PRE-REGULATORY DRAFT

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 as a voters' 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 harm 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, birth defects or other reproductive harm. There are four ways chemicals are added to the Proposition 65 list[2]. These are: (1) chemicals identified by reference to certain subsections of the California Labor Code, (2) identification by the State's Qualified Experts, (3) identification by designated Authoritative Bodies, and (4) chemicals "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

[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)

> 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 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:

> "The listings referred to in subdivision (a) are as follows:
> (1) 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 must look to the named sources identified in the specific subsections of the Labor Code that are incorporated into Proposition 65. The proposed regulation explains the process by which OEHHA determines that chemicals or substances are identified by these scientific organizations and how chemicals can be removed from the list where they are no longer identified via these subdivisions of the Labor Code.

PROBLEM BEING ADDRESSED BY THIS PROPOSED RULEMAKING

Although not required by statute, OEHHA has adopted regulations setting out the criteria used for listing chemicals via the other three listing mechanisms under Proposition 65[4]. In order to insure transparency, certainty and clarity for the business and enforcement community, OEHHA has determined that adopting a regulation is appropriate.

NECESSITY

Although the process for listing chemicals under Proposition 65 is expressly excluded from the Administrative Procedure Act[5], OEHHA has previously adopted regulations setting out the general criteria for listing chemicals via the other three listing mechanisms[6]. The purpose of this proposed regulation is to clarify and explain to the public the way OEHHA identifies chemicals and substances that must be added to the Proposition 65 list based on

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[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)

their identification by reference via the Labor Code provisions incorporated by reference in Proposition 65[7]. Each provision of the proposed regulation is discussed in greater detail later in this document.

BENEFITS OF THE PROPOSED REGULATION

These regulatory amendments will provide further information and clarification for the criteria for listing chemicals via the Labor Code section of Proposition 65. The amendments will provide an increase in openness and transparency in business and government.

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. 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 pending trial court case *Sierra Club et al. v. Brown et al.* (Alameda County Superior Court case number RG07356881). Copies of these court decisions will be included in the record.

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 and related materials publicly available on the federal Occupational Safety and Health Administration website (www.osha.gov). No other technical, theoretical or empirical material was relied upon by OEHHA in proposing the adoption of this regulation. The relevant provisions of the federal regulations will be included in the rulemaking file for this action.

OEHHA also relied on the attached Economic Impact Analysis in developing this proposed 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 should have the opportunity to know and understand the

[7] Health and Safety Code section 25249.8(a)

process by which OEHHA currently adds chemicals and substances to the Proposition 65 list via the Labor Code mechanism. The proposed regulation also provides OEHHA's interpretation of recent court decisions[8] and federal regulatory changes. The regulation also explains the procedure for removing chemicals from the list in the event they no longer qualify for listing via this mechanism and provides for a public comment period to be held prior to OEHHA listing the chemical.

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 employees[9]. 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.

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 California law indirectly incorporates by reference the federal Hazard Communications Standard ensures that California avoids duplication of effort in identifying chemical hazards, but does not duplicate federal requirements.

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[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)

SUMMARY AND RATIONALE OF REGULATION

Each provision of the proposed new regulation is discussed below:

Subsection (a)(1) of the proposed regulation explains which chemicals will be added to the list based on the reference to the "director's list" in Labor Code subsection 6382(d)[10]. The Director's List of Hazardous Chemicals is found in Title 8, Cal. Code of Regulations, section 339. The regulatory list adopted by the Department of Industrial Relations does not currently include a reference to the endpoint(s) that triggered the addition of a given chemical to the list. However, the regulation provides references to the source lists of chemicals that have been incorporated into the director's list. OEHHA reviews the source lists and supporting documentation to determine the basis for inclusion of the chemical on the Director's List. If a basis for the listing is cancer, reproductive or developmental toxicity, OEHHA will include the chemical on the Proposition 65 list.

Subsection (a)(2) of the proposed regulation describes the process by which OEHHA identifies chemicals or substances that are "within the scope" of the federal Hazard Communication Standard and are identified as human or animal carcinogens or reproductive toxicants, and therefore must be included on the list by reference to Labor Code section 6382(d). To identify these substances, OEHHA cannot simply refer to a list of chemicals with corresponding endpoints. While the federal Occupational Safety and Health Administration (OSHA) identifies a number of secondary sources for identifying potential chemical hazards in Title 29 of the Federal Code of Regulations, section 1910.1200, of Subpart Z[11], that regulation does not expressly list every chemical covered by the regulation or identify the relevant endpoints of concern for each covered chemical.

The federal Hazard Communication Standard is a regulation promulgated by OSHA that, among other things, requires chemical manufacturers and importers to provide information to downstream users of the chemicals they manufacture, such as safety data sheets, warning labels and employee training, to inform employees about hazards in the workplace and thereby minimize worker exposures to those substances.

Title 29, of the Code of Federal Regulations, section 1910.1200 contains the following definitions:

> (c)…[H]azardous chemical means any chemical which is classified as a physical hazard or a health hazard, a simple asphyxiant, combustible dust, pyrophoric gas, or hazard not otherwise classified.[12]

[10] 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 (Title 29 Code of Federal Regulations section 1910.1200) is a hazardous substance subject to this chapter."

[11] 29 C.F.R § 1910.1200

[12] 29 C.F.R § 1910(c)

> ’[H]ealth hazard’ means a chemical which is classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; **carcinogenicity**; **reproductive toxicity**; specific target organ toxicity (single or repeated exposure); or aspiration hazard. The criteria for determining whether a chemical is classified as a health hazard are detailed in Appendix A to §1910.1200 – Health Hazard Criteria[13]…(emphasis added)

It further provides that:

> …(d)(2) Chemical manufacturers, importers or employers classifying chemicals shall identify and consider the full range of available scientific literature and other evidence concerning the potential hazards. There is no requirement to test the chemical to determine how to classify its hazards. Appendix A to §1910.1200 shall be consulted for classification of health hazards, and Appendix B to §1910.1200 shall be considered for the classification of physical hazards.”[14]

Note: Appendices A through E of Title 29 C.F.R. 1910.1200 are mandatory, Appendix F is non-mandatory.

Appendix A, subsection A., 6 defines a carcinogen as:

> … “[A] substance or a mixture of substances which induce cancer or increase its incidence. Substances and mixtures which have induced benign and malignant tumors in well-performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumor formation is not relevant for humans. Classification of a substance or mixture as posing a carcinogenic hazard is based on its inherent properties and does not provide information on the level of the human cancer risk which the use of the substance or mixture may represent.”[15]

Subsection A.6. Classifies carcinogens into two categories, the first being those that are known or presumed human carcinogens. This classification is further divided into two subcategories:

> **…“Category 1A:** Known to have carcinogenic potential for humans. Classification in this category is largely based on human evidence.
>
> **Category 1B:** Presumed to have carcinogenic potential for humans. Classification in this category is largely based on animal evidence.
>
> “The classification of a substance in Category 1A and 1B is based on

[13] 29 C.F.R § 1910(c)
[14] 29 C.F.R § 1910 (d)(2) (2012)
[15] 29 C.F.R § 1910,App. A, subsection A.6.1 (2012)

strength of evidence together with weight of evidence considerations… Such evidence may be derived from:

- human studies that establish a causal relationship between human exposure to a substance and the development of cancer (known human carcinogen); or
- animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity (presumed human carcinogen).

In addition, on a case by case basis, scientific judgment may warrant a decision of presumed human carcinogenicity derived from studies showing limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in experimental animals"[16].

The second category in subsection A.6 pertains to suspected human carcinogens. Here the classification is:

"…done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1A or B. This classification is based on strength of evidence together with weight of evidence considerations… Such evidence may be from either limited evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies."[17]

Other considerations in the classification of carcinogens include:

"Where the weight of evidence for the carcinogenicity of a substance does not meet the above criteria, any positive study conducted in accordance with established scientific principles, and which reports statistically significant findings regarding the carcinogenic potential of the substance, must be noted on the safety data sheet."[18]

Appendix A to §1910.1200, subsection A.7 defines reproductive toxicity as including adverse effects on sexual function and fertility in adult males and females, as well as adverse effects on development of the offspring. Similarly to the classification of carcinogens, reproductive toxicants are divided into the following categories:

"Category 1: Known or presumed human reproductive toxicant - Substance shall be classified in Category 1 for reproductive toxicity when they are known to have produced an adverse effect on sexual function and fertility or on development in humans or when there is evidence from animal studies, possibly supplemented with other information, to provide a strong presumption that the substance has the capacity to interfere with

[16] 29 C.F.R § 1910 App. A, subsection A.6.2.1 (2012)
[17] 29 C.F.R § 1910 App. A, subsection A.6.2.1 (2012)
[18] 29 C.F.R § 1910 (d)(2) (2012)

reproduction in humans. The classification of a substance is further distinguished on the basis of whether the evidence for classification is primarily from human data (Category 1A) or from animal data (Category 1B).

Category 1A: Known human reproductive toxicant - The classification of a substance in this category is largely based on evidence from humans.

Category 1B: Presumed human reproductive toxicant - The classification of a substance in this category is largely based on evidence from experimental animals. Data from animal studies shall provide sufficient evidence of an adverse effect on sexual function and fertility or on development in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of other toxic effects. However, when there is mechanistic information that raises doubt about the relevance of the effect for humans, classification in Category 2 may be more appropriate.

Category 2: Suspected human reproductive toxicant - Substances shall be classified in Category 2 for reproductive toxicity when there is some evidence from humans or experimental animals, possibly supplemented with other information, of an adverse effect on sexual function and fertility, or on development, in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of the other toxic effects, and where the evidence is not sufficiently convincing to place the substance in Category 1. For instance, deficiencies in the study may make the quality of evidence less convincing, and in view of this, Category 2 would be the more appropriate classification."[19]

Thus, when a chemical is classified by a manufacturer or employer as a carcinogen or a developmental or reproductive toxin pursuant to the above mandatory criteria, the chemical is, by definition, within the scope of the Hazard Communication Standard and will be listed under Proposition 65.

In addition, Title 29, Code of Federal Regulations, section 1910.1200; Mandatory Appendix D lists the minimum information that must be included on Safety Data Sheets. Subsection (11) requires that:

"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."[20]

[19] Title 29 Code of Federal Regulations section 1910.1200 App. A, subsection A.7.2. (2012)
[20] Title 29 Code of Federal Regulations section 1910.1200 App. D, subsection D.1.11 (2012)

Thus, chemical manufacturers must include any identification of the chemical as known to cause cancer by these three organizations on the safety data sheets. These chemical identifications are "within the scope" of the Federal Hazard communication standard and are used to identify chemicals that are known to cause cancer.

Subsection (a)(3) of the proposed regulation explains how OEHHA identifies chemicals or substances that have been evaluated by the National Toxicology Program (NTP) and listed in its Report on Carcinogens as carcinogens. These chemicals are included on the Proposition 65 list based upon mandatory Appendix A to Title 29 Code of Federal Regulation 1910.1200 quoted above, which allows a manufacturer or employer to rely on the NTP designations for purposes of classifying chemicals, and to Appendix D of Regulation 1910.1200, based on the requirement for safety data sheets to disclose NTP's carcinogen identifications on safety data sheets.

According to information published on the NTP website at: http://ntp-server.niehs.nih.gov/, the federal Department of Health and Human Services' National Toxicology Program (NTP) is "an interagency program whose mission is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology. The program maintains an objective, science-based approach in dealing with critical issues in toxicology and is committed to using the best science available to prioritize, design, conduct, and interpret its studies. To that end, the NTP is continually evolving to remain at the cutting edge of scientific research and to develop and apply new technologies".[21]

The National Toxicology Program's Report on Carcinogens (12th edition), describes the criteria used by that agency for classifying carcinogens as follows:

> **"Known To Be Human Carcinogen:**
> There is sufficient evidence of carcinogenicity from studies in humans*[22], which indicates a causal relationship between exposure to the agent, substance, or mixture, and human cancer.
>
> **"Reasonably Anticipated To Be Human Carcinogen:**
> There is limited evidence of carcinogenicity from studies in humans*, which indicates that causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding factors, could not adequately be excluded,
>
> or
>
> "there is sufficient evidence of carcinogenicity from studies in experimental animals, which indicates there is an increased incidence of malignant and/or a combination of malignant and benign tumors (1) in multiple species or at multiple tissue sites, or (2) by multiple routes of exposure, or (3) to an

[21] http://ntp-server.niehs.nih.gov/?objectid=7201637B-BDB7-CEBA-F57E39896A08F1BB

[22] Asterisks in original note the following: "This evidence can include traditional cancer epidemiology studies, data from clinical studies, and/or data derived from the study of tissues or cells from humans exposed to the substance in question that can be useful for evaluating whether a relevant cancer mechanism is operating in people."

> unusual degree with regard to incidence, site, or type of tumor, or age at onset,
>
> or
>
> "there is less than sufficient evidence of carcinogenicity in humans or laboratory animals; however, the agent, substance, or mixture belongs to a well-defined, structurally related class of substances whose members are listed in a previous Report on Carcinogens as either known to be a human carcinogen or reasonably anticipated to be a human carcinogen, or there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans."

The NTP further states:

> "Conclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information. Relevant information includes, but is not limited to, dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive sub-populations, genetic effects, or other data relating to mechanism of action or factors that may be unique to a given substance. For example, there may be substances for which there is evidence of carcinogenicity in laboratory animals, but there are compelling data indicating that the agent acts through mechanisms which do not operate in humans and would therefore not reasonably be anticipated to cause cancer in humans."

OEHHA must rely upon NTP's determinations that are based on sufficient evidence in human or animal studies.[23]

Subsection (a)(4) 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, which 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 above. However, both provisions can apply to carcinogens identified by IARC.

According to information available on its website at: www.iarc.fr/:

> "IARC's mission is to coordinate and conduct research on the causes of human cancer, the mechanisms of carcinogenesis, and to develop scientific strategies for cancer control. The Agency is involved in both epidemiological and laboratory research and disseminates scientific information through publications, meetings, courses, and fellowships."

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[23] *Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment*, No. C064301 3rd Ct. App. WL 5834844, 2012 at 12

IARC has a multi-tiered, rigorous scientific identification system for chemicals that have been scientifically evaluated for carcinogenicity. Each of these is discussed briefly below.

Carcinogenic to humans

The preamble to the IARC Monographs on the Evaluation of Carcinogenic Risks to Humans (last revised in 2006), states that an agent is designated as "carcinogenic to humans (Group 1)" when the following criteria are met.

> "Group 1: The agent is *carcinogenic to humans*.
> This category is used when there is *sufficient evidence of carcinogenicity* in humans. Exceptionally, an agent may be placed in this category when evidence of carcinogenicity 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."

Sufficient Evidence of Carcinogenicity in Animals

The Preamble goes on to explain that chemicals with sufficient evidence of carcinogenicity in animals may be classified in Group 1, 2A, or 2B, using the following criteria to determine sufficiency of evidence in animals:

> "(b) Carcinogenicity in experimental animals
>
> "….The evidence relevant to carcinogenicity in experimental animals is classified into one of the following categories:
>
> *"Sufficient evidence of carcinogenicity*: The Working Group considers that a causal relationship has been established between the agent and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms in (a) two or more species of animals or (b) two or more independent studies in one species carried out at different times or in different laboratories or under different protocols. An increased incidence of tumours in both sexes of a single species in a well-conducted study, ideally conducted under Good Laboratory Practices, can also provide *sufficient evidence*.
>
> "A single study in one species and sex might be considered to provide *sufficient evidence of carcinogenicity* when malignant neoplasms occur to an unusual degree with regard to incidence, site, type of tumour or age at onset, or when there are strong findings of tumours at multiple sites."

IARC Classifications

In addition to being identified as having "sufficient evidence of carcinogenicity in experimental animals, the chemical is classified into Group 1, 2A, or 2B as follows:

"Group 1: The agent is *carcinogenic to humans*.
This category is used when there is *sufficient evidence of carcinogenicity* in humans. Exceptionally, an agent may be placed in this category when evidence of carcinogenicity 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."

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

"This category is used when there is *limited evidence of carcinogenicity* in humans and *sufficient evidence of carcinogenicity* in experimental animals. In some cases, an agent may be classified in this category when there is *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. Exceptionally, an agent may be classified in this category solely on the basis of *limited evidence of carcinogenicity* in humans. An agent may be assigned to this category if it clearly belongs, based on mechanistic considerations, to a class of agents for which one or more members have been classified in Group 1 or Group 2A."

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

"This category is used for agents for which there is *limited evidence of carcinogenicity* in humans and less than *sufficient evidence of carcinogenicity* in experimental animals. It may also be used when there is *inadequate evidence of carcinogenicity* in humans but there is *sufficient evidence of carcinogenicity* in experimental animals…"

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 <u>not</u> triggered by agents that may have *sufficient evidence in experimental animals*, but which have been classified in *Group 3: The agent is not classifiable as to its carcinogenicity to humans*. 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, will not meet the criteria for listing by Labor Code section 6382(b)(1). IARC provides the following description of Group 3 chemicals.

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

"This category is used most commonly for agents for which the evidence of carcinogenicity is inadequate in humans and *inadequate* or *limited* in experimental animals.

"Exceptionally, agents for which the evidence of carcinogenicity is *inadequate* in humans but *sufficient* in experimental animals may be placed in this category when

there is strong evidence that the mechanism of carcinogenicity in experimental animals does not operate in humans.

"Agents that do not fall in to any other group are also placed in this category.

"An evaluation in Group 3 is not a determination of non-carcinogenicity or overall safety. It often means that further research is needed, especially when exposures are widespread or the cancer data are consistent with differing interpretations."

Subsection (b) provides that at least 45 days prior to adding a chemical to the list that meets the criteria established in section (a), 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. This process promotes transparency and provides members of the public an opportunity to comment on whether they believe the chemical is identified by reference in the Labor Code as causing cancer or reproductive toxicity. Since the listing procedure for this mechanism is ministerial and therefore essentially automatic, OEHHA restricts comment to the identification of a chemical and 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 there is no way to guarantee that the lead agency would know of all chemicals which 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 to refer a listed chemical to the Carcinogen Identification Committee or the Developmental and Reproductive Toxicant Identification Committee when a chemical no longer meets the criteria in this Section, Section 25306 (listings under the authoritative bodies mechanism), or Section 25902 (listings under the "formally required" mechanism). This subsection also explains that until the appropriate committee has considered whether the chemical must be delisted, the chemical remains on the list. This will reduce potential confusion that could occur if a chemical were to be de-listed, and then relisted again if the committee determines it is known to cause cancer or reproductive toxicity, and is consistent with the de-listing 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 amendments do not impose any costs because businesses are already subject to Proposition 65. The amendments simply clarify the Labor Code section of Proposition 65.

Problem being addressed by this proposed rulemaking:

Other listing methods under Proposition 65 have existing regulations that explain the listing processes. The Labor Code method has no clarifying 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:

These proposed amendments clarify 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

These regulatory amendments will not affect the creation or elimination of jobs within the State of California. The proposed amendments simply clarify 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 for listing chemicals via the Labor Code provision established in Health and Safety Code section 25249.8(a).