

**INITIAL STATEMENT OF REASONS
TITLE 27, CALIFORNIA CODE OF REGULATIONS**

**PROPOSED SECTION 25904
LISTINGS BY REFERENCE TO THE CALIFORNIA LABOR CODE**

**SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
PROPOSITION 65**

PURPOSE

The Safe Drinking Water and Toxic Enforcement Act of 1986,¹ commonly known as Proposition 65 was enacted by the voters as a ballot initiative on November 4, 1986. The Office of Environmental Health Hazard Assessment (OEHHA) is the state entity responsible for the implementation of the Act. OEHHA has the authority to promulgate and amend regulations to further the purposes of the Act. Proposition 65 prohibits businesses from contaminating sources of drinking water with chemicals known to the state to cause cancer or reproductive toxicity and requires businesses to provide warnings before exposing individuals to these chemicals.

OEHHA is responsible for maintaining the list of chemicals that are known to the state to cause cancer or reproductive toxicity. There are four ways chemicals are added to the Proposition 65 list². Listing is required when chemicals are: (1) identified by reference to certain subsections of the California Labor Code, (2) identified by the state's qualified experts, (3) identified by designated authoritative bodies, or (4) "formally required" to be labeled or identified as causing cancer or reproductive toxicity by a state or federal agency.

AUTHORITY

OEHHA is the designated lead agency for Proposition 65 and has the authority to adopt regulations "as necessary to conform with and implement this chapter [Proposition 65] and further its purposes."³

Health and Safety Code Section 25249.8(a) provides that:

"On or before March 1, 1987, the Governor shall cause to be published a list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter, and he shall cause such list to be revised and republished in light of additional knowledge at least once per year thereafter. *Such list shall include at a minimum those substances identified by reference in Labor Code Section*

¹ Codified at Health and Safety Code section 25249.5 et seq., hereinafter referred to as "Proposition 65" or "the Act".

² Health and Safety Code section 25249.8

³ Health and Safety Code section 25249.12(a) and Title 27, Cal Code of Regulations section 25102(o)

6382(b)(1) and those substances identified additionally by reference in Labor Code Section 6382(d)." (Emphasis added)

Labor Code subsection 6382(b)(1) provides:

"Substances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC)."

Labor Code section 6382(d) provides:

"Notwithstanding Section 6381, in addition to those substances on the director's list of hazardous substances, any substance within the scope of the federal Hazard Communication Standard (29 C.F.R. Sec. 1910.1200) is a hazardous substance subject to this chapter."

Thus, Proposition 65 did not adopt by reference the entire California Labor Code, or even a full section of that code, but only certain sub-parts of two sections. To identify chemicals that must be listed via this mechanism, OEHHA looks to the named sources identified in the specific subsections of the Labor Code that are incorporated into Proposition 65.

PROBLEM BEING ADDRESSED BY THIS PROPOSED RULEMAKING

Although not required to do so, OEHHA has adopted regulations setting out the general criteria used by OEHHA for listing chemicals via other listing mechanisms under Proposition 65⁴, but not the Labor Code listing mechanism. In order to ensure transparency, certainty and clarity for the general public, non-governmental organizations, and the business and enforcement communities, OEHHA is proposing a regulation for the Labor Code mechanism.

NECESSITY

Although the process for listing chemicals under Proposition 65 is expressly excluded from the Administrative Procedure Act⁵, OEHHA has previously adopted regulations setting out the general criteria for listing chemicals via the other three listing mechanisms⁶. The purpose of this proposed regulation is to clarify and explain to interested parties the way OEHHA identifies chemicals and substances that must be added to the Proposition 65 list based on their identification by reference via the Labor Code provisions in Proposition 65⁷ and explain the process for reconsidering chemicals that have been listed via this mechanism. Each provision of the proposed regulation is discussed in greater detail later in this document.

⁴ Title 27, Cal. Code of Regs., sections 25306 (authoritative bodies), 25902 (formally required) and 25305 (State's Qualified Experts)

⁵ Health and Safety Code section 25249.8(e)

⁶ Title 27, Cal. Code of Regs., sections 25306 (authoritative bodies), 25902 (formally required) and 25305 (State's Qualified Experts)

⁷ Health and Safety Code section 25249.8(a)

BENEFITS OF THE PROPOSED REGULATION

This proposed regulation will provide information and clarification to the interested parties regarding how OEHHA identifies chemicals for potential listing via the Labor Code. The proposed regulation would provide increased openness and transparency for businesses and others affected by these listings.

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

On June 17, 2008 OEHHA held a public, pre-regulatory workshop to discuss the possibility of adopting a regulation concerning listing chemicals via the Labor Code mechanism. A written public comment period closed on July 17, 2008. OEHHA carefully reviewed and considered the oral and written comments received at the workshop and during the comment period.

On June 17, 2013, OEHHA again held a public, pre-regulatory workshop to discuss a proposed regulation. A written public comment period closed on July 1, 2012. Eight comments were received and have been carefully considered in this new proposed language.

OEHHA staff also reviewed the decisions of the Court of Appeal in *AFL-CIO v. Deukmejian* (1989, 3rd Dist.) 212 Cal.App. 3d., 425, *California Chamber of Commerce v. Brown* (2011, 1st District) 196 Cal.App. 4th, 23; *Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment*, (October 31, 2012, 3rd District), and interim orders issued in the trial court case *Sierra Club et al. v. Brown et al.* (Alameda County Superior Court case number RG07356881). Copies of these court decisions, which addressed various legal questions relating to the Labor Code listing mechanism, will be included in the rulemaking record for this proposed action.

In addition, OEHHA staff reviewed recent changes (effective May 2012) to the federal Hazard Communication Standard regulations found in Title 29 of the Code of Federal Regulations, section 1910.1200. In particular, OEHHA reviewed Mandatory Appendix D to the regulation and related materials discussing recent changes to the regulations that are publicly available on the federal Occupational Safety and Health Administration website (www.osha.gov). Copies of these materials will be included in the record for this proposed regulatory action. The relevant provisions of the federal regulations will be included in the rulemaking file for this proposed action.

OEHHA also relied on the attached Economic Impact Analysis in developing this proposed regulation. No other technical, theoretical or empirical material was relied upon by OEHHA in proposing the adoption of this regulation.

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

One alternative to the proposed regulation that was considered by OEHHA was to refrain from proposing a regulation at all. This alternative was rejected because OEHHA believes that businesses subject to the Act and other members of the public should know and understand the process by which OEHHA adds chemicals and substances to the Proposition 65 list via the Labor Code mechanism. The proposed regulation is based on OEHHA's interpretation of recent court decisions⁸ and certain changes to the relevant federal regulations. The proposed regulation also explains the procedure for removing chemicals from the list in the event they no longer qualify for listing via this mechanism and establishes a public comment period to be held prior to OEHHA listing a chemical via this mechanism.

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

The proposed regulatory action will not adversely impact small business. The provisions of Proposition 65 are applicable only to businesses with 10 or more employees⁹. Further, the proposed regulation is intended to provide clarity and certainty related to OEHHA's interpretation of recent court decisions and changes to the applicable federal regulations as they apply to Labor Code listings. The proposed regulatory action does not impose any new requirement upon any business, including small business. Instead, it provides businesses and other members of the public with information concerning this mechanism for listing chemicals under Proposition 65.

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

The proposed regulatory action will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The proposed regulation does not impose any new requirements upon private persons or business because it clarifies an existing process already used by OEHHA for listing and de-listing chemicals under Proposition 65. While the act of listing a particular chemical may affect a business because a warning may eventually be required for certain exposures, or discharges of those chemicals may be prohibited, the proposed regulation does not impose those requirements. It simply describes the process by which OEHHA determines if a chemical must be listed via the Labor Code mechanism.

⁸ Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment (2012) 148 Cal.App.4th 1082; *California Chamber of Commerce v Brown* (2011, 1st District) 196 Cal.App. 4th, 23

⁹ Health and Safety Code §§ 25249.5, 25249.6 and 25249.11(b)

AVOID UNNECESSARY DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS

Proposition 65 is a California law that has no federal counterpart. There are no federal regulations addressing chemical listings under Proposition 65. Thus, there is no duplication or conflict with federal regulations. The fact that both Proposition 65 and the California Labor Code incorporate the federal Hazard Communications Standard ensures that California avoids duplication of effort in identifying chemical hazards and does not duplicate federal requirements.

SUMMARY AND RATIONALE OF REGULATION

Each provision of the proposed new regulation is discussed below:

Subsection (a)(1) explains how OEHHA identifies chemicals or substances that have been evaluated by the World Health Organization's International Agency for Research on Cancer (IARC) and found to cause cancer. These chemicals must be added to the list by reference to California Labor Code section 6382(b)(1). This provision is separate from the provisions of Labor Code section 6382(d) discussed below. However, both provisions can apply to carcinogens identified by IARC.

IARC has a rigorous, multi-tiered scientific identification system that groups chemicals by the evidence of their carcinogenicity. Each of these is discussed briefly below in the context of listing under Proposition 65 via the Labor Code mechanism, provision 6382(b)(1).

“Group 1: The agent is *carcinogenic to humans*.”

This category is used when there is *sufficient evidence of carcinogenicity* in humans, or exceptionally when evidence in humans is less than *sufficient* but there is *sufficient evidence of carcinogenicity* in experimental animals and strong evidence in exposed humans that the agent acts through a relevant mechanism of carcinogenicity.

Chemicals in this category are therefore either human carcinogens, animal carcinogens, or both. The Proposition 65 list must include IARC Group 1 carcinogens because they are identified by reference in Labor Code section 6382(b)(1), which in turn is identified by reference in Proposition 65 itself.

“Group 2A: The agent is *probably carcinogenic to humans*.”

This category is used when there is: a) *limited evidence of carcinogenicity* in humans and *sufficient evidence of carcinogenicity* in experimental animals; b) *inadequate evidence of carcinogenicity* in humans and *sufficient evidence of carcinogenicity* in experimental animals and strong evidence that the carcinogenesis is mediated by a mechanism that also operates in humans; or c) exceptionally, there is *limited evidence of carcinogenicity* in

humans and there is strong mechanistic evidence it falls in a class of agents for which one or more members have been classified in Group 1 or Group 2A.

Chemicals in Group 2A by reason of a) or b) above are animal carcinogens and therefore, via Labor Code section 6382(b)(1), listing under Proposition 65 would be required. However, chemicals in this category by reason of c) have less than sufficient animal and human evidence and would not qualify for listing via Labor Code section 6382(b)(1), as explained below.

“Group 2B: The agent is *possibly carcinogenic to humans*.”

This category is used for agents when there is a) *sufficient evidence of carcinogenicity in experimental animals*, b) *limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals*, or c) in some instances, less than sufficient evidence in animals and *inadequate evidence in humans* but good mechanistic data.

Chemicals in Group 2B with sufficient animal evidence under subsection (a) are animal carcinogens and therefore, listing under Proposition 65 is required. Chemicals that have not been by IARC as human or animal carcinogens based on sufficient evidence are not listed via Labor Code section 6382(b)(1).

“**Group 3. The agent is *not classifiable as to its carcinogenicity to humans*.**”

This category is used for agents not fitting into the other IARC categories (including Group 4 – “The agent is probably not carcinogenic to humans”). It includes chemicals with *sufficient evidence of carcinogenicity in experimental animals* when there is strong evidence that the mechanism of carcinogenicity in experimental animals does not operate in humans.

Proposition 65 requires the listing of both human and animal carcinogens (*AFL-CIO v. Deukmejian* (1989) 212 Cal. App. 3d. 425). However, since the purpose of Proposition 65 is to protect public (human) health, listing under Labor Code section 6382(b)(1) is not triggered by agents that may have *sufficient evidence in experimental animals*, but which have been identified as “*not classifiable as to its carcinogenicity to humans*”, that are placed in Group 3. Thus, agents for which IARC determines that there is strong evidence that the mechanism of carcinogenicity in experimental animals does not operate in humans, but for which the evidence in animals is sufficient, do not meet the criteria for listing by Labor Code section 6382(b)(1).

Subsection (a)(2) of the proposed regulation describes the process by which OEHHHA identifies chemicals or substances that are “within the scope” of the federal Hazard Communication Standard.

Labor Code section 6382(d) provides:

“Notwithstanding Section 6381, in addition to those substances on the director's list of hazardous substances, *any substance within the scope of the federal Hazard Communication Standard (29 C.F.R. Sec. 1910.1200) is a hazardous substance* subject to this chapter.” (Emphasis added)

In March 2012, OSHA extensively amended the regulations contained in Title 29, C.F.R., section 1910.1200. Title 29, C.F.R 1910.1200(d)(3)(ii), which had specifically referred to the American Conference of Governmental Industrial Hygienists Threshold Limit Values for occupational exposures to chemical hazards, was deleted in the 2012 version of the regulation. OEHHA has determined that these changes have eliminated the Threshold Limit Values as a definitive source for identifying chemicals that are known to cause reproductive toxicity. Therefore, OEHHA is no longer proposing chemical listings based on the Threshold Limit Values, which have been the basis to date for the listing of reproductive toxicants under the Labor code mechanism. However, the proposed regulation includes the phrase “or reproductive toxicity” in subsection (a)(2) to track the express language in the Health and Safety Code section 25249.8(a) so that chemicals could be listed as reproductive toxicants in the future if they are otherwise identified as “within the scope” of the Hazard Communication Standard.

New Mandatory Appendix D of the 2012 version of the federal Hazard Communication Standard provides that a “safety data sheet (SDS) *shall* include the information specified in Table D.1...”(emphasis added). Item 11 of Table D.1 is entitled “Toxicological Information” and states that the SDS must include a description of the various toxicological (health) effects and the available data used to identify those effects, including:

...“(e) Whether the hazardous chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA”...

Because Mandatory Appendix D of the Hazard Communication Standard requires a safety data sheet to disclose that a workplace chemical is listed in the NTP Report on Carcinogens or has been found to be a potential carcinogen in the IARC Monographs, such chemicals clearly fall “within the scope” of the federal Hazard Communication Standard for purposes of Labor Code Section 6382(d), and therefore must be included on the Proposition 65 list.

The requirement to list NTP and IARC-identified carcinogens via the Labor Code mechanism is consistent with the principal objective of Proposition 65. The mandatory disclosure on an SDS of NTP’s and IARC’s determinations of a chemical’s carcinogenic effects is intended to provide workers with critical information about the chemicals they are being exposed to in the workplace. By requiring that the Proposition 65 list “shall include, at a minimum, those substances....identified additionally by reference in Labor Code

Section 6382(d),” Proposition 65 clearly is intended to ensure Californians are informed about exposures to these same chemicals.

In October, 2012, the 3rd District Court of Appeal stated in *Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment*, (October 31, 2012, 3rd District), that chemicals listing via the Labor Code method must be based on sufficient animal or human evidence. Therefore, the phrase “based on sufficient animal or human evidence” was added to the proposed regulatory language.

Subsection (b) of the proposed regulation provides that at least 45 days prior to adding a chemical that meets the criteria established in section (a) to the list, the lead agency shall publish a notice of intent to list the chemical and provide a 30 day public comment period on whether or not the chemical has been identified by reference in either Labor Code section 6382(b)(1) or 6382(d), or both. Although this notice process is not statutorily required for Proposition 65 listings, it will promote transparency and provide members of the public an opportunity to comment on whether they believe the chemical has been identified by reference in the Labor Code as causing cancer. Since the listing procedure for this mechanism is ministerial and therefore essentially automatic, OEHHA restricts comment to the identification of a chemical as causing cancer or reproductive toxicity, not the underlying scientific determinations supporting the identification.

Subsection (c) provides the mechanism by which a person can petition the lead agency to consider a chemical for listing under this section. Since the lead agency may not be aware that some chemicals are potentially covered by this section, this subsection provides a formal mechanism by which persons can bring such information to the attention of the lead agency. The person filing the petition is required to identify the chemical in question and identify which mechanism described in subsection (a) applies.

Subsection (d) explains the process OEHHA follows when a chemical listed using the Labor Code mechanism no longer meets the criteria in this section. OEHHA first determines if the chemical meets the criteria for listing under Section 25306 (listings under the authoritative bodies mechanism), or Section 25902 (listings under the “formally required” mechanism). If the chemical does not meet the criteria in either of those two sections, OEHHA refers the chemical to either the Carcinogen Identification Committee or the Developmental and Reproductive Toxicant Identification Committee for a determination as to whether the chemical should remain on the Proposition 65 list. This subsection also explains that until the appropriate committee has made such a determination, the chemical remains on the list. This will reduce potential confusion that could otherwise occur if a chemical were to be delisted pending a committee decision, and then relisted if the committee determines it causes cancer or reproductive toxicity, or both. This is consistent with the delisting processes used for the other three listing mechanisms.

ECONOMIC IMPACT ANALYSIS
Gov. Code section 11346.3(b)

OEHHA finds there will be no economic impact related to this proposed regulatory language. The proposed regulation would not impose any costs because businesses are already subject to Proposition 65, nor does it propose any requirements on businesses. The proposed regulation simply clarifies the process and criteria used to list chemicals under Proposition 65.

Problem being addressed by this proposed rulemaking:

Other listing methods under Proposition 65 have existing regulations that generally explain the listing processes. The Labor Code mechanism has no implementing regulations. The proposed regulation will provide more transparency and clarity concerning how listings are made via this listing mechanism.

How this regulation will address the problem:

This proposed regulation clarifies the process for listing chemicals via the Labor Code provision established in Health and Safety Code section 25249.8(a).

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

The proposed regulation will not affect the creation or elimination of jobs within the State of California. The proposed regulation simply clarifies the process OEHHA follows for listing chemicals via the Labor Code provision established in Health and Safety Code section 25249.8(a).

Benefits of the Proposed Regulation

The proposed regulation will provide clarification on the process OEHHA uses for listing chemicals via the Labor Code mechanism established in Health and Safety Code section 25249.8(a).