductive toxicity.[24]

---

[22] 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.

[23] *Id*.

[24] 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,

OEHHA has included the symbol as one of the required elements of the warning in the proposed regulation because it is consistent with these other authorities. Using a graphic symbol will enhance the effectiveness of the warnings in a manner that is consistent with the requirements of other governmental warning programs including those that were adopted by federal OSHA and the California Division of Occupational Safety and Health Program (commonly referred to as Cal/OSHA). These pictograms are already being used by many manufacturers and employers.

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,[25] including this signal word is fully consistent with the Act and furthers its purposes.

Subsections (a)(2)(A-C) sets out the minimum 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" messages is the use of the phrase "will expose you to", rather than the word "contains". Since the existing regulation was adopted over 25 years ago, it has become clear that using the word "contains" does not communicate the fact that individuals will actually be exposed to a chemical if they use a given consumer product. 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 individual 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). On the other hand, consumers who see a warning for the contents of a product often will not know if they actually will be exposed to a listed chemical. Therefore, OEHHA has determined that the phrase "will expose you to" is more clear and consistent with the requirements of the Act than the "safe harbor" language in the existing regulation.

---

mutagenicity, reproductive toxicity, respiratory sensitizer, target organ toxicity and aspiration toxicity.

[25] Health and Safety Code section 25249.6

Some stakeholders have objected to the use of the word "expose" 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 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 *right*s:

… (b) To be informed about *exposures* to chemicals that cause cancer, birth defects, or other reproductive harm…." (Emphasis added)[26]

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 potentially meaningless 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.

Subsection (a)(3) allows a business to provide a warning in a specific way and with specific content, where a warning covering that exposure has been adopted by OEHHA. The Agency included this provision in the proposed regulation in order to insure consistency. The Agency has included several product, area or chemical-specific warnings in this proposed regulation[27] and intends to propose others in the future. In order to promote consistency and efficiency and ensure that individuals receive a "clear and reasonable" warning for common exposures to listed chemicals, the Agency believes the warnings set out in the regulation should be given in one of the mandatory formats set out in the regulation. However, the regulation provides flexibility for businesses to choose between the

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

[27] See, e.g., Cal. Code of Regs., Title 27, section 25607.8-9 (Alcoholic Beverage Warnings); section 25607.17(a)-(b) Parking Facilities; section 25607.17(c)-(d) Apartment, Hotels and other Lodging Facilities; section 25607.17(e)-(f) Amusement Parks.

more general warnings and those that are adopted for specific chemical exposures, depending on their particular situation.

Subsection (b) sets out a specific warning that may be used for on-product warnings. This provision proposes 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 simply not fit on the labeling or packaging of some 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. The current proposal includes the use of a Uniform Resource Locator (URL) so that the information on OEHHA's website can be accessed easily by most consumers.

When a business chooses to provide the warning on the product, information concerning the chemical exposures for which warnings are being provided is still required to be provided on the warning, the names of chemicals identified in Section 25605. Other chemicals will be disclosed to OEHHA pursuant to Section 25604. This information will be made available on the OEHHA website to those members of the public who are interested in the full list of chemical names for which the warning is being given. OEHHA believes that this approach strikes a balance between providing useful information to consumers while avoiding unwieldy on-product warnings. Further, the warning is more clear and direct than the existing "safe harbor" warnings being used by most businesses.

Section 25607.3 - Food Exposure Warnings – Methods of Transmission for Food Products

While all the provisions of the proposed regulations that apply to consumer products equally apply to foods, which are a subset of consumer products, OEHHA recognizes that the provision of warnings for foods poses special issues that should be addressed differently.

Subsection (a) clarifies that all the methods of transmitting the warning for other consumer products are equally available to businesses that sell foods, but the content of the warning will be different.

Section 25607.4 - 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 consumer products. OEHHA has adopted regulations dealing with the issue of naturally-occurring chemicals in

foods[28] and has issued several Interpretive Guideline documents specific to potential exposures to listed chemicals in foods.[29] Perhaps for this reason, very few food products currently carry Proposition 65 warnings.[30] Those that do sometimes include additional information about the origin of the chemical in the food,[31] the target audience, such as pregnant women and children,[32] types of foods affected,[33] and a URL for more information.[34] These warnings were developed in response to litigation and are not universally accepted or 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, the Agency intends to ensure that warnings are consistent, accurate and understandable and that these approved warnings and methods are available to all businesses, not just those who are parties to litigation. To the extent that existing warnings meet the minimum requirements of this section, OEHHA will consider adopting them into the regulations as appropriate.

Subsection (a) of the proposed regulation closely tracks the consumer product warning provisions of Section 25607.2, with two main exceptions. First the pictogram is not required for food product warnings. OEHHA has not included

---

[28] Title 27, Cal Code Regs., section 25501. *Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652 (Ct. App. 1991).

[29] 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.

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

[31] 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.

[32] 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….")

[33] 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.

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

the pictogram as a mandatory requirement for food exposure warnings because food product labeling does not generally include pictograms. Use 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)(2-3) is tailored to describe exposures that occur through consumption of a food product. Thus the warning message states "consuming this product will expose you to …." Using this phrase focuses the individual on the route of exposure (oral or ingestion) as opposed to the existing safe harbor language that simply says the product "contains" a listed chemical.

The same information concerning the chemical exposures for which warnings are being provided is still required to be provided to OEHHA pursuant to proposed Section 25604 and this information will be made available on the OEHHA website to those members of the public who are interested in the full list of chemical names for which the warning is being given. OEHHA believes that this approach strikes a balance between providing useful information to consumers while avoiding unwieldy warnings.

Subsection (b) sets out specific warning content that may be used for on-product warnings. Consistent with the proposed content for other consumer products, this provision proposes 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. 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. The current proposal includes the use of a URL so that the information on OEHHA's website can be accessed easily by most consumers.

When a business chooses to provide the warning on the product, information concerning the chemical exposures for which warnings are being provided is still required to be provided to OEHHA pursuant to Section 25604. This information will be made available on the OEHHA website to those members of the public who are interested in the full list of chemical names for which the warning is being given. OEHHA believes that this approach strikes a balance between providing useful information to consumers while avoiding unwieldy on-product warnings. Further, the warning is more clear and direct than the existing "safe harbor" warnings being used by some businesses.

Subsection (c) of the regulation expressly allows a business to include additional contextual information in a pamphlet or other supplemental materials. 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),[35] in the warning. However, where that is infeasible, the proposed regulation sets out certain types of information that should be included in any supplemental materials that are provided to the consumer.

Subsection (d) allows a business to provide a warning in a specific way and with specific content, where a warning covering that exposure has been adopted by OEHHA. The Agency included this provision in the proposed regulation in order to insure consistency. The Agency has included several examples of specific consumer product and environmental warnings in the proposed regulation[36] but has not proposed any food-specific warnings at this time. OEHHA will consider proposals for food or chemical-specific warnings during the pre-regulatory and formal regulatory process. In order to promote consistency and efficiency and ensure that individuals receive a "clear and reasonable" warning for common exposures to listed chemicals, the Agency believes the warnings set out in the regulation must be given in one of the two formats set out in the regulation. Businesses may choose to use the more specific warnings, depending on their particular situation.

Section 25607.5 - Warnings for Prescription Drugs and Prescription Medical Devices

Subsection (a) of the proposed regulation is similar to the existing regulation, but has been broadened in two ways. First, it would expressly apply to prescription medical devices as well as prescription drugs. Second, it clarifies that in order to avoid providing a consumer product warning consistent with Section 25607.2, the warning message that is provided under federal law must include reference to

[35] 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.

[36] See, e.g., Cal. Code Regs., section 25607.5 (prescription drugs and medical devices); 25607.6-7 (dental care); 25607.8-9 (alcoholic beverages); section 25607.10 (restaurants); section 25607.17(a)-(b) parking facilities; section 25607.17(c)-(d) apartment, hotels and other lodging facilities; section 25607.17(e)-(f) amusement parks.

the prescription medical device or drug posing a risk of causing cancer or reproductive toxicity.

As to the expansion of the provision to include prescription medical devices, there appears to be no functional difference between warnings for the two types of products. Each is being prescribed by a medical professional and is required by the federal Food and Drug Administration to include warnings for hazards associated with the drug or device.[37]

The clarification in subsection (b) that the label or other materials include a reference to a risk of cancer or reproductive toxicity is implicit in the existing regulation, but is included in the proposed regulation for purposes of clarity.

Given that drugs and medical devices 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, OEHHA has included the phrase "except where prohibited by federal law" in the proposed regulation, consistent with Section 25249.10(a) of the Act.[38]

Subsection (c) of the proposed regulation maintains the existing regulation concerning emergency medical care. It is intended to clarify the approach where an emergency situation arises and is consistent with existing medical procedures.

25607.6 - Dental Care Warnings – Methods of Transmission

This proposed section is new. As discussed earlier in this document, OEHHA proposes to adopt more specific regulations to address common exposure scenarios. While the target audience for dental care warnings may be primarily employees, the proposed warnings are intended to cover patients as well. In order to provide consistency in the format, size and placement of the warnings, OEHHA is proposing this section. Setting these requirements out in the regulation will also provide certainty for businesses providing dental care services that they are compliant with the Act if they follow 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 dental care

[37] Title 21 U.S.C. Section 352 (f).
[38] *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.")

provider.

Section 25607.7 - Dental Care Warnings – Content

This section incorporates the same mandatory minimum elements of the warnings for food products, while at the same time it tailors the warning message to address the specific types of exposures that may occur in a dental office. The basic message states, "Certain dental procedures provided in this office, will expose you to nitrous oxide or mercury, chemicals known to the State of California to cause birth defects and other reproductive harm. For more information ask your dental service provider or go to www.P65Warnings.ca.gov." This language ensures the warning is clear to the person being exposed, since it explains that the exposure is occurring through the receipt of dental care, identifies two chemicals commonly associated with dental procedures, the type of hazard posed, and it provides an avenue for getting more information that is specific to the chemicals and types of exposures being discussed. Referring the individual first to the dental care provider, then to the OEHHA website is consistent with advice given in other medical settings[39] and dental offices.[40]

Subsection (b) clarifies that where a particular dental care provider does not expose an individual to nitrous oxide or mercury, those chemicals need not be named in the warning.

Subsection (c) expressly allows a dental care provider to provide additional contextual information concerning an exposure to a patient or employee as long as that information does not dilute or negate the required warning.

Section 25607.8 - Alcoholic Beverage Warnings – Methods of Transmission

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

[39] 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.

[40] 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.

requirements for size, font, and placement of warnings for exposures from alcoholic beverages. All the options for these warnings are off-product as the federal requirements for on-label warnings are mandatory and are also consistent with the requirements of Proposition 65, except that there is no specific federal warning for carcinogenicity.

The new provisions in 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. For example, the existing regulation specifies the use of a 10-by-10 inch warning sign. The proposed regulation allows for the use of an 8 1/2-by-11 inch sign because these can easily be printed out from a computer template as can a 5-by-5 inch sign, thus making it easier for businesses to comply with the regulation using existing technology.

Similarly, the proposed provisions streamline the process for providing the warnings and allow for the use of the alternative methods being proposed in Section 25607.1 for other consumer product exposures. As noted above, the existing provision explaining the relative responsibilities of the manufacturer, distributor and retail seller has been moved to a separate Section 25606(a) that now covers all consumer product warnings, including those for alcoholic beverages and was slightly modified to fit its wider application.

Section 25607.9 - Alcoholic Beverage Warnings – Content

Subsection (a) includes the mandatory minimum requirements for providing a warning that have been described above. The language in subsection (a)(2) is tailored to exposures that occur through consumption of alcohol and closely tracks the language in the existing regulation with two exceptions. First, the language now includes the sentence, “According to the Surgeon General, pregnant women should not drink alcohol,” which is similar to the language suggested by health advocates and mirrors the on-label warning required under federal law.[41] In addition to the URL for OEHHA, this warning also includes the

[41] *See* 27 C.F.R. section 16.21, which requires the label to read:
“GOVERNMENT WARNING:
(1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects.
(2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.

URL for the Surgeon General's website which has detailed information available about the effects of fetal alcohol spectrum disorders.[42]

Subsection (b) allows the business to provide additional supplemental information, as is allowed for other consumer product exposures as long as that information does not dilute or negate the required warning.

Section 25607.10 - Restaurant Warnings, not Including Alcoholic Beverage Warnings – Methods of Transmission

Providing warnings for exposures to foods sold or served in restaurants poses certain challenges that may not be present in other consumer product settings. For example, restaurants may frequently change their menu choices, food preparation methods may not be uniform, use small local produce suppliers, or otherwise have difficulty determining when a particular food will cause an exposure to a listed chemical that requires a warning. Additionally, some restaurants may serve alcoholic beverages, and some may not. Further, the content of the alcohol warning is significantly different than the warnings provided for other consumer products, including food. Therefore the current proposal does not attempt to combine alcoholic beverage warnings which must be provided separately pursuant to subsections 25607.8-9.

The required warning method in the proposed regulation will alert the consumer through a simple warning sign posted at the entrance to the restaurant along with an explanatory pamphlet or other materials. OEHHA has determined that this two-part warning provides the consumer with the required warning, while at the same time allows the restaurant to provide a warning about the kinds of exposures that may occur through consumption of its foods in a more nuanced manner than some other situations. OEHHA encourages restaurants to work through their associations in order to develop a pamphlet that is informative and includes information on all foods sold at a restaurant that may cause an exposure, including the names of the chemicals involved and ways the exposure might be avoided or reduced, if any, consistent with the requirements of Section 25607.11(b).

[42] http://www.surgeongeneral.gov/news/2005/02/sg02222005.html, 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."

Section 25607.11 - Restaurant Warnings not Including Alcoholic Beverage Warnings – Content

The content required by subsection (a) is intended to cover exposures to chemicals in foods and non-alcoholic beverages sold at restaurants. It includes the same signal word as the other warnings in this regulation related to food exposures, but the content of the warning message has been tailored to match the type of setting in which the warning is being provided.

As noted above, exposures to listed chemicals in foods prepared or served at restaurants can vary significantly depending on the items being offered, how consistently they are being prepared, and where the restaurant obtains a given ingredient. For these reasons, OEHHA has determined that providing detailed information concerning the types of exposures that occur in restaurants is best addressed through the provision of more detailed information than can reasonably be included on a posted sign.

Therefore, subsections (a) and (b) of the proposed regulation requires both a posted sign and a pamphlet or other material is made available to the customer. The pamphlet should be in plain sight and available to all customers prior to ordering their meals. A customer should not be required to request the pamphlet since it is an integral part of the warning message required by Health and Safety Code section 25249.6.

Consistent with other parts of the proposed regulation, subsection (b) prohibits restaurants from including anything in the pamphlet or other materials that would dilute or negate the warning message.

Section 25607.12 - Occupational Exposure Warnings – Methods of Transmission

Given that warnings for occupational exposures are also regulated by federal and state entities, including the federal Occupational Safety and Health Administration, where possible the provisions of the proposed regulation attempts to harmonize with the existing federal and state laws and regulation in this area. The warning methods are substantially the same as the existing regulatory requirements, including the provisions incorporating the requirements of federal and state law related to occupational exposures.

Subsection (b) allows the business to provide additional supplemental information to employees, as is allowed for other types of exposures, as long as that information does not dilute or negate the required warning.

Section 25607.13 - Occupational Exposure Warnings – Content

The proposed warning content requirements are consistent with the requirements for other types of exposures to Proposition 65 listed chemicals. The message has been tailored to address occupational exposures by stating that "entering this area will expose you to" a listed chemical. OEHHA is not aware that any of the warning content requirements in the proposed regulation are inconsistent with or in conflict with federal law, but in an abundance of caution has expressly provided that the content requirements of the regulation are only effective if they are not prohibited by federal law. This approach is consistent with Health and Safety Code section 25249.10(a), which provides an exemption from the warning requirements of the Act where federal law preempts such warnings.

Subsection (c) allows a business to provide additional information concerning an exposure to an employee as long as that information does not dilute or negate the required warning.

Subsection (d) allows a business to provide a warning in a specific way and with specific content, where a warning covering that exposure has been adopted by OEHHA. The Agency included this provision in the proposed regulation in order to ensure consistency in the event a specific warning is adopted for a given occupational exposure. For example, the Agency has included several product/area/chemical-specific warnings in the proposed regulation[43] and intends to include others following stakeholder input.

Section 25607.14 - Warnings for Specific Occupational Exposures

This section is a placeholder in the event OEHHA determines that a more specific warning is needed for a certain type of exposure.

[43] See, e.g., Cal. Code of Regs., section 25607.8-9 (Alcoholic Beverage Warnings); section 25607.17(a)-(b) Parking Facilities; section 25607.17(c)-(d) Apartment, Hotels and other Lodging Facilities; section 25607.17(e)-(f) Amusement Parks.

Section 25607.15 - Environmental Exposure Warnings – Methods of Transmission

Section 25607.15 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 requirement in subsection (b) requiring the business to provide the warning in the languages commonly spoken in the area, in addition to English, is intended to make it more likely that individuals who are being exposed to a listed chemical actually receive and understand the warning.

Section 25607.16- Environmental Exposure Warnings – Content

Section 25607.16 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.

Subsection (b) of the proposed regulation allows businesses to use location-specific warnings where they have been adopted by OEHHA in its regulations. These currently include warnings specific to parking facilities, hotels and other lodging facilities and amusement parks. Providing the 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.

Subsection (c) repeats the requirement in other sections of the proposed regulation that allows supplemental materials to be provided with the warning as long as it does not contain information that may negate or dilute the warning message since this would result in a failure to warn under the Act.

Section 25607.17 - Warnings for Specific Environmental Exposures

OEHHA has determined, based on stakeholder input that certain environmental exposure scenarios should have their own 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 at these facilities.

OEHHA has provided the following provisions as examples of regulatory provisions that could address these specific exposure scenarios. The Agency will

also consider adopting additional area-specific warnings as appropriate, based on stakeholder input.

(a) Parking Facilities – Method of Transmission

This provision would provide 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. Specific provisions concerning the size of the sign and text on the sign will be included when the regulation is formally proposed, after OEHHA has received input from interested parties.

(b) Parking Facilities – Content

The content requirements in this section continue the use of the pictogram symbol and signal word required for other warnings in the proposed regulation. 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, along with advice about how to reduce the person's exposure to the chemicals. OEHHA intends for the warning to be more informative than the existing warnings that merely state the area "contains" listed chemicals. The requirement to include the URL for the OEHHA website is also repeated here.

Subsections (c) Apartments, Hotels and other Lodging Facilities – Method of Transmission and (d) Apartment, Hotels and other Lodging Facilities – Content

Unlike many other facilities, apartment complexes, hotels and other lodging facilities can present many different potential exposure scenarios. The proposed regulation contains placeholder language concerning the placement of warning signs, size and font requirements and the potential contents of those warnings. The hotel and lodging industry currently provides warnings and supplemental materials such as pamphlets that could be adapted to the new format and content requirements being proposed for other scenarios in this proposed regulation. OEHHA welcomes stakeholder comments and ideas concerning how best to approach the complex environment of such facilities, while providing individuals with adequate, informative warnings for the exposures that are likely to occur, while discouraging the practice of warning for exposures to chemicals when a

warning is not actually required.

It is possible that different methods or content should be required for certain types of facilities within this category based on the size of the facility, for example. These situations will be addressed after stakeholder input.

Subsection (d)(4) again allows supplemental materials to be provided with the warning so long as it does not contain information that may negate or dilute the warning message since this would result in a failure to warn under the Act.

(e) Amusement Parks – Method of Transmission, and (f) Amusement Parks – Content

Amusement and theme parks present another example of the types of facilities that likely need specific method and content regulations as these facilities can present many different potential exposure scenarios. The proposed regulation currently contains placeholder language concerning the placement, size and font of warning signs, use of supplemental materials and the content of warnings.

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 warning materials such as a pamphlet that is provided to each patron before they enter the facility, rather than at every potential point of contact with the chemical. OEHHA welcomes stakeholder comments and ideas concerning how best to approach the complex environment of such facilities, while providing patrons with adequate, informative warnings for the exposures that are likely to occur there.

It is possible that different methods or content should be required for certain types of facilities within this category based on the size of the facility, for example. These situations will be addressed following stakeholder input.

The provision in subsection (e)(2) is intended to require these facilities to use the warning methods and content proposed elsewhere in the regulation for certain exposures that occur at the facility (such as consumer product exposures, restaurant exposures, alcoholic beverage exposures and parking structure exposures). This ensures consistency with the way warnings for these kinds of exposures are provided elsewhere in California.

Subsection (f)(4) requires that the required warning be provided in both English and other languages where the facility provides other signage in those

languages. OEHHA believes that this provision is particularly important at amusement and theme parks since many non-English speaking individual may visit the parks.

PROBLEMS BEING ADDRESSED BY THIS PROPOSED RULEMAKING

Since Section 25601 was adopted in 1988, concerns have been voiced about the lack of specificity in the current safe harbor environmental warning language, which merely says 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, , or ways that they can reduce or eliminate these exposures. A key objective of the proposed regulation is to provide consistent, understandable information concerning exposures to listed chemicals. It does this by integrating technology and methods for communication that were not available at the time the original regulations were adopted.

In addition, OEHHA over the years has received many requests for amendments to the regulations. Manufacturer and retailer 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 versus 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…."[44]

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 useful, informative warnings for individuals who may be exposed to listed chemicals. Many stakeholders have requested modifications to the regulations throughout the last several years to reduce the number of unnecessary warnings, make the

[44] Health and Safety Code section 25249.11(f)

warnings more informative, and reduce uncertainty for businesses who must comply with the warning requirements of the Act.

BENEFITS OF THE PROPOSED REGULATION

The regulatory amendments OEHHA is proposing would repeal the current Article 6 and adopt a new Article 6 that better serves the public by requiring more detailed information concerning Proposition 65 warnings including how to avoid or reduce their exposure to listed chemicals. The regulation would establish a website operated by OEHHA that would provide public access to this detailed warning information provided by businesses, as well as general information on the health effects of listed chemicals that OEHHA would provide. This furthers the "right-to-know" purposes of the statute. This access to more detailed information would further promote public health and safety. The added clarity to the occupational warnings would increase worker safety.

The regulatory amendments also provide 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 a consumer product, including foods and exposures that occur in occupational or environmental settings. Since the regulations would create mandatory minimum content for the warnings and also prescribe acceptable warning methods, businesses would be able to rely on their compliance with the regulations, and litigation concerning the adequacy of warnings should be reduced.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS

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
- Numerous consent judgments and settlements as referenced in previous.

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 prior during the development of this proposal.

OEHHA will also rely on an Economic Impact Analysis in developing this proposed regulation. The Economic Impact Statement will be prepared during the formal regulatory process. OEHHA invites interested stakeholders to identify economic impacts that OEHHA should consider.

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

Alternatives were offered by the American Apparel & Footwear Association, the American Coatings Association, the Center for Environmental Health, Californians for a Healthy & Green Economy, the Council for Responsible Nutrition, the Fashion Accessories Shippers Association, the Information Technology Industry Council, the Lexington Law Group, PPG Architectural Finishes, and Travel Goods Association. These suggestions were taken into careful consideration and some portions were incorporated into this regulatory proposal. OEHHA's statutory responsibility is to ensure that this regulatory effort remains consistent with the purpose of the statute. [45] Many 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 including Sections 25606 and 25607 are specifically designed to lessen the existing burdens on retail businesses with less than 25 employees that are nonetheless subject to the warning requirements of the Act.

[45] Health and Safety Code section 25249.12(a)

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

[A formal Economic Impact Statement has not been prepared for this pre-regulatory draft of the regulation.]

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 and the proposed regulations specifically provide that they are only effective to the extent they do not conflict with federal law.[46]

[46] 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.

ECONOMIC IMPACT ANALYSIS

Gov. Code section 11346.3(b)

NOTE: OEHHA will prepare an Economic Impact Statement during the formal regulatory process. Input from interested stakeholders concerning anticipated impacts is encouraged.

Problems being addressed by this proposed rulemaking:

How this regulation will address the problem:

Impact on the Creation, Elimination, or Expansion of Jobs/Businesses in California

Benefits of the Proposed Regulation