



March 20, 2015

Ms. Monet Vela
Public Records Act Coordinator, Office of Chief Counsel
Office of Environmental Health Hazard Assessment
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RE: *COMMENTS ON PROPOSED REVISION TO LABOR CODE SECTION 6382(b)(1)*

Dear Ms. Vela:

On behalf of the Western Plant Health Association (“WPHA”),¹ thank you for this opportunity to comment on OEHHA’s February 27, 2015 modification to the text of proposed Section 25904 under Title 27 of the California Code of Regulations, adding a new provision to the agency’s implementing regulations under the Safe Drinking Water and Toxic Enforcement Act of 1986, known as “Proposition 65.”² In this regard, we understand from the March 11, 2015 notice on the OEHHA website that the deadline for these comments has been extended from March 13 until March 20, 2015. Thank you for expanding the opportunity for public comment.

The proposed regulation, according to the Initial Statement of Reasons, is being promulgated to provide the public and the regulated community guidance regarding the implementation of the so-called “Labor Code Mechanism” for listing chemicals pursuant to Proposition 65, taking into account a recent decision by the Court of Appeal in addressing chemicals that have been “listed” as carcinogens by the International Agency for Research on Cancer (“IARC”). *Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment* (2012) 210 Cal. App. 4th 1082, (“*SIRC v. OEHHA*”). The proposal, if adopted, would modify a previous version of the draft regulation, which the Office of Administrative Law disapproved on January 22, 2015, finding that the proposed regulation did not meet required standards for “clarity.” See Decision of Disapproval by the Office of Administrative Law, Office of Administrative Law File No. 2014-1202-04S (Jan. 22, 2015).

¹ WPHA represents the interests of fertilizer and crop protection manufacturers, distributors, formulators and retailers in California, Arizona, and Hawaii, and our members comprise more than ninety percent of all the companies marketing crop protection products in these states.

² Cal. Health & Safety Code § 24249.5, *et seq.*

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For reasons we explain below, the modified text that was proposed in the February 27 Notice continues to lack “clarity,” so much so that the proposed regulation can be misunderstood to require listing of chemicals that fall outside the boundaries established in *Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment* (2012) 210 Cal. App. 4th 1082, (“*SIRC v. OEHHA*”). To summarize, we believe that the regulation continues to lack clarity in describing when chemicals classified in Group 2A and Group 2B may be listed under Proposition 65; that the definition of “sufficient evidence” is confusing and suffers from the additional flaw under the Administrative Procedure Act that it is a “moving standard” subject to change; and that the use of the undefined term “substance” to accompany the term “chemical,” without explanation of the difference between the two, renders that provision unclear as well.

To address these concerns, we propose that OEHHA adopt the text that appears in the attachment to this letter. For your convenience, we have prepared the attachment in “track changes” mode, and with the changes “accepted.”

STATUTORY PROVISION AT ISSUE

Proposition 65, enacted by a voters’ initiative in 1986, required the Governor to establish and update a list of chemicals “known to the state to cause cancer or reproductive toxicity” (Health & Safety Code § 25249.8(a).)³ The principal sources for identifying such chemicals at that time were the list of hazardous substances maintained by the Department of Labor pursuant to Labor Code Section 6382(b)(1) and substances identified by reference in Labor Code Section 6382(d).” The “listing” of chemicals from these Labor Code provisions has become known as the “Labor Code Mechanism.” The provision at issue in this rulemaking is Section 6382(b)(1), which provides for the listing of

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

As discussed further below, there have been controversies since Proposition 65 was enacted as to whether chemicals identified from these Labor Code sources should be restricted to “human carcinogens” or should include “animal carcinogens,” *see AFL-CIO v. Deukmejian*, (1989) 212 Cal.App.3d 425; whether this so-called “Labor Code Mechanism” should serve as a

³ Chemicals that appear on the “Proposition 65 List” are the subject of two other provisions, which impose requirements on persons doing business in the State. The first prohibits persons in the course of business from discharging Proposition 65 chemicals into drinking water or water or land that may become a source of drinking water. Cal. Health & Safety Code § 25249.5. The second makes it unlawful for a person in the course of business to “expose” any individual in California to a Proposition 65-listed chemical without first providing a “clear and reasonable” warning. Cal. Health & Safety Code § 25249.6.

continuing source of listings or was intended only as a source of chemicals for the “original list” published in 1987, see *California Chamber of Commerce v. Brown*, (2011) 196 Cal. App.4th 233, 238-39; and whether chemicals designated by IARC as “probable” or “possible” human carcinogens can be regarded as chemicals that are “known to cause cancer” for purposes of Proposition 65, see *Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment* (2012) 210 Cal. App. 4th 1082, (“*SIRC v. OEHHA*”). All of those controversies, as resolved by the cases above, come into play in consideration of the proposed text of Section 25904.

IARC LISTING OF HUMAN AND ANIMAL CARCINOGENS

IARC, a specialized agency of the World Health Organization devoted to research on cancer, publishes findings regarding the carcinogenicity of chemicals that it studies in a series of monographs, entitled IARC Monograph on the Evaluation of Carcinogenic Risks to Humans. The Monograph that gave rise to the contested listing of styrene, at issue in *SIRC v. OEHHA*, was Monograph Volume 82, addressing the potential carcinogenic risks of “Some Traditional Herbal Medicines, Some Mycotoxins, Naphthalene and Styrene.”⁴ The most recent IARC Monograph that is publicly available, Volume 108, addresses the carcinogenic risks of “Some Drugs and Herbal Products.”⁵

Each Monograph includes a Preamble that summarizes the agency’s approach to evaluating and classifying chemicals into groups or categories according to the risk of carcinogenicity to humans most recently in Monograph Volume 108, published in 2013.⁶ Based on its review of scientific data and studies, IARC will place a substance in one of the following four categories.

“Group 1: This 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.”

⁴ Available online at: <http://monographs.iarc.fr/ENG/Monographs/vol82/index.php>

⁵ Available online at <http://monographs.iarc.fr/ENG/Monographs/vol108/index.php>

⁶ Available online at <http://monographs.iarc.fr/ENG/Monographs/vol103/mono103-F06.pdf>

* * * *

“Group 2A: This 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 will 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: This 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. In some instances, an agent for which there is *inadequate evidence of carcinogenicity* in humans and less than *sufficient evidence of carcinogenicity* in experimental animals together with supporting evidence from mechanistic and other relevant data may be placed in this group. An agent may be classified in this category solely on the basis of strong evidence from mechanistic and other relevant data.”

“Group 3: The Agent is not classifiable as to its carcinogenicity to humans.”

“This category is used where evidence of carcinogenicity is inadequate in humans and inadequate or limited in experimental animals.”

“Group 4: The agent is probably not carcinogenic to humans.”

“This category is used for agents for which there is evidence suggesting lack of carcinogenicity in humans and experimental animals.”

**RELEVANT CASE LAW REGARDING THE LISTING OF CHEMICALS
AS “KNOWN TO THE STATE TO CAUSE CANCER”**

The Governor published the initial Proposition 65 list on February 27, 1987. The list included 26 known human carcinogens and three known human reproductive toxins. It did not include any chemicals identified as carcinogens or reproductive toxins in animals.

A suit was filed to compel the Governor to include on the list any chemical known to cause cancer or reproductive toxicity in animals, as referred to in Cal. Labor Code § 6382, subdivisions (b)(1) and (d). *AFL-CIO v. Deukmejian*, (1989) 212 Cal.App.3d 425. The trial court agreed with the plaintiffs and issued a preliminary injunction requiring the Governor to publish a new list containing the indicated substances, and the Court of Appeals affirmed. OEHHA thereafter added to its Proposition 65 list “those chemicals identified by the Labor Code reference method without regard to whether the chemicals had been identified as human or animal carcinogens or reproductive toxins.” *California Chamber of Commerce v. Brown* (2011) 196 Cal. App. 4th at 221.

Litigation over use of the Labor Code Mechanism arose from an OEHHA proposal in 2009 to list styrene and vinyl acetate as chemicals “known to cause cancer.” The proposal to list vinyl acetate was based on a 1995 IARC monograph categorizing vinyl acetate as “possibly carcinogenic” under Group 2B, based on inadequate evidence of carcinogenicity in humans and limited evidence of carcinogenicity in experimental animals. The proposal to list styrene was based on a 2002 IARC monograph identifying styrene as “possibly carcinogenic” within Group 2B, based on limited evidence of carcinogenicity in both humans and experimental animals.

The Styrene Information and Research Center (“SIRC”) filed suit seeking declaratory judgment to invalidate the listing for styrene, on the ground that IARC had not classified styrene as a “known carcinogen.” Celanese intervened, asserting that vinyl acetate was not a known carcinogen either, based on the IARC monograph. *Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment Office*, (2012) 210 Cal. App. 4th 1082, (*SIRC v. OEHHA*). The trial court agreed with the plaintiffs, and thus held that that vinyl acetate and styrene should not be listed. OEHHA appealed the decision.

The question on appeal was whether chemicals classified in Group 2B (“possibly carcinogenic”) by IARC could be listed as “known carcinogens” under Proposition 65. The Court of Appeals concluded that the key determinant was not the Group 2B label, but rather the evidence underlying a 2B classification by IARC. Referring to its prior decision in *Deukmejian*, the Court of Appeals notes:

In *Deukmejian*, we pointed out that the IARC Group 1 chemicals are those for which there is sufficient evidence of a causal connection between exposure and cancer in humans. (Supra, at 434.) We also noted the IARC Group 2 chemicals include those “for which there is ‘sufficient evidence’ of carcinogenicity in animals.” (*Id.*) Of these, Group 2A was usually reserved for those “for which there was a least *limited evidence* of carcinogenicity to humans,” whereas Group 2B included those for which there was sufficient evidence of carcinogenicity in animals but inadequate evidence for humans. (*Id.*) In a footnote, we explained that while the IARC does not use the term “known carcinogen,” the parties agreed, “for the purpose of interpreting the IARC monographs, ‘sufficient evidence’ of carcinogenicity is the equivalent of ‘known’ carcinogenicity.”⁷

Thus, the court concluded that a substance that is classified in Group 2B (“possibly carcinogenic in humans”) could be listed as a “known carcinogen” under Proposition 65, *provided* that there is “sufficient evidence of carcinogenicity in either humans or animals.” *SIRC v. OEHHA*, 210 Cal. App. 4th at 1095.

OEHHA RULEMAKING PROPOSING AN IMPLEMENTING REGULATION FOR THE LABOR CODE MECHANISM

Two years after the Court of Appeals handed down its decision in *SIRC v. OEHHA*, OEHHA issued a notice proposing an implementing regulation for the Labor Code Mechanism. Specifically, OEHHA proposed Section 25904, which remains in draft and is the subject of the rulemaking here, and the subject of these comments.

In its original form, the proposed regulation appeared as follows:

Title 27 California Code of Regulations section 25904.

Chemical Listings by Reference to the California Labor Code

(a) Pursuant to Section 25249.8(a), of the Act, a chemical shall be included on the list of chemicals known to the state to cause cancer or reproductive toxicity if it is a substance identified by reference in Labor Code Section 6382(b)(1) or by reference in Labor Code Section 6382(d) as causing cancer or reproductive toxicity.

⁷ *Id.* at 1095.

(1) A chemical shall be included on the list if it is identified by the International Agency for Research on Cancer in its IARC Monographs series on the Evaluation of Carcinogenic Risks to Humans (most recent edition), based on sufficient animal or human evidence as:

- a. Carcinogenic to humans (Group 1)
- b. Probably carcinogenic to humans (Group 2A)
- c. Possibly carcinogenic to humans (Group 2B)

(2) A chemical shall be included on the list if it is within the scope of the Federal Hazard Communications Standard and is identified in the most recent version of Title 29 of the Code of Federal Regulations, part 1910.1200, adopted by the federal Occupational Safety and Health Administration, as causing cancer or reproductive toxicity based on sufficient animal or human evidence.

(b) 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.

(c) Any person may petition the lead agency to consider adding a chemical to the list pursuant to this section. The petition shall identify the chemical in question, the provision of subdivision (a) above that provides the basis for listing and any other information necessary to determine whether the chemical meets the requirements of this section.

(d) If the lead agency determines that a listed chemical no longer meets the criteria in this section, the lead agency shall determine if the criteria for listing established in Section 25306 or Section 25902 are met. If the criteria in those sections are not met, the lead agency shall refer the chemical to the appropriate committee established in Section 25302, namely the Carcinogen Identification Committee or the Developmental and Reproductive Toxicant Identification Committee, for a recommendation as to whether the chemical should continue to be included on the list of chemicals known to the state to cause cancer or reproductive toxicity. The chemical shall remain on the list pending review by the Carcinogen Identification Committee or the Developmental and Reproductive Toxicant Identification Committee.

**DISAPPROVAL OF THE PROPOSED REGULATION
BY THE OFFICE OF ADMINISTRATIVE LAW**

On January 15, 2015, the California Office of Administrative Law (“OAL”) disapproved the proposed regulation because, among other reasons, the proposal failed to comply with the clarity standard of Government Code Section 11349.1. OAL noted that the phrases “*probably* carcinogenic to humans with sufficient animal evidence” and “*possibly* carcinogenic to humans with sufficient animal evidence” are unclear because “what the animal evidence is supposed to show is unspecified.” Additionally, OAL noted that the term “sufficient animal evidence” may have the same meaning for both phrases or it may have a different meaning. In other words, the threshold for what constitutes sufficient animal evidence may either be the same for both subdivisions (a)(1)(B) and (a)(1)(C) or it may be different.

NOTICE OF MODIFICATION OF TEXT OF PROPOSED REGULATION

On February 27, 2015, OEHHA published notice of a modification of the text of the proposed regulation, in an effort to cure the flaws that caused OAL to disapprove the regulation. The proposed regulation, with modifications appearing in the “track changes” mode, appears in full below:

Title 27 California Code of Regulations section 25904

Chemical Listings by Reference to ~~the~~ California Labor Code section 6382(b)(1)

- (a) Pursuant to Section 25249.8(a) of the Act, a chemical or substance shall be included on the list of chemicals known to the state to cause cancer ~~or reproductive toxicity~~ if it is a chemical or substance identified by reference in Labor Code Section 6382(b)(1) ~~or by reference in Labor Code Section 6382(d)~~ as causing cancer ~~or reproductive toxicity~~.
- (b) ~~(1)~~A ~~chemical~~ chemical or substance shall be included on the list if it is ~~identified~~ classified by the International Agency for Research on Cancer in IARC Monographs series on the Evaluation of Carcinogenic Risks to Humans (most recent ~~edition~~ Monograph on the chemical or substance) ~~based on sufficient animal or human evidence as:~~
- ~~(A) Carcinogenic to human (Group 1), or~~
~~(B) Probably carcinogenic to humans (Group 2A) with sufficient~~

~~animal~~ ~~evidence,~~ ~~or~~
~~(C) Possibly carcinogenic to humans (Group 2B) with sufficient animal evidence in Group 1, 2A or 2B and such classification is based in whole or in part on identification by IARC of sufficient evidence of carcinogenicity in humans or animals. For the purpose of this subsection, the term "sufficient evidence" as it applies to experimental animal or human evidence is as defined in the most recent IARC Monograph on the chemical or substance.~~

~~(2) A Chemical shall be included on the list if it is within the scope of the Federal Hazard Communication Standard and it is identified in the most recent version of Title 29 of the Code of Federal Regulations, part 1910.1200, adopted by the federal Occupational Safety and Health Administration, as causing cancer or reproductive toxicity based on sufficient animal or human evidence.~~

~~(c)~~ ~~(b)~~ At least 45 days prior to adding a chemical or substance that meets the criteria established in subsection (a) to the list, the lead agency shall publish a notice of intent to list the chemical or substance and provide a 30 day public comment period on whether or not the chemical or substance has been identified by reference in ~~either~~ Labor Code section 6382(b)(1) ~~or 6382(d) or both.~~

~~(d)~~ ~~(e)~~ Any person may petition the lead agency to consider adding a chemical or substance from to the list pursuant to this section. The petition shall identify the chemical or substance in question, ~~the provision of subdivision subsection (a) above that provides the basis for listing the IARC Monograph that is the claimed basis for the listing,~~ and any other information necessary to determine whether the chemical or substance meets the requirements of this section.

~~(e)~~ ~~(d)~~ Any person may petition the lead agency to consider removing a chemical or substance from the list pursuant to this section. The petition shall identify the chemical or substance in question and the reasons why the provisions of subsection (a) are not met.

~~(d)(e)(f)~~ If the lead agency determines that a listed chemical or substance no longer meets the ~~criteria~~ requirements in this section, the lead agency shall determine if the criteria for listing established in Section 25306 or

Section 25902 are met. If the criteria in those sections are not met, the lead agency shall refer the chemical *or substance* to the ~~appropriate committee established in Section 25302, namely the~~ Carcinogen Identification Committee ~~or the Developmental and Reproductive Toxicant Identification Committee~~, for a ~~determination~~ recommendation as to whether the chemical *or substance* should continue to be included on the list of chemicals known to the state to cause cancer ~~or reproductive toxicity~~. ~~The chemical shall remain on the list pending review by the Carcinogen Identification Committee or the Developmental and Reproductive Toxicant Identification Committee.~~

NOTE: Authority Cited: Section 25249.12, Health and Safety Code. Reference: Section 25249.8(a), Health and Safety Code.

WPHA COMMENTS AND SUGGESTIONS REGARDING MODIFICATIONS TO TEXT

For clarity and ease of presentation, we present our comments and suggestions on the proposed regulation, subsection-by-subsection, in the text of this letter below. In Attachment 1, we present the text of the Proposed Regulation, including our suggested changes, in “track-changes” mode. In Attachment 2, we present the text of the Proposed Regulation, including our suggested changes, with the changes accepted.

Title of Proposed Regulation. We believe the changes are appropriate to clarify that the proposed regulation applies only to listings that may take place as a result of activities under Section 6382(b)(1) and not under Section 6382(d) of the Labor Code, which might be thought to comprise a portion of the Labor Code Listing Mechanism. We understand from the deletion of the provision of the subsection concerning the Hazard Communication Standard that OEHHA is withdrawing for the present those parts of the proposed regulation that relate to Section 6382(d).

Subsection (a). We believe that the insertion of the term “or substance” to follow and accompany the term “chemical” is both inappropriate and confusing. It is inappropriate because the provisions of Proposition 65 from which this regulation is derived calls for the listing of “chemicals known to the state cause cancer or reproductive toxicity.” The insertion of the term “or substance” to follow “chemical” implies that OEHHA intends to invoke the regulation to list some form of matter that is not definable as a “chemical” and thus must be referred to as a “substance.” On a related note, the term “substance” is not defined in the proposed regulation. Thus, it is not clear what OEHHA intends by use of the word “substance” in contrast to the word “chemical.” The regulation itself thus fails to reach the standard of clarity referred to in the previous decision by OAL. (We note that this problem arises throughout the regulation, as there

is a pattern throughout nearly of all of subsections of inserting the word “substance” following chemical, or inserting the word “chemical” wherever “substance” appears alone).

Subsection (b). As noted above, OAL objected in the original draft of the regulation that the meaning of the term “sufficient evidence” (or various iterations of the term, with reference to evidence of carcinogenicity in humans or animals humans was so unclear that the regulation failed to meet the standard of clarity required under Cal. Govt. Code § 11349.1. The modified text of the proposed regulation thus attempts to provide a definition by referring to the term “as it applies to experimental animal or human evidence . . . as defined in the most recent IARC Monograph on the chemical or substance.”⁸

In our view, this definition of “sufficient evidence” remains unclear, and is quite confusing. Furthermore, the adoption of a definition by reference to the term in its potential **application** to an unknown chemical in another, unspecified IARC Monograph in the future is improper. In *Palermo v. Stockton Theatres, Inc.*, (1948) 32 Cal.2d 53, our Supreme Court said:

[W]here a statute adopts by specific reference the provisions of another statute, regulation or ordinance, such provisions are incorporated in the form in which they exist at the time of the reference and not as subsequently modified

Id. at 58-59. See also *SIRC v. OEHHA*, at 1097 (citing *Palermo*). The adoption of a cross-referenced definition by its potential use in another future IARC Monograph suffers from the same flaw: neither OEHHA nor the regulated community can anticipate how IARC may use or define the term in the future, or how it may apply the term to another chemical.

There is a valid alternative to this approach, which we believe would accomplish the same goal that OEHHA is trying to achieve, and in which the regulated community could find the requisite level of clarity and certainty in its application. That is to adopt explicitly the definitions of “sufficient evidence” in the Preamble to the most recent IARC Monograph, and to incorporate their text word-by-word.

Specifically, the 2013 Preamble to the IARC Monograph Volume 108, discussed and quoted above, provides two explicit definitions for “sufficient evidence” – one for sufficient evidence of carcinogenicity in humans and one for sufficient evidence of carcinogenicity in animals. See IARC Preamble at 27-28 (Ex. 1). We believe that those two IARC standards should be incorporated into the OEHHA proposed rule, as follows:

⁸ Please note the concern we expressed above to the repeated use of the undefined term “substance” as a counterpoint to the term “chemical.” The same objection applies here.

(b) A chemical is identified by reference in Labor Code Section 6382(b)(1) if it is listed by the International Agency for Research on Cancer (“IARC”) as a human or animal carcinogen, by its classification in in Group 1, 2A or 2B in the most recent IARC Monograph on the Evaluation of Carcinogenic Risks for that chemical, provided that such classification is based on sufficient evidence of carcinogenicity in humans or sufficient evidence of carcinogenicity in experimental animals. For purposes of this subsection:

(1) the term “sufficient evidence of carcinogenicity in humans” shall mean that a causal relationship has been established between exposure to the chemical and human cancer, i.e., that a positive relationship has been observed between the exposure and cancer in studies in which chance, bias and confounding could be ruled out with reasonable confidence.

(2) the term “sufficient evidence of carcinogenicity in experimental animals” shall mean that a causal relationship has been established between the chemical 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 tumors 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 in experimental animals when malignant neoplasms occur to an unusual degree with regard to incidence, site, type of tumor or age at onset, or when there are strong findings of tumors at multiple sites.

See Attachment, our suggested modification to the text of the proposed regulation.

Subsection (c). We repeat our continuing objection to the repeated insertion of the undefined term “substance” as an alternative to “chemical.”

Subsection (d). This provision allows interested parties to petition for the removal from the Proposition 65 list of chemicals that were listed as a result of the application of the Labor Code Mechanism. We believe this provision is appropriate, particularly in light of the provision that allows persons to petition for the addition of chemicals to the Proposition 65 list.

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Subsection (e). This provision allows for the removal of chemicals from the Proposition 65 list that were placed on the list as a result of the Labor Code Mechanism, if circumstances that provided for their listing later change. We believe this provision is appropriate. As above, repeat our continuing objection to the repeated insertion of the undefined term “substance” as an alternative to “chemical.”

(New) Subsection (f). We have adapted this provision from Section 25306(f), where it provides that a chemical should not be listed under the Authoritative Bodies Mechanism if data that were not considered by the authoritative body clearly establish that the chemical under consideration do not satisfy the criteria for listing.

(Renumbered) Subsection (g). Assuming that a new subsection (f) is added per the suggestion above, former subsection (f) would become subsection (g). We concur with the changes that OEHHA has proposed to that subsection.

CONCLUSION

We appreciate the opportunity to participate in this important rulemaking process, and look forward to the Agency’s response.

Sincerely,



Renee Pinel
President/CEO

Attachment 1 to WPHA Comments
(WPHA suggestions in track changes mode)

Title 27 California Code of Regulations section 25904

Chemical Listings by Reference to ~~the~~ California Labor Code section 6382(b)(1)

(a) Pursuant to Section 25249.8(a) of the Act, a chemical shall be included on the list of chemicals known to the state to cause cancer ~~or reproductive toxicity~~ if it is a chemical substance identified by reference in Labor Code Section 6382(b)(1) ~~or by reference in Labor Code Section 6382(d)~~ as causing cancer ~~or reproductive toxicity~~.

(b) A chemical is identified by reference in Labor Code Section 6382(b)(1) if it is listed by the International Agency for Research on Cancer (“IARC”) as a human or animal carcinogen, by its classification in Group 1, 2A or 2B in the most recent IARC Monograph on the Evaluation of Carcinogenic Risks for that chemical, provided that such classification is based on sufficient evidence of carcinogenicity in humans or sufficient evidence of carcinogenicity in experimental animals. For purposes of this subsection:

(1) the term “sufficient evidence of carcinogenicity in humans” shall mean that a causal relationship has been established between exposure to the chemical and human cancer, i.e., that a positive relationship has been observed between the exposure and cancer in studies in which chance, bias and confounding could be ruled out with reasonable confidence.

(2) the term “sufficient evidence of carcinogenicity in experimental animals” shall mean that a causal relationship has been established between the chemical 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 tumors 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 in experimental animals when malignant neoplasms occur to an unusual degree with regard to incidence, site, type of tumor or age at onset, or when there are strong findings of tumors at multiple sites.

~~shall be included on the list if it is identified by the International Agency for Research on Cancer in its IARC Monograph on the Evaluation of Carcinogenic Risks to Humans (most recent edition) based on sufficient animal or human evidence as:~~

~~(A) — Carcinogenic to humans (Group 1)~~

~~(B) — Probably carcinogenic to humans (Group 2A)~~

~~(C) — Possibly carcinogenic to humans (Group 2B)~~

**Attachment 1 to WPHA Comments
(WPHA suggestions in track changes mode)**

~~(2) A chemical shall be included on the list if it is within the scope of the Federal Hazard Communication Standard and it is identified in the most recent version of Title 29 of the Code of Federal Regulations, part 1910.1200, adopted by the federal Occupational Safety and Health Administration, as causing cancer or reproductive toxicity based on sufficient animal or human evidence.~~

(c) At least 45 days prior to adding a chemical that meets the criteria established in subsection (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.~~

(d) Any person may petition the lead agency to consider adding a chemical to the list pursuant to this section. The petition shall identify the chemical in question, the ~~provision of subdivision (a) above that provides the~~ IARC Monograph that is the claimed basis for the listing, and any other information necessary to determine whether the chemical meets the requirements of this section.

~~(e) Any person may petition the lead agency to consider removing a chemical from the list pursuant to this section. The petition shall identify the chemical in question and the reasons why the provisions of subsection (a) are not met.~~

~~(f) The lead agency shall find that a chemical does not satisfy the definition of “as causing cancer” if scientifically valid data which were not considered by the authoritative body clearly establish that the chemical does not satisfy the criteria at subsection (b).~~

~~(g)(f)~~ If the lead agency determines that a listed chemical no longer meets the criteria requirement in this section, the lead agency shall determine if the criteria for listing established in Section 25306 ~~or Section 25902~~ are met. If the criteria in that section are not met, the lead agency shall refer the chemical to ~~the appropriate committee established in Section 25302, namely the~~ Carcinogen Identification Committee ~~or the Developmental and Reproductive Toxicant Identification Committee~~, for a recommendation as to whether the chemical should continue to be included on the list of chemicals known to the state to cause cancer ~~or reproductive toxicity~~. ~~The chemical shall remain on the list pending review by the Carcinogen Identification Committee or the Developmental and Reproductive Toxicant Identification Committee.~~

**Attachment 2 to WPHA Comments
(WPHA suggestions with changes accepted)**

Title 27 California Code of Regulations section 25904

Chemical Listings by Reference to California Labor Code section 6382(b)(1)

(a) Pursuant to Section 25249.8(a) of the Act, a chemical shall be included on the list of chemicals known to the state to cause cancer if it is a chemical identified by reference in Labor Code Section 6382(b)(1) as causing cancer.

(b) A chemical is identified by reference in Labor Code Section 6382(b)(1) if it is listed by the International Agency for Research on Cancer (“IARC”) as a human or animal carcinogen, by its classification in Group 1, 2A or 2B in the most recent IARC Monograph on the Evaluation of Carcinogenic Risks for that chemical, provided that such classification is based on sufficient evidence of carcinogenicity in humans or sufficient evidence of carcinogenicity in experimental animals. For purposes of this subsection:

(1) the term “sufficient evidence of carcinogenicity in humans” shall mean that a causal relationship has been established between exposure to the chemical and human cancer, i.e., that a positive relationship has been observed between the exposure and cancer in studies in which chance, bias and confounding could be ruled out with reasonable confidence.

(2) the term “sufficient evidence of carcinogenicity in experimental animals” shall mean that a causal relationship has been established between the chemical 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 tumors 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 in experimental animals when malignant neoplasms occur to an unusual degree with regard to incidence, site, type of tumor or age at onset, or when there are strong findings of tumors at multiple sites.

(c) At least 45 days prior to adding a chemical that meets the criteria established in subsection (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 Labor Code section 6382(b)(1).

(d) Any person may petition the lead agency to consider adding a chemical to the list pursuant to this section. The petition shall identify the chemical in question, the IARC Monograph that is the claimed basis for the listing, and any other information necessary to determine whether the chemical meets the requirements of this section.

Attachment 2 to WPHA Comments
(WPHA suggestions with changes accepted)

(e) Any person may petition the lead agency to consider removing a chemical from the list pursuant to this section. The petition shall identify the chemical in question and the reasons why the provisions of subsection (a) are not met.

(f) The lead agency shall find that a chemical does not satisfy the definition of “as causing cancer” if scientifically valid data which were not considered by the authoritative body clearly establish that the chemical does not satisfy the criteria at subsection (b).

(g) If the lead agency determines that a listed chemical no longer meets the criteria requirements in this section, the lead agency shall determine if the criteria for listing established in Section 25306 are met. If the criteria in that section are not met, the lead agency shall refer the chemical to the Carcinogen Identification Committee for a recommendation as to whether the chemical should continue to be included on the list of chemicals known to the state to cause cancer.