INITIAL STATEMENT OF REASONS

TITLE 27, CALIFORNIA CODE OF REGULATIONS

PROPOSED ADOPTION OF ARTICLE 2, SECTION 25205

LEAD AGENCY WEBSITE

JANUARY 16, 2015

SUMMARY

The Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency that implements Proposition 65¹ and has the authority to promulgate and amend regulations to further the purposes of the Act. This new regulation furthers the "right-to-know" purposes of the statute by establishing the framework for a website operated by OEHHA that would provide more detailed information to the public about exposures to listed chemicals for which warnings are being provided pursuant to Section 25249.6 of the Act.

This regulation is being proposed concurrently with the proposed repeal of Article 6 and the adoption of a new Article 6 with two Subarticles. Article 6 includes general provisions clarifying the relative responsibilities of product manufacturers and others in the chain of distribution, versus product retailers, and "safe harbor" guidance concerning the methods of providing warnings and the content to be provided for exposures to listed chemicals that occur from products, occupational activities and various environmental settings. ²

The lead agency website regulation is being proposed for adoption in Article 2 because the information requested and provided under the proposed regulation is not a requisite part of the clear and reasonable warnings. Article 2 primarily relates to lead agency activities. The website will further the purposes of Proposition 65 by providing valuable supplemental information to the public regarding warnings that are being provided for listed chemicals. This proposed regulation is intended to be separate and apart from Article 6, and it is not enforceable by private plaintiffs.

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

² Cal.Code of Regs., Title 27, Article 6, Subarticles 1-2, section 25600, *et seq*. All further references are to sections of Title 27 unless otherwise indicated.

Background

After seeing a Proposition 65 warning, many members of the public contact businesses and OEHHA seeking additional information concerning the listed chemical that is the subject of the warning, the potential routes of exposure and preventive measures to minimize or eliminate exposures. Members of the public currently have no centralized source for obtaining this supplemental information. A key objective of the proposed regulation is to increase the availability of consistent, understandable information to the public regarding warnings provided for potential exposures to listed chemicals. The proposed regulation would establish a one-stop shop for supplemental information concerning the warnings Californians see on products and at locations throughout the state.

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." (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."

On July 30, 2013, OEHHA held a public workshop where concepts for possible amendments to the Proposition 65 warning regulations were discussed, (http://www.oehha.ca.gov/prop65/pdf/073013p65wkshp.pdf). On March 7, 2014, OEHHA posted a proposed draft regulation to replace the existing OEHHA Clear and Reasonable Warnings regulation and to establish an OEHHA web site containing information on Proposition 65 warnings. The posting initiated a written public-comment period that closed on June 13, 2014. On April 14, 2014, OEHHA held a public workshop for the purpose of discussing this possible regulatory action. During this pre-regulatory phase, more than fifty interested parties submitted comment letters on the draft regulations. Since the workshop, OEHHA has held over thirty meetings with stakeholder groups to discuss their comments regarding the proposed warning and website regulations.

One concern voiced by several stakeholders was that the website provision in the April 2014 pre-regulatory version of the warning regulation would increase the likelihood of private litigation if a business failed to provide all the requested

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³ 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.

⁴ 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.

information to OEHHA for use on the website. After carefully considering this input from stakeholders, OEHHA made significant changes to the pre-regulatory draft of the clear and reasonable warning regulations, including relocating the proposed lead agency website provision to Article 2 and adding specific language in this proposed regulation clarifying that the website is intended to provide information to the public that supplements the warnings required under Section 25249.6 of the Act. The information that will be provided there is not a substitute for a clear and reasonable warning for a given exposure. Further, non-compliance with OEHHA requests for information it may find necessary is not enforceable as a violation of the "clear and reasonable" warning requirements of the Act.

However, a link to the OEHHA website will be required to be included in all safeharbor warnings under the proposed new Subarticle 6.2 regulations so that people can easily access the supplemental information OEHHA will provide there.

PROPOSED REGULATION

This proposed regulation is intended to leverage the public's existing and future use of the Internet in order to provide supplemental, contextual information about potential exposures to listed chemicals. This will allow the public to make informed choices concerning those exposures, thus furthering the purposes of the statute. OEHHA intends to develop chemical and exposure information, as resources allow, that is supplemental to the warnings required by the Act. In some cases, OEHHA may request information directly from a particular industry or business that is providing a warning. However, OEHHA primarily intends to collect existing, publicly available information and make it accessible to those who may have questions when they see a Proposition 65 warning. OEHHA anticipates that some businesses and trade associations will proactively provide information for the OEHHA website so that there will seldom be a need to formally request such information.

Following is a brief discussion of each provision of the proposed regulation.

Section 25205 - Lead Agency Website

Under this proposed regulation, OEHHA as lead agency will develop and maintain a website to provide the public with information regarding warnings provided for potential exposures to listed chemicals. OEHHA may request information from businesses concerning the warnings they are providing,

including the name of the listed chemical or chemicals for which a warning is being provided, the location and concentration of the chemical or chemicals, and the anticipated routes and pathways of potential exposure. With few exceptions, this supplemental 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 the supplemental information it will provide on the website will aid interested individuals who receive a warning to learn about the chemicals involved in a potential exposure, how they can be exposed to those chemicals, and any steps they could take to reduce or eliminate a potential exposure. This will further the purposes of the Act by supplementing the basic information conveyed by Proposition 65 warnings so individuals are able to make informed decisions about those exposures.

Section 25205(a)

In the 25 years since the original implementing regulations were adopted, electronic methods of communication have become ubiquitous. Tools such as computers, the Internet and smart phones offer most Californians instant access to a wealth of information. OEHHA intends to tap into these communication methods to provide information concerning potential exposures to listed chemicals through products, foods and the environment.

Under subsection (a), OEHHA will develop a website for the purpose of providing information to the public concerning warnings they receive for potential exposures to listed chemicals. The information will be obtained primarily from public sources or be developed by OEHHA, and occasionally from industry sectors or businesses providing warnings.

The purpose of the website is to utilize the Internet as a means to provide supplemental information to individuals regarding potential exposures to listed chemicals. Immediate access to supplemental 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. It may also indirectly encourage businesses to reduce or eliminate those exposures, when feasible. The establishment of the lead agency website in no way precludes businesses from providing supplemental information through some other mechanism in addition to the "clear and reasonable" warnings required under Section 25249.6 of the Act.

Pursuant to subsection (a)(2), the agency will provide a process for a person to request a correction of potentially inaccurate information. This provision is intended to aid in the removal of incorrect information that has been included on the OEHHA website. To ensure the validity of the information on the website, a person making a request to change or remove information must provide documentation substantiating the request. Any person is also free to provide OEHHA with information or materials for the website, which OEHHA may post at its sole discretion.

Under subsection (a)(3), OEHHA will post information for the public concerning the listed chemicals for which warnings may be provided, 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.

Subsection (a)(4) explains that OEHHA will provide links, as appropriate, 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 potential exposure. This can assist individuals who receive warnings to find out more about listed chemicals, nutritional benefits of some products, health concerns and other related issues so they can make informed decisions about the relative risks and benefits involved in a given exposure.

Subsection (a)(5) explains that OEHHA will provide reasonably available information regarding the anticipated level of human exposure to the listed chemical from a particular source, given available information and resources. OEHHA anticipates that the website will provide user-friendly search processes that cross-reference listed chemicals with examples of products that may contain those listed chemicals (e.g., upholstered chairs, food products, gas stations, parking structures, etc.). OEHHA will provide information in a form that is easily understandable to the public. Such information may include the anticipated frequency or duration of contact with a given chemical or product that could result in an exposure requiring a warning or issues such as portion size or dose compared to exposure levels established under Proposition 65.

Subsection (a)(6) explains that OEHHA cannot assure the accuracy of information it has received from businesses or other sources. OEHHA will strive to maintain and post accurate information on the website. By posting information provided by businesses or other sources on the website, however, OEHHA is not validating or guaranteeing the reliability of that information. As noted above, subsection (a)(2) creates a process for correcting erroneous information posted

on the website, and serves as an additional safeguard against inaccurate information being provided to the public.

Section 25205(b)

An objective of this section is to fill in gaps of data related to exposures to listed chemicals. These data are not always publicly available; a manufacturer, producer distributor, or importer of a product is typically in the best position to provide this information. For a specific facility, the owner or operator may have additional information about the types and quantities of listed chemicals emitted into the surrounding environment. Subsection (b) requires businesses to give OEHHA information regarding the warnings a business is providing, upon request, including the following:

- The name and contact information for the person providing the information.
- The name and contact information for the manufacturer of the product.
- The name of the listed chemical or chemicals for which a warning is being provided.
- The location of the chemical or chemicals in the area.
- The location of the chemical or chemicals on or in the product.
- The concentration (mean, minimum, maximum) of the chemical or chemicals in the product. If the product contains multiple component parts, the concentrations (mean, minimum, maximum) of the chemical or chemicals in each of the component parts.
- The matrix in which the listed chemical or chemicals is found in the product and the concentration of the listed chemical(s) in the product matrix, if known.⁵
- The anticipated routes and pathways of exposure to the listed chemical(s) for which the warning is being provided.
- The estimated level of exposure to the chemical or chemicals.
- Any other information that OEHHA may deem necessary.

The manufacturer or producer of the product or the business that is providing an environmental/area warning generally has the most knowledge regarding the chemicals involved in the potential exposure. The business should also know why it is providing a warning for a given product or location. Therefore it should

⁵ The term "matrix" has the same meaning as defined in Cal. Code of Regs., Title 27, Article 9. Subsection 25900(g)(2) defines "matrix" as "the component or substrate that contains the chemical in question".

have access to some or all the technical information listed in this subsection. OEHHA will not be asking for information the business does not already have. Such information, however, is critical to understanding the exposures that may occur and may not reasonably be available from other public sources. This section does not confer any responsibility on a business to do new testing or analysis in response to a request from OEHHA. If the business does not have the requested information, then it would be sufficient for it to respond to an information request by providing the responsive information that it does have and informing OEHHA that it does not possess the other requested information.

The ability to request "any other information that OEHHA may deem necessary" is intended to capture information not otherwise identified in this subsection relevant to an exposure to a listed chemical. Some stakeholders have commented that this provision is too broad. The scope of information that may be requested, however, is limited to information related to potential exposures to listed chemicals for which warnings are already being provided under the Act. Some exposure scenarios are unusual or unique, making it difficult for OEHHA to anticipate the full range of questions that might arise from the public related to warnings provided under the Act. This section will help OEHHA obtain information not readily available to the public concerning products, exposures, or environmental situations where a warning is being provided, in order to convey this information to Californians who desire additional information. Additionally, subsection (c) of this proposed regulation provides a safeguard against the publication or production of proprietary business information.

Some stakeholders have expressed that businesses should not be required to provide information to OEHHA for the Proposition 65 website. Proposition 65 is a right-to-know law. The lead agency's statutory responsibility is to ensure that this regulatory effort remains consistent with the purpose of the statute, namely to provide people with notice concerning their *exposures* to listed chemicals. ⁶ By proposing this regulation, OEHHA is implementing and furthering the purposes of the Act by collecting information relevant to those exposures and providing it to the public in a convenient location. 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...

⁶ Health and Safety Code section 25249.12(a); see *Environmental Law Foundation v. Wykle Research, Inc.* (2005) 134 Cal. App. 4th 60, 791.

- ... 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.)⁷

Generally, the persons or groups providing the warning are the only source of certain information regarding the exposure such as the location, concentration and matrix within which the chemical occurs. This information is inextricably linked to the right of the people of California to be informed about exposures to listed chemicals and OEHHA has a statutory responsibility to adopt regulations that further the purposes of the act.

In order to make the process efficient and cost-effective for both the businesses and the state, OEHHA encourages businesses to collaborate with each other and voluntarily provide information to OEHHA for use on the Proposition 65 website. Businesses may coordinate reporting through their trade groups or other organizations since many exposures to listed chemicals occur throughout an industry, not from a single product, occupational or environmental scenario. For example, in recent years, trade groups representing the wood product, apartment, hotel hotel and automobile industries have jointly developed and distributed warning materials for their members. Providing these materials to OEHHA for potential use on the lead agency website should not increase costs for businesses.

Some stakeholders have suggested that a business should be allowed to provide the required information on its own business website rather than on the lead agency website. OEHHA has determined that having the website developed and managed by OEHHA will ensure that the warning information will be provided in a neutral, consistent format, and in a way that is easily accessible to the public. 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

⁹ See, e.g., the San Francisco Apartment Association's "Legal Corner Q&A," available at http://www.sfaa.org/0505legalqa.html.

⁷ Ballot Pamphlet, Proposed Law, Gen. Elec. (Nov. 4, 1986) p. 53. http://www.oehha.ca.gov/prop65/law/pdf_zip/Prop65Ballot1986.pdf

⁸ 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.

¹⁰ 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.

¹¹ See, e.g., the California New Car Dealers Association's "Proposition 65 Compliance Handbook," available at www.cncda.org/secure/GetFile.aspx?ID=2195.

commensurate requirement for private websites. Nothing in the regulation, however, precludes any business from providing supplemental information on its own website as well.

Section 25205(c)

During the pre-regulatory development of this proposed regulation, some stakeholders from various industries expressed concern that the requirement to provide information to OEHHA upon request would result in the release of confidential, proprietary information including "trade secrets". In proposing subsection (c), OEHHA is attempting to strike a balance between the statutory requirement of informing the people of California regarding exposures to listed chemicals and the business's need to protect confidential, proprietary information. To that end, this subsection provides that a business may request that information submitted to OEHHA be treated as Confidential Business Information ("CBI") and therefore not be available for public inspection under provisions of the Public Records Act¹² and Evidence Code. ¹³ OEHHA can use information that is CBI to inform exposure calculations and other information for the website without disclosing the CBI. However, if OEHHA determines that the information is not CBI, OEHHA must provide 15 days' notice to the business of its intent to disclose such information. During the 15 day period, the business may provide additional justification for the claim or assert their claim in an appropriate forum. The 15-day notice period is necessary to allow OEHHA to timely respond to Public Record Act requests 14 with responsive records. The timeframe is intended to allow sufficient time for a party to commence any proceedings required to protect the information.

Section 25205(d)

Some stakeholders have voiced concern that the use of a website to provide supplemental information regarding listed chemicals will allow a business to avoid its legal obligation to provide warnings under Section 25249.6 of the Act. However, subsection (d) clarifies that providing information to OEHHA for the website does not constitute a clear and reasonable warning under the Act. This section is not to be interpreted in such a way that a business may rely exclusively on any website (whether OEHHA's or otherwise), or other device to attempt to provide a warning where the consumer must seek out the mandatory minimum

¹² Government Code section 6250 et seq.

¹³ Evidence Code sections 1040 and 1060.

¹⁴ Government Code section 6253(c).

information required in Section 25249.5 of the Act. For example, a general reference to a website that is not associated with a specific product or exposure would not comply with the Act. Similarly, an invitation to determine which products within a retail facility require a warning via a website would not comply with the Act. ¹⁵

This proposed regulation was separated from the clear and reasonable warning regulations being proposed for Article 6 in order to address concerns raised by stakeholders regarding the potential for increased litigation by private-party enforcers. This section simply articulates the intended effect of dividing the regulations; namely, that the failure to comply with the requirements of this section is not a violation of the clear and reasonable warning requirements of the Act.

NECESSITY

The existing regulations were adopted more than 25 years ago, shortly after Proposition 65 was passed. The regulations are in need of updating and reform to ensure that they take advantage of newer communications processes and provide useful, informative information to supplement Proposition 65 warnings for exposure to listed chemicals. While OEHHA could develop a website containing this information without the need for a regulation, adopting the regulation provides transparency, context and a framework for the website. It also clarifies that OEHHA has the authority under Section 25249.11 of the Act to require a given business or industry to provide it with certain information related to the warnings businesses may be providing, should that become necessary. Further, it expressly provides a process for a business or individual to request correction of the information OEHHA provides on the website and protection for trade secret or otherwise confidential business information.

BENEFITS OF THE PROPOSED REGULATION

The proposed regulation would establish the general framework for a website operated by OEHHA that would provide public access to information relevant to potential exposures to listed chemicals as well as general information on the health effects of listed chemicals and preventive measures to reduce likelihood of exposure. This access to more detailed information would further promote public health and safety, thus furthering the "right-to-know" purposes of the statute.

¹⁵ See *Ingredient Communication Council, Inc. v. Lungren*, 2 Cal. App. 4th 1480 (1992).

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

OEHHA 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 proposed regulation.

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

OEHHA received more than 50 comment letters in response to the pre-regulatory workshop and pre-regulatory draft regulation for clear and reasonable warnings that initially included the lead agency website provision. OEHHA also participated in 31 meetings with a wide range of stakeholders. Alternatives to the proposed lead agency website provision were offered by the American Chemistry Council, American Herbal Products Association, American Coatings Association, Auto Alliance, California Apartment Association, California Chamber of Commerce, California Retailers Association, Californians for a Healthy and Green Economy, Center for Environmental Health, Clean Water Action, Consumer Specialty Products Association, Frozen Potato Products Institute, Global Automakers, Law Offices of David Roe, Lexington Law Group, Personal Care Products Council, Rubber Manufacturer's Association, and Phylmar Group. OEHHA carefully considered each alternative and OEHHA incorporated both substantive and non-substantive input offered by stakeholders into this regulatory proposal. The Agency's statutory responsibility is to ensure that this regulatory effort remains consistent with the purpose of the statute. 16 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)). Small businesses with 10 or more employees will not be adversely

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¹⁶ Health and Safety Code section 25249.12(a)

impacted because, other than occasional requests for specific information, the bulk of the work on the website will be performed by OEHHA staff.

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 significant new requirements upon private persons. While the regulation requires businesses to provide information regarding listed chemicals to OEHHA upon request, this information is similar to that obtained by the business for the purpose of determining whether to provide a Proposition 65 warning. OEHHA anticipates that most businesses will voluntarily provide it with information and there will seldom be a need for it to specifically request information from a given business. The more likely approach would be to request information from an entire business sector through an association, thus reducing any potential costs.

EFFORTS TO AVOID UNNECESSARY DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS CONTAINED IN THE CODE OF FEDERAL REGULATIONS ADDRESSING THE SAME ISSUES

Proposition 65 is a California law that has no federal counterpart. OEHHA has determined that, as drafted, the regulations do not duplicate and will not conflict with federal regulations. In fact, the statute specifically provides that it is only effective to the extent it does not conflict with federal law.¹⁷

ECONOMIC IMPACT ASSESSMENT

Gov. Code section 11346.3(b)

OEHHA finds there will be no significant economic impact related to this proposed regulation. The proposed regulation would not impose any significant costs because businesses are already subject to the warning requirements of Proposition 65. Businesses that may be asked to provide information under this proposed regulation would only be required to provide existing information the

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¹⁷ 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.

business used for its own assessment of whether a warning is required for a given exposure. Incremental costs associated with OEHHA requests for information are not expected to be significant.

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 simply sets out a framework for an OEHHA website to provide supplemental information for members of the public seeking information regarding exposure to a listed chemical.

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 simply sets out a framework for an OEHHA website to provide supplemental information for members of the public seeking information regarding exposure to a listed chemical.

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 simply sets out a framework for an OEHHA website to provide supplemental information for members of the public seeking information regarding exposure to a listed chemical.

Benefits of the Proposed Regulation

The proposed regulation would establish the general framework for a website operated by OEHHA that would provide public access to information relevant to potential exposures to listed chemicals as well as general information on the health effects of listed chemicals and preventive measures to reduce the likelihood of significant exposures. This access to more detailed information would further promote public health and safety. The proposed regulation will further the 'right to know" purposes of Proposition 65 by providing important supplemental and contextual information to the public regarding potential exposures to listed chemicals in furtherance of the purposes of the Act.