Title 27, California Code of Regulations
Proposed Section 25904
Listings by Reference to the California Labor Code

UPDATE TO FINAL STATEMENT OF REASONS

The Office of Environmental Health Hazard Assessment (OEHHA) published the **Initial Statement of Reasons (ISOR)** for this action on **January 31, 2014**, and held a public hearing on **March 21, 2014**. The initial comment period ended on **April 4, 2014** and OEHHA received eight comments. After consideration of the comments, clarifying changes were made to subsection 25904(a)(1) to more closely track the statutory language of Proposition 65, to better clarify the impact of the 2012 changes to the federal Hazard Communication Standards (HCS) adopted by the Occupational Safety and Health Administration (OSHA), and to further reflect the decision in *Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment* (2012) 210 Cal. App. 4th 1082. Substantive changes were also made to the proposed regulation by adding subsection 25904(d), which addressed the process for petitioning the agency to remove a chemical from the Proposition 65 list. Additionally, changes were made on pages 7 and 8 of the Initial Statement of Reasons. Specifically, the language that identified Appendix D, Table D.1., of the 2012 HCS as being "within the scope" of the HCS was removed. This reflects OSHA's elimination of the express provisions in their 2012 regulation identifying the NTP's Report on Carcinogens and the IARC monographs as mandatory bases for classifying chemicals as carcinogens.

On **June 20, 2014**, OEHHA published a **Notice of Modification to Text of Proposed Regulation and a modified statement of reasons**. The public comment period ended **July 7, 2014** and three comments were received. After reviewing the comments, the Office further modified and augmented the record for the proposed regulation. Subsection (e) was amended to remove the language that stated that once a chemical no longer meets the requirements for listing via the Labor Code mechanism, it would remain on the list pending committee review.[1]

OEHHA published a **second Notice of Modification of Proposed Text** on **September 12, 2014**. The comment period ended **September 29, 201**4 and no comments were received.

On **January 15, 2015**, the Office of Administrative Law (OAL) issued a **Decision of Disapproval of Regulatory Action.** The decision was based on failure to comply with the clarity standard of Government Code section 11349.1 and Administrative Procedure Act (APA) procedural requirements. After careful consideration of the OAL

[1] Title 27, Cal. Code of Regulations, section 25302 establishes the Carcinogen Identification Committee and the Developmental and Reproductive Toxicant Identification Committee.

determination, OEHHA modified the proposed regulatory language in subsection (a)(1) to clarify that chemicals shall be included on the list if the chemical or substance is classified by the International Agency for Research (IARC) Monographs in Group 1, 2A or 2B and based in whole or in part on identification by IARC of sufficient evidence of carcinogenicity in humans or animals.[2] The regulatory text additionally defined the term "sufficient evidence" by reference to the most recent IARC Monograph on the chemical or substance. After reviewing and considering stakeholder comments concerning subsection (a)(2), and changes to the federal Hazard Communication Standard (HCS) adopted by the federal Occupational Safety and Health Administration (OSHA) in 2012, OEHHA decided not to include potential listing under the HCS as part of this regulatory action.[3] Therefore, Subsection (a)(2) in the proposed regulation and all references to Labor Code section 6382(d) were removed from the regulatory language. The record was also augmented to include additional documents relied upon by OEHHA during the development of this proposed regulation; including the Preamble to the IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, and 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. These changes were published in the **third Notice of Modification to Text of Proposed Regulation and Augmentation of Record** on **February 27, 2015**. In response to a request from the Western Plant Health Association, the comment period was extended from **March 13, 2015** to **March 20, 2015**. One comment was received during this comment period.

OEHHA subsequently modified the proposed text to increase clarity and to ensure consistency with the decision in *Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment*, (2012) 210 Cal. App. 4th 1082. The regulatory language was modified to clearly exclude from listing any chemicals or substances classified by IARC as Group 2B based on limited evidence of carcinogenicity in experimental animals. Additionally, the regulatory text was modified for consistency with the Second Interim Order in the *Sierra Club v. Schwarzenegger (Brown)* case (Case No. RG07356881). In the *Sierra Club* case, the court ordered OEHHA to list any chemical for which IARC has concluded there is "sufficient" evidence of cancer in humans or animals, including agents added to the IARC list of Agents Classified by the IARC Monographs, *whether or not the final monograph has been published*. Thus, OEHHA modified the proposed text to include chemicals or substances classified by IARC as Group 1, 2, and 2B in the list of *Agents Classified by the IARC Monographs*.

[2] Subsection (a)(1) was renumbered as subsection (b) in the modified regulatory text.
[3] The decision to forego listing was based on the current HCS; if OEHHA at a later time chooses to include listing based on the HCS, OEHHA will submit a new regulatory proposal.

OEHHA also further considered comments in the OAL disapproval decision letter concerning subsection (b) that requires the lead agency to provide a 30 day public comment period prior to adding a chemical meeting the criteria for listing a chemical or substance with reference to the Labor Code section 6382(b)(1). In the proposed regulation, public comment must focus "on whether or not the chemical has been identified by reference in Labor Code section 6382 (b)(1)." According to the OAL decision of disapproval, the Initial Statement of Reasons (ISOR) expressly excludes comments related to the underlying scientific determinations supporting the identification. OAL concluded that this subsection lacked clarity because a person directly affected by the regulation would not understand that the regulation expressly excludes comments related to the underlying scientific determination. The regulatory text was modified so as to accurately reflect OEHHA's intent that was correctly expressed in the ISOR. The modified subsection thus excludes comments related to the underlying scientific determinations in support of the identification of the chemical or substance with reference in Labor Code section 6382(b)(1) as causing cancer, because these listings are ministerial in nature.

The record was also augmented to include the Second Interim Order on Labor Code Claims from *Sierra Club v. Schwarzenegger (Brown)* (Case No. RG07356881), the decision in *SIRC v. OEHHA* (2012) 210 Cal. App. 4th 1082, and the United States Occupational Safety & Health Administration (OSHA) "Side-by-Side Comparison of OSHA's Existing Hazard Communication Standard (HCS 1994) vs. the Revised Hazard Communication Standard (HCS 2012)" published on the OSHA website at https://www.osha.gov/dsg/hazcom/side-by-side.html. On **May 1, 2015** OEHHA published a **fourth Notice of Modification to Text of Proposed Regulation and Augmentation of Record** to reflect these changes to the rulemaking record. The comment period closed on **May 15, 2015**. One comment letter was received. The letter was carefully considered and the proposed regulatory text was not modified. OEHHA's response to the comments is incorporated within this Final Statement of Reasons (FSOR).

The FSOR has also been revised to include detailed responses to comments as requested by OAL in its disapproval memorandum. Previous responses to comments have been updated in the FSOR to accurately reflect subsequent, relevant changes to the proposed regulatory language.

In written and oral comments submitted throughout the regulatory process, many parties included observations about these regulations or other laws and regulations that do not constitute an objection or recommendation directed at the proposed action or the procedures followed in this rulemaking action. Also, many parties offered their interpretation of these regulations or other laws and regulations, sometimes in connection with their support of, or decision not to object to the regulations, which again

does not constitute an objection or recommendation directed at the proposed action or the procedures followed in this rulemaking action. Accordingly, OEHHA is not required under APA to respond to such remarks in this FSOR. Since OEHHA is constrained by limitations upon its time and resources, and is not obligated by law to respond to such remarks,[4] OEHHA does not provide responses to these remarks in this FSOR. However, the absence of responses to such remarks should not be construed to mean that OEHHA in any way concurs with them.

I. SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL COMMENT PERIOD OF JANUARY 31, 2014 THROUGH APRIL 4, 2014.

The following organizations submitted comments on the proposed regulation to OEHHA during the initial comment period:

American Chemistry Council (ACC)
APTCO, LLC. (APTCO)
California Chamber of Commerce (CalChamber)
Center for Environmental Health (CEH)
National Federation of Independent Business and Western Growers (NFIB)
Styrene Information and Research Center (SIRC)
SNR Denton (SNR)[5]
Vinyl Acetate Council (VAC)

A. Section 25904 (a)(1)

Several commenters (APTCO, CalChamber, NFIB, and VAC) stated in effect that the language in subsection (a)(1) of the proposed regulation can create the impression that all chemicals classified by IARC as Group 1, Group 2A and 2B meet the "sufficiency of the evidence" standard discussed in *Styrene Information and Research Center v. Office of Environmental Health Hazard and Assessment* (October 31, 2012, 3rd District). OEHHA carefully considered the comments and amended this subsection to provide further clarity by specifying that substances classified by IARC in Groups 2A and 2B are to be included on the Proposition 65 list only if there is sufficient evidence of carcinogenicity in animals. Individual comments relating to subsection (a)(1) are addressed below.

[4] California Government Code section 11346.9 (a)(3)

[5] SNR Denton's comments were not directly related to this regulatory proposal. The commenter submitted comments concerning the chemical pulegone and requested that OEHHA revise the proposed regulation "in a manner that responds to concerns" expressed in the pulegone document. OEHHA is only responding to comments applicable to this rulemaking proposal in this document.

Comment (APTCO): In Subsection (a)(1), OEHHA should move the phrase "based on sufficient animal or human evidence" to the end of the subsection, after the three subparts, and it should clarify the phrase to provide that OEHHA will not include chemicals on the Proposition 65 list from Groups 1, 2A or 2B Office of Environmental Health Hazard Assessment "unless the IARC chemical listings are based on at least sufficient human or sufficient animal evidence."

Response: OEHHA modified section (a)(1) to require "sufficient evidence of carcinogenicity in humans or animals" as a requisite to listing chemicals under this section that are classified by IARC as Groups 1, 2A or 2B. The term "sufficient evidence" is defined by reference to the most recent IARC Monograph on the chemical or substance or in the IARC list of Agents Classified by the IARC Monographs.

Comment (CalChamber): Subsection (a)(1) invites an overly inclusive interpretation and could be misinterpreted to include all Group 2A and 2B chemicals, not only those with sufficient evidence.

Response: OEHHA modified section (a)(1) to require "sufficient evidence of carcinogenicity in humans or animals" as a requisite to listing chemicals under this section that are classified by IARC as Groups 1, 2A or 2B. The term "sufficient evidence" is defined by reference to the IARC Monographs series on the Evaluation of Carcinogenic Risks to Humans or in the IARC list of Agents Classified by the IARC Monographs.

Comment (CalChamber): OEHHA's position that listing pursuant to the Labor Code listing mechanism is "essentially automatic" flies in the face of the SIRC decision, which expressly held that such a position is "entitled to little or no deference." In establishing a new "sufficient evidence" standard, OEHHA is obligated to provide the public with an opportunity to comment on whether the sufficient evidence standard for a given listing proposal has been established.

Response: OEHHA has not established a "new standard"; pursuant to the final version of the regulation, the term "sufficient evidence" is defined by reference to the most recent IARC Monograph on the chemical or substance or in the IARC list of Agents Classified by the IARC Monographs. The listing of chemicals under Proposition 65 is exempt from the APA and no provision of Proposition 65 or case law requires OEHHA to provide an opportunity for public comment concerning listing decisions via this mechanism.[6] Although OEHHA is under no obligation to provide an opportunity for the public to comment when considering the ministerial listing of a chemical under the Labor Code, it has been OEHHA's practice to publish a Notice of Intent to List in the California Regulatory Notice Register (CRNR) and invite comments concerning whether the chemical has been identified by reference in the Labor Code and provide

[6] California Health and Safety Code section 25249.8(e)

a 30-day comment period on that narrow issue. This practice is incorporated in the regulation in subsection (c). The SIRC decision was decided prior to the current regulatory proposal and has been taken into account in the drafting of the regulation.

Comment (NFIB): Case law states that chemicals may be listed "by reference" under the Labor Code only when there is sufficient evidence of reproductive toxicity or carcinogenicity. The regulation must clearly and accurately state the applicable standard of evidence.

Response: OEHHA modified section (a)(1) to require "sufficient evidence of carcinogenicity in humans or animals" as a requisite to listing chemicals under this section that are classified by IARC as Groups 1, 2A or 2B. The term "sufficient evidence" is defined by reference to the most recent IARC Monograph on the chemical or substance or in the IARC list of Agents Classified by the IARC Monographs.

Comment (NFIB): Commenter recommends moving the "as" to precede the "based on sufficient animal or human evidence" phrase, and adding "and within one of the following," to clarify that the chemical must fall within Groups 1A, 2A, or 2B.

Response: Because of the modifications to the text in subsection (a)(1), the specific recommendations are no longer applicable. The modifications to the text, however, achieve the same result as the changes proposed by the commenter; namely, to require "sufficient evidence" of carcinogenicity for listing of chemicals classified under the IARC Monograph as Groups 1, 2A or 2B.

Comment (SIRC): Proposed regulatory text at section (a)(1) "is not in question." SIRC does not dispute Proposition 65 listing of "a chemical determined to be a carcinogen by IARC based on sufficient animal or human evidence."

Response: This comment does not require a response.

Comment (SIRC): The proposed rule correctly excludes the California Director's list.

Response: This comment does not require a response.

Comment (SIRC): It was correct for OEHHA to permit additions of chemicals to the list only where "sufficient evidence" of carcinogenicity exists, per case law.

Response: This comment does not require a response.

Comment (SNR Denton): Courts have held that not all "hazardous chemicals" identified in the Labor Code, and indeed not all "possible carcinogens" are necessarily "known carcinogens".

Response: OEHHA modified section (a)(1) to require "sufficient evidence of carcinogenicity in humans or animals" as a requisite to listing chemicals under this section that are classified by IARC as Groups 1, 2A or 2B. The term "sufficient

evidence" is defined by reference to the most recent IARC Monograph on the chemical or substance or in the IARC list of Agents Classified by the IARC Monographs.

Comment (SNR Denton): IARC's criteria for carcinogenicity have materially changed since 1986 but OEHHA must conclude that the IARC determination would have been the same under the old criteria adopted by specific reference in Proposition 65.

Response: SNR gave no compelling legal or scientific authority for such a conclusion. Proposition 65 was approved by voters in 1986, but there is nothing in the statute or the implementing regulations that supports the contention that the IARC criteria for identifying carcinogens were expressly or implicitly incorporated by reference or otherwise. The Labor Code similarly does not limit the IARC identifications to only those made pursuant to the 1986 criteria. Instead, it references the monographs prepared by IARC, which are based on the most current scientific criteria being used by IARC at a given point in time. Additionally, in the Second Interim Order in the *Sierra Club v. Schwarzenegger (Brown)* case (Case No. RG07356881), the court ordered OEHHA to list any chemical for which IARC has concluded there is "sufficient" evidence of cancer in humans or animals. The order requires OEHHA to include agents added to the IARC list of Agents Classified by the IARC Monographs even where the final monograph has not been published. As a party to that litigation, OEHHA must follow the court's order, which is now final. Therefore, OEHHA made no change to the regulation based on this comment.

Comment (VAC): Usage by OEHHA of IARC Group 2B has been "the most problematic category" and is commonly used when there is limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals, or otherwise when there is inadequate evidence of human carcinogenicity.

Response: OEHHA amended this subsection to provide further clarity by specifying that substances classified by IARC in Group 2B are to be included on the Proposition 65 list only if there is sufficient evidence of carcinogenicity in animals.

Comment (VAC): Language should clarify that the chemical should have been listed as carcinogenic based on sufficient evidence in animals or humans.

Response: OEHHA modified section (a)(1) to require "sufficient evidence of carcinogenicity in humans or animals" as a requisite to listing chemicals under this section that are classified by IARC as Groups 1, 2A or 2B. The term "sufficient evidence" is defined by reference to the most recent IARC Monograph on the chemical or substance or in the IARC list of Agents Classified by the IARC Monographs.

B. Section 25904(a)(2)

Comment (ACC): Language should be amended to clarify that NTP and IARC listings are no longer "within the scope" of the HCS. Only those chemicals listed in subpart Z

are "within the scope" of HCS. The regulation appears to call only for the listing of chemicals identified in the HCS. The ISOR suggests an ambiguity that opens the door for misapplication [language in ISOR that refers to mandatory Appendix D].

Response: After reviewing and considering changes to the HCS, OEHHA decided not to include potential listings under the HCS in this regulatory action. OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issues raised in this comment.

Comment (ACC): ACC expressed concern about OEHHA's interpretation of the term "within the scope" of the Hazard Communication Standard (HCS) ACC stated:

"…chemicals are only identified (*i.e*., listed and named) in the HCS by inclusion in subpart Z. The listing of a substance in NTP's [National Toxicology Program] Report on Carcinogens or IARC's [International Agency for Research on Cancer] Monographs does not make it within the scope of the HCS standard."

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issues raised in this comment.

Comment (ACC): The proposed rule is preempted by federal law because it effectively adopts the HCS's former policy and ignores revisions adopted by OSHA in 2012. While the revised HCS no longer deems a chemical's inclusion on the NTP Annual Report or IARC Monographs as conclusive evidence of carcinogenicity, OEHHA proposes to continue to do so.

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issues raised in this comment.

Comment (APTCO): Subsection (a)(2) and Section (d) would be preempted by federal law. The proposed provisions of this regulation that are based on a new interpretation of OEHHA's listing authority by reference to SDS [Safety Data Sheet] information will create a conflict between Proposition 65 and federal HCS requirements.

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issues raised in this comment.

Comment (APTCO): The NTP's Report on Carcinogens and IARC's Monographs are no longer definitive sources for identifying chemicals. Safety Data Sheets (SDS) are for "information" about chemicals, not "identification of carcinogens".

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

Comment (APTCO): OEHHA does not tell the public in the proposed regulation that it intends to use SDSs as a listing source and that the courts have never ruled that Proposition 65 authorizes OEHHA to list chemicals by reference to SDS information.

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot those issues raised in this comment.

Comment (APTCO) : Subsection (a)(2) conflicts with the Department of Industrial Relations' statutory scheme and its use of Labor Code section 6382(d) to list chemicals from OSHA's "listings" on the Director of Industrial Relations' hazardous substances list only by reference to OSHA's mandatory chemical identification or classification "listings." See Cal. Labor Code § 6382(a) (providing that the Director's List is to be composed of substances "designated" in "listings" of other agencies).

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issues raised in this comment.

Comment (APTCO): OEHHA's emphasis on two words in Appendix D – "mandatory" and "shall" – to justify why it now proposes to list from SDS "information" is arbitrary and capricious.

Response: After reviewing and considering changes to the HCS, OEHHA decided not to include potential listing under the HCS in this regulatory action. OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issues raised in this comment.

Comment (APTCO): The HCS has always contained this purportedly "new" SDS rule OEHHA claims justifies a new interpretation and OSHA simply amended SDS formatting requirements. Furthermore, OEHHA's misplaced emphasis on the word "shall" is analytically flawed—the word refers to what is required to be employed on an SDS, not to how a chemical is identified as a carcinogen. OEHHA's justification for doing nothing is misleading because OEHHA does not "currently" add chemicals and substances to the Proposition 65 list by reference to SDS rules, so this proposal does not simply clarify OEHHA's current procedures.

Response: After reviewing and considering changes to the HCS, OEHHA decided not to include potential listing under the HCS in this regulatory action. OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section

6382(d). The modified regulatory text, therefore, renders moot the issues raised in this comment.

Comment (APTCO): OEHHA is required under the APA to consider reasonable alternatives that are less burdensome and equally effective. Because the public would be denied the opportunity to object to OEHHA's imposed listings by reference to the proposed SDS rule, it is not reasonable that OEHHA would deny the public the benefits of and protections against potentially unwarranted listings afforded by the two existing legal and reasonable alternatives, the Authoritative Bodies mechanism and consideration by the Carcinogen Identification Committee.

Response: OEHHA carefully considered reasonable alternatives when pursuing this rulemaking. In regard to the SDS rule, OEHHA has removed the section in the ISOR that referred to the SDS as a source for identifying chemicals that are "within the scope" of the HSC. The portion of the comment regarding the commenter's preference for two of the other listing mechanisms is irrelevant and outside the scope of this proposed regulatory action.

Comment (APTCO): Subsection (a)(2) is not transparent because it does not mention SDSs in the regulation, OEHHA waits to tell the public until page seven of its nine page document that it intends to list chemicals by reference to the SDS rule.

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

Comment (APTCO): California citizens and employers would be deprived of making exports that would be deselected because of the improperly required Proposition 65 warning that was based on information on an SDS—not a classification by OSHA that the product is a carcinogen.

Response: The portion of the comment regarding the commenter's opinion about the impact of a Proposition 65 listing is irrelevant and outside the scope of this proposed regulatory action. In any event, OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

Comment (APTCO): *"AFL-CIO v. Deukmejian, Chamber of Commerce v. Brown* and *SIRC v. OEHHA* state that OEHHA may list only chemicals that have been identified in OSHA's 'floor lists.' The floor lists contain the substances that OSHA mandates that all manufacturers must *classify* as carcinogens or reproductive toxins." OEHHA cannot expand its authority from listing by reference to mandatory chemical identifications to listing by reference to SDS information, even if what is required to be in an SDS is "mandatory."

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

Comment (APTCO): OEHHA must completely rewrite Subsection (a)(2) so that it is clear and readily understandable, so that it accurately reflects OEHHA's listing power, and so that it eliminates any reference to "reproductive toxicity".

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

Comment (APTCO): The 2012 HCS amendments are irrelevant to OEHHA's listing authority and therefore cannot justify expanding its authority in Subsection (a)(2).

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

Comment (APTCO): The HCS's mandatory lists changed in 2012, but OEHHA's listing authority to list from OSHA's mandatory lists has not changed. The fact that OEHHA is permitted now to list from only one list does not mean that it can simply write a regulation that would expand its listing authority for the first time in 28 years to list by reference to a different, non-relevant rule in the HCS.

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

Comment (APTCO): OEHHA explains in its ISOR that it can no longer list from the ACGIH list. ISOR, p. 7. This list was one of OSHA's floor lists—just as was the NTP's, the IARC's and OSHA's. For the same legal reasons that OEHHA can longer list from the ACGIH list by reference to the HCS, OEHHA may no longer list from the NTP's and IARC's lists by reference to the HCS. It is confusing and unclear, and it is not supported by the law for OEHHA to propose a regulation allowing it to list from the NTP's and IARC's lists while recognizing that it can no longer list from the ACGIH's list. There is no principled or legal difference.

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

Comment (APTCO): The people of California, through Proposition 65, give OEHHA its listing authority. Not OSHA. Not the HCS. The relevant language in Proposition 65 has not changed. OSHA's 2012 HCS amendments therefore cannot be used to justify an

expansion of OEHHA' authority to list in a brand new way in order to be able to continue to list from the NTP's Report on Carcinogens (RoC) without scientific review.

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

Comment (APTCO): Subsection (a)(2) must be rewritten to permit OEHHA to list only from OSHA's mandatory list of carcinogens in Subpart Z of the HCS.

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

Comment (APTCO): By "expanding" OEHHA's authority in subsection (a)(2) and subsection (d), OEHHA is violating the public's First Amendment rights by compelling businesses to provide false warnings.

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

Comment (APTCO): Subsection (a)(2) and Section (d) would violate the public's First Amendment Freedom of Speech rights. California businesses would be required to make false and damaging statements about their products.

Response: This comment is irrelevant and requires no response to the proposed action because the proposed regulation itself does not require anyone to provide a warning (Government Code section 11346.9 (a)(3)). The regulation clarifies one of the methods OEHHA uses for listing chemicals under Proposition 65. Warnings are required by Health and Safety Code section 25249.6. Further, OEHHA has stricken Section 25904(a)(2) in its entirety, including all references to Labor Code Section 6382(d).

Comment (CalChamber): OEHHA's position that reproductive toxicants may be within the scope of a future HCS does not justify including reproductive toxicants in subsection (a)(2).

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d) which renders this comment moot.

Comment (CalChamber): OEHHA erroneously interprets "within the scope" of the HCS in subsection (a)(2) by treating NTP and IARC determinations as conclusive findings of carcinogenicity. CalChamber commented that the NTP's Report on Carcinogens and IARC's Monographs are no longer definitive sources for identifying chemicals.

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

Comment (CalChamber): Subsection (a)(2) must expressly state that reproductive toxicants shall not be listed until such time as OSHA amends its HCS to reintroduce Threshold Limit Values or another metric as a definite source for identifying chemicals.

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

Comment (CEH): Supports subsection (a)(2) because it allows OEHHA to avoid duplicating work done through the HCS.

Response: This comment requires no response.

Comment (NFIB): There is lack of clarity in the regulation as to what constitutes "within the scope" of the federal HCS, as amended. The SDS is mandatory, but that does not make the IARC/ NTP listings mandatory, because OSHA "permits but does not require" the SDS designation for NTP or IARC chemicals. OSHA's rule uses the word "may." OEHHA's ISOR "re-writes" the federal regulation by making this into a mandatory rule.

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

Comment (SIRC): The NTP's Report on Carcinogens and IARC's Monographs are no longer definitive sources for identifying chemicals.

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

Comment (SIRC): The agency must amend the "Summary and Rationale of Regulation" section of its Initial Statement of Reasons and delete all discussions suggesting that the requirements to disclose on a SDS that a workplace chemical is listed in the NTP RoC or has been found to be a carcinogen in the IARC Monographs brings that substance within the scope of the HCS.

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the underlying issue raised in this comment.

Comment (SIRC): OEHHA must stop its attempts to draw in the NTP RoC.

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

Comment (SIRC): Requirement for listing on SDS is just an "informational reference" and thus is not "within the scope" of HCS. The requirement is not a hazard classification and is "merely informational."

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issue raised in this comment.

C. Section 25904(d)

Comment (ACC): The process for delisting chemicals under section 25904 should be streamlined so that chemicals are removed promptly from the list if the basis for listing no longer exists.

Response: OEHHA modified subsection (d) to remove the provision requiring the chemicals to remain on the list pending review by the appropriate committee. The modification renders this argument moot.

Comment (APTCO): It is unlawful to require California businesses to be subject to Proposition 65's warning requirements for any period of time if a chemical is not proven to cause cancer.

Response: OEHHA modified subsection (d) to remove the provision requiring the chemicals to remain on the list pending review by the appropriate committee. The modification renders this argument moot.

Comment (APTCO): Subsection (d) is arbitrary because chemicals are not automatically delisted when they no longer meet requirements. OEHHA has not performed the required Economic Impact Analysis addressing impacts from chemicals remaining listed.

Response: OEHHA modified subsection (d) to remove the provision requiring the chemicals to remain on the list pending review by the appropriate committee. The modification renders this argument moot.

Comment (APTCO): Proposed Subsection (d) is invalid because it is arbitrary and inconsistent, conflicts with other listing mechanisms and violates due process under the law.

Response: OEHHA modified subsection (d) to remove the provision requiring the chemicals to remain on the list pending review by the appropriate committee. The modification renders this argument moot.

Comment (CalChamber): Confusion is not a legal basis for keeping chemicals on the list. Absent such a legal basis, OEHHA cannot allow a chemical which does not meet listing criteria to nonetheless remain on the list pending the formal delisting process.

Response: OEHHA modified subsection (d) to remove the provision requiring the chemicals to remain on the list pending review by the appropriate committee. The modification renders this argument moot.

D. Economic Impact Analysis

Comment (APTCO): OEHHA was required to comply with the "major regulation" EIA provisions of the APA because it knew (or should have known) this proposed regulation could have an estimated economic impact exceeding $50 million.

Response: OEHHA disagrees. The proposed regulation simply clarifies an existing requirement under Proposition 65, to list chemicals by reference to Labor Code section 6382(b)(1). The regulation will not result in any significant costs to business because the chemicals will continue to be listed when required whether or not the regulation is adopted. Further, the act of listing a chemical under Proposition 65 is exempt from the provisions of the APA.[7] It appears that this comment is directed to the act of listing chemicals and therefore is not relevant to this regulatory action or the procedure by which it was adopted and requires no response.

Comment (APTCO): OEHHA's Economic Impact Statement does not contain any facts or data to support its finding of 'no economic impact'.

Response: Section 11346.3 of the California Government Code requires that an agency look at whether the proposed regulation will impact (A) the creation or elimination of jobs within the State of California, (B) the creation of new businesses or the elimination of existing businesses within the State of California, (C) the expansion of businesses currently doing business within the State of California, and (D) the benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment. Because the proposed regulation simply formalizes a procedure used for many years by OEHHA to make listings that are statutorily mandated, no new economic impact will arise from the proposed regulation. No further analysis is required. The regulations will not result in any significant costs to business because the chemicals will continue to be listed when required whether or not the regulation is adopted. Further, the act of listing a chemical under Proposition 65 is exempt from the provisions of the APA. It appears that this comment is directed to the act of listing chemicals and therefore is not relevant to this regulatory action or the procedure by which it was adopted.

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

E. Miscellaneous/General Comments

Comment (ACC): Proposed section 25904 is similar to the May 15, 2013 version. There has been no announcement that the May 15, 2013 proposal was abandoned. This should be stated explicitly in the FSOR for this proposed section 25904.

Response: The May 2013 proposal was a pre-regulatory proposal. It was published by OEHHA in April 2013 and two public workshops were held to obtain public recommendations for an official rulemaking process. The rulemaking record opened in January 2014. There was no need therefore to state in the FSOR that language in a pre-regulatory draft had been abandoned.

Comment (APTCO): This is OEHHA's fourth interpretation of its Labor Code listing authority since 2008. It proposed its first Labor Code regulation in 2008, and its interpretation then of its authority was more consistent with the established holdings of the Courts of Appeal. Since then, OEHHA not only has changed its mind three times but has repeatedly violated the due process rights of the public.

Response: This comment is not specifically directed at the agency's proposed action or to the procedures followed by the agency in proposing or adopting the action. Therefore, under Government Code section 11346.9 (a)(3) this comment is irrelevant and requires no response.

Comment (APTCO): OEHHA has frequently deprived the public of meaningful and effective public participation since it proposed its first Labor Code regulation. In some cases, it even precluded all public participation.

Response: OEHHA has complied with all procedural requirements for public comments during this rulemaking. To the extent the comment is not specifically directed at the agency's current proposed action or to the procedures followed by the agency in proposing or adopting this action, this comment is irrelevant and requires no response (Government Code section 11346.9 (a)(3)).

Comment (APTCO): Proposed Subsection (a)(2) is arbitrary and capricious and consistent with OEHHA's pattern in recent years of ignoring Proposition 65's statutory language, established case law, rigorous scientific review and public participation.

Response: This is the commenter's characterization of OEHHA's motives or thought processes in proposing the regulation and requires no response.

Comment (APTCO): OEHHA's regulation fails to satisfy the cardinal requirements of the APA. Agencies may promulgate regulations that reasonably interpret the statute they implement, explain specifically how they perform their authorized statutory duties or define terms that the public may not understand. See Cal. Gov't Code § 11342.2. Regulations must also be clear and consistent with an agency's delegation of authority. Id. at 11342.1-.2. They must not be confusing or use undefined terms, they must be

readily understandable, they must not have more than one meaning, and they must avoid technical terms. Id. at 11342.580; 11349 et seq. OEHHA's regulation does not satisfy any of these requirements.

Response: The authority cited by the commenter, Cal. Gov't Code § 11342.2, provides as follows:

> "Whenever by the express or implied terms of any statute a state agency has authority to adopt regulations to implement, interpret, make specific or otherwise carry out the provisions of the statute, no regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of the statute."

The proposed regulation reasonably interprets the statute it implements. OEHHA has fully complied with the requirements of the APA in proposing this regulation.

Comment (CEH): Supports the regulation, especially subsection (a)(2) because it allows OEHHA to avoid duplicating work done by other scientific entities through reference to the HCS.

Response: This comment does not require a response.

Comment (CEH): CEH supports this regulatory project.

Response: This comment does not require a response.

Comment (CEH): OEHHA should clarify regulations so that the new toxicology testing with cell-based or tissue-based systems that NAS described in a recent report will be acceptable for P65 listing purposes when deemed acceptable by IARC.

Response: This comment is beyond the scope of this rulemaking, which does not address the scientific basis for IARC's listing.

Comment (NFIB): Reiterate comments of July 31, 2013, calling for "clarity and certainty," although new proposal is somewhat better.

Response: Comments on pre-regulatory draft. This comment requires no response.

I. SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE COMMENT PERIOD OF JUNE 20, 2014 THROUGH JULY 7, 2014.

Comments were received from the following organizations:

APTCO
CalChamber
SIRC

A. Section 25904 (a)(1)

Comment (APTCO): Subsection (e) is arbitrary because chemicals are not automatically delisted when they no longer meet requirements. OEHHA has not performed the required Economic Impact Analysis addressing impacts from chemicals remaining listed.

Response: OEHHA modified subsection (e) to remove the provision requiring the chemicals to remain on the list pending review by the appropriate committee. The modification renders this argument moot.

Comment (CalChamber): Supports changes to (a)(1).

Response: No response to this comment is required.

B. Section 25904 (a)(2)

Comment (APTCO): Subsection (a)(2) must expressly state that OEHHA is authorized to list substances only from OSHA's mandatory list of carcinogens in Subpart Z of the HCS and explain this clearly in the ISOR.

Response: OEHHA has stricken Section 25904(a)(2) in its entirety as well as all references to Labor Code Section 6382(d). The modified regulatory text, therefore, renders moot the issues raised in this comment.

Comment (APTCO): Subsection (a)(2) does not describe the process by which OEHHA identifies chemicals, therefore it does not satisfy "necessity" standard for a regulation. It just repeats the Labor Code.

Response: Subsection (a)(2) has been stricken from the proposed regulation. The modification renders this argument moot.

Comment (APTCO): The phrase "reproductive toxicity" is outside the authority of this regulation because OEHHA cannot currently list reproductive toxicants.

Response: All references to the phrase "reproductive toxicity" have been removed from the regulation. The modification to the regulatory language renders this comment moot.

Comment (APTCO): If OEHHA does not specify which list in the HCS it is permitted to list from and if OEHHA does not remove references to "reproductive toxicity" from in Section (a), people will have a hard time understanding what chemicals are covered to petition for listing or delisting.

Response: Subsection (a)(2) has been stricken from the proposed regulation. All references to "reproductive toxicity" have been stricken from the regulation. These changes make the comment moot.

Comment (APTCO): The public is entitled to know OEHHA is not authorized to list substances on the basis of the CDIR's "Director's List".

Response: Subsection (a)(2) has been stricken from the proposed regulation. The modification renders this argument moot.

Comment (CalChamber): Supports changes to (a)(2).

Response: The comment requires no response.

C. Section 25904 (b)

Comment (CalChamber): Does not support (b) and asks that public may comment regarding whether the sufficient evidence standard has been satisfied. Court in SIRC stated listing was not ministerial or automatic.

Response: The listing of chemicals under Proposition 65 is exempt from the APA and no provision of Proposition 65 or case law requires OEHHA to provide an opportunity for public comment concerning listing decisions via this mechanism[8]. Although OEHHA is under no obligation to provide an opportunity for the public to comment when considering the listing of a chemical under the Labor Code, it has been OEHHA's practice to publish a Notice of Intent to List in the CRNR and invite comments concerning whether the chemical has been identified by reference in the Labor Code and provide a 30-day comment period on that narrow issue. This practice is incorporated in the regulation in subsection (b). Listings via the Labor Code mechanism are ministerial in nature and OEHHA does not analyze the underlying scientific basis for the identification. The approach of the proposed formal regulation is consistent with OEHHA's practice of listing chemicals under the Act through a Notice of Intent to List and a comment period focusing on the specific issue of whether the chemical has been identified as a carcinogen by IARC based on its determination that there is sufficient scientific evidence in humans or animals to support the listing; therefore OEHHA did not make the requested change.

D. Section 25904 (d)

Comment (CalChamber): Supports new subsection (d).

Response: This comment does not require a response.

E. Section 25904 (e)

Comment (CalChamber): Subsection (e) is not supported. "Confusion" is not a legal basis for keeping a chemical on the list after OEHHA has determined that it doesn't meet listing criteria.

Response: OEHHA modified subsection (e) to remove the provision requiring the chemicals to remain on the list pending review by the appropriate committee. The modification renders this comment moot.

[8] California Health and Safety Code section 25249.8 (e)

II. SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE COMMENT PERIOD OF SEPTEMBER 12, 2014 THROUGH SEPTEMBER 29, 2014.

No comments were received during this comment period.

III. SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE COMMENT PERIOD OF FEBRUARY 27, 2015 THROUGH MARCH 20, 2015.[9]

The following organizations submitted comments during this comment period:

Hardwood Plywood and Veneer Association (HPVA)

Tesoro

Western Plant Health Association (WPHA)

A. Title of Regulation

Comment (WPHA): *Title of Proposed Regulation.* The changes to the title of the proposed regulation 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.

Response: This comment does not require a response.

B. Section 25904 (a)

Comment (WPHA): *Subsection (a).* Insertion of the term "or substance" to follow and accompany the term "chemical" is 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.

Response: Health and Safety Code Section 25249.8(a) requires the listing of "*substances* identified additionally by reference in Labor Code Section 6382(b)(1). The term "substances" is used in Labor Code section 6382(b)(1) and is consistent with

[9] The comment period was extended to March 20, 2015 in response to a request for extension.

the use of the term in the IARC Monograph.

Comment (Tesoro): Commenter asked for rationale for using the term "substance" and whether the use of the term would "cover more chemicals as a result of this change". Commenter also noted that the term "substance" was not required by OAL in its disapproval decision.

Response: Health and Safety Code Section 25249.8(a) requires the listing of substances identified additionally by reference in Labor Code Section 6382(b)(1). The term "substances" is used in Labor Code section 6382(b)(1) and is consistent with the use of the term in the IARC Monograph. The addition of the term "substance" aligns the nomenclature of the regulation with the Labor Code and the Act, and does not expand the scope of this listing mechanism. The commenter is correct that the term "substance" was not required by OAL in its disapproval; OEHHA is not, however, limited solely to responding to the OAL disapproval comments when proposing regulatory text. The 15-day notice of modification of regulatory text was published in the CRNR in accordance with the APA.

C. Section 25904(b)

Comment (WPHA): The definition of "sufficient evidence" remains unclear and confusing. 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. Commenter referenced the rule of construction set forth in *Palermo v. Stockton Theatres, Inc*., (1948) 32 Cal.2d 53 [where a statute adopts by specific reference the provisions of another statute, regulation or ordinance; and such provisions are incorporated in the form in which they exist at the time of the reference and not as subsequently modified]. The commenter states that the adoption of a cross-referenced definition by its potential use in another future IARC Monograph is similarly flawed in that 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. Commenter recommends adopting explicitly the definitions of "sufficient evidence" in the 2006 Preamble to the most recent IARC Monograph, and to incorporate the IARC text word-by-word.

Response: The rule of construction referenced in the comment letter by WPHA was considered by the court in *California Chamber v. Brown,* (2011) 196 Cal.App.4th 233 in the context of Proposition 65 listings via Labor Code section 6382. The court in *Palermo* found the federal treaty in *Palermo* distinguishable from the Labor Code Section 6382(b). In the *Chamber of Commerce* case the court firmly rejected the expansive interpretation of the *Palermo* decision proffered by the Chamber with regard to Labor Code section 6382, stating:

> "Thus, what CalChamber actually urges is that *Palermo* extends beyond the expressly incorporated statutes—indeed, beyond even the regulations expressly incorporated by the expressly incorporated statutes—to reach the specific substances identified on the lists referenced by Labor Code section 6382, subdivisions (b)(1) and (d), at the time Proposition 65 was enacted. In other words, according to CalChamber, what must be deemed to have been written into Proposition 65 is not only the language of Labor Code section 6382, subdivisions (b)(1) and (d), and the language of the "the federal [HCS] (29 C.F.R. § 1910.1200)," but also all lists of identified substances referenced by these statutory and regulatory provisions. Nothing in *Palermo* requires such a burdensome or labyrinthine result. Furthermore, unlike in *Palermo*, the incorporating statute here, section 25249.8, subdivision (a), anticipates change, by mandating annual revision and republication of the Proposition 65 list. (§ 25249.8, subd. (a).)"

Further, in the Second Interim Order in the *Sierra Club v. Schwarzenegger (Brown)* case (Case No. RG07356881), the court ordered OEHHA to list any chemical for which IARC has concluded there is "sufficient" evidence of cancer in humans or animals, including agents added to the IARC list of Agents Classified by the IARC Monographs. This includes agents for which the final monograph has not been published.

After carefully considering the comments from WPHA, including the commenter's articulated legal basis for the recommended changes; OEHHA has determined that the regulatory language proposed in subsection (b) is in accordance with applicable case law precedent and the court's express order in *Sierra Club v. Schwarzenegger (Brown)*. OEHHA has therefore decided not to incorporate the revisions to subsection (b) recommended by the WPHA.

D. Section 25904(c)

Comment (WPHA): Commenter repeated objection to the use of the "undefined term 'substance' as an alternative to 'chemical.'"

Response: Health and Safety Code Section 25249.8(a) requires the listing of "substances identified additionally by reference in Labor Code Section 6382(b)(1). The term "substances" is used in Labor Code section 6382(b)(1) and is consistent with the use of the term in the IARC Monograph.

E. Section 25904(d)

Comment (WPHA): The provision allowing 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 is appropriate, particularly in light of the provision that allows persons to petition for the addition of chemicals to the Proposition

65 list.

Response: This comment requires no response.

F. Section 25904(e)

Comment (WPHA): 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. This provision is appropriate.

Response: This comment requires no response.

Comment (WPHA): Commenter repeated objection to the use of the "undefined term 'substance' as an alternative to 'chemical.'"

Response: Health and Safety Code Section 25249.8(a) requires the listing of "substances identified additionally by reference in Labor Code Section 6382(b)(1). The term "substances" is used in Labor Code section 6382(b)(1) and is consistent with the use of the term in the IARC Monograph.

G. Section 25904(f) [New proposed section]

Comment (WPHA): ***(Proposed New Subsection (f)).*** Commenter recommended duplicating a provision from Section 25306(f), that 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.

Response: The approach would require the agency to use the same authoritative body listing process used in Article 3 of the regulations. Whereas the authoritative body listing process of Article 3 is statutorily based on section 25249.8(b) of the Act, which provides for the authoritative bodies listing mechanism, the proposed regulation is based on the statutory authority of 25249.8(a), which provides for the Labor Code listing mechanism. OEHHA has determined that the authoritative bodies approach (which requires OEHHA to determine when a chemical has been "formally identified" by an authoritative body as a carcinogen or reproductive toxicant) is not consistent with the statutory language in the Labor Code that identify chemicals by reference as carcinogens or reproductive toxicants, which contemplates a ministerial listing process. This recommendation is therefore not incorporated within the regulation.

H. Section 25904(g) [Renumbered section]

Comment (WPHA): Assuming that a new subsection (f) is added per the suggestion above, former subsection (f) would become subsection (g). Concur with the changes that OEHHA has proposed to that subsection.

Response: This comment does not require a response.

H. Miscellaneous/General Comments

Comment (HPVA): A company in legal compliance with California Air Resources Board emissions standards should receive reciprocity recognition as meeting the requirements of Prop 65.

Response (OEHHA): This comment is not directed towards this proposed regulatory action and does not require a response.

IV. SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE COMMENT PERIOD OF MAY 1, 2015 THROUGH MAY 15, 2015.

Comments were received from the following organizations:

CalChamber

A. Section 25904 (b)

Comment (CalChamber): Without a final monograph, there is no way for OEHHA to properly evaluate whether the basis for IARC's determination meets the criteria for listing.

Response: in the Second Interim Order in the *Sierra Club v. Schwarzenegger (Brown)* case (Case No. RG07356881), the court ordered OEHHA to list any chemical for which IARC has concluded there is "sufficient" evidence of cancer in humans or animals, including agents added to the IARC list of Agents Classified by the IARC Monographs for which the final monograph has not been published.

Comment (CalChamber): OEHHA must adopt the procedures of the Director of Industrial Relations, including presumptions, tests, and administrative procedures that must be followed in order to list a chemical via the Labor Code mechanism.

Response: The commenter cites no authority for the proposition that OEHHA is required to follow the procedures of the Department of Industrial Relations in order to list a chemical by reference to the Labor Code. Such an assertion is contrary to all case law and court orders issued regarding the requirements for implementing this listing mechanism. No changes were made in response to this comment.

Comment (CalChamber): OEHHA struck out all reference to Labor Code Section 6382(d) because OEHHA recognized that Section 6382(d) was a procedure.

Response: This comment is an inaccurate characterization of OEHHA's rationale for deleting the provisions relating to listing by reference to Labor Code Section 6382(d) as part of this regulatory process. This comment is cumulatively commenting on changes already subject to public comment and response, and is irrelevant to the changes

proposed in this comment period.

V. SUMMARY AND RESPONSE TO OFFICE OF ADMINISTRATIVE LAW DECISION OF DISAPPROVAL OF REGULATORY ACTION DATED JANUARY 22, 2015

On January 22, 2015, OAL notified OEHHA that OAL disapproved the proposed regulations for failure to comply with the clarity standard of Government Code section 11349.1, and for failure to follow certain procedural requirements of the APA. In response to the OAL disapproval decision, OEHHA has resolved all clarity issues; and in accordance with APA procedural requirements, has notified the public of all modified regulatory text and of the availability of all records relied on during this rulemaking.

A. Clarity Standard

1. Proposed section 25904, subdivision (a)(1)

In the disapproval decision, OAL noted that the phrases "probably carcinogenic to humans with sufficient animal evidence" and "possibly carcinogenic to humans with sufficient animal evidence" were unclear because the regulation did not describe what the animal evidence was supposed to show, i.e., whether the animal evidence is required to show a potential carcinogenic effect on humans or a carcinogenic effect on animals. The decision further noted that it was unclear whether the term "sufficient animal evidence" had the same meaning for both phrases or if it had a different meaning. The decision noted that the ISOR provided supplemental information that needs to "made clear in the text of the regulations itself".

On February 23, 2015, OEHHA modified the regulatory text to clarify that chemicals shall be included on the list if the chemical or substance is classified by the International Agency for Research (IARC) Monographs in Group 1, 2A or 2B and based in whole or in part on identification by IARC of sufficient evidence of carcinogenicity in humans or animals.[10] The regulatory text additionally defines the term "sufficient evidence" by reference to the most recent IARC Monograph on the chemical or substance.

On May 1, 2015 OEHHA further modified the text to increase clarity and ensure consistency with the decision in *Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment*, (2012) 210 Cal. App. 4th 1082. The text was modified to clearly exclude from listing any chemicals or substances classified by IARC as Group 2B based on limited evidence of carcinogenicity in experimental animals. Additionally, the modified text reflected the Second Interim Order in the *Sierra Club v. Schwarzenegger (Brown)* case (Case No. RG07356881 wherein the court ordered OEHHA to list any chemical for which IARC has concluded there is "sufficient" evidence of cancer in humans or animals, including agents added to the IARC list of Agents

[10] Subsection (a)(1) was renumbered as subsection (b) in the modified regulatory text.

Classified by the IARC Monographs, *whether or not the final monograph has been published*. To ensure clarity and consistency with this court order, OEHHA modified the proposed text to include chemicals or substances classified by IARC as Group 1, 2, and 2B in the list of Agents Classified by the IARC Monographs.

2. Proposed section 25904, subdivision (a)(2)

The disapproval decision noted that subdivision (a)(2) was unclear based on the same issues as subdivision (a)(1). Additionally, OAL noted that there was a conflict between the language of the regulation and of the ISOR. Having carefully considered the disapproval decision as well as comments received during the regulatory process, OEHHA has decided not to pursue a regulation concerning listing via the federal Hazard Communications (HCS) at this time. As listings via the HSC are no longer part of the regulation, the clarity issue has become moot.

3. Proposed section 25904, subdivision (b)

The OAL disapproval decision states that there is a conflict between the ISOR and the regulatory language. Namely, the ISOR states that comment is restricted to the identification of a chemical as causing cancer or reproductive toxicity, not the underlying scientific determinations supporting the identification"; the regulatory language, on the other hand, "does not expressly exclude comments related to the underlying scientific determinations supporting the identification." In response to this comment, on May 1 2015, OEHHA modified the proposed regulatory text to expressly restrict comment to the issue of whether the identification of the chemical or substance meets the requirements of this section of the Labor Code. The proposed regulatory text also expressly states that the lead agency shall not consider comments related to the underlying scientific basis for classification of a chemical by IARC as causing cancer, which is consistent with case law and the operative provision of the Labor Code.

B. Procedural Requirements

1. Summary and Response to Comments

OAL stated that OEHHA did not adequately summarize all comments in the FSOR and provide a required explanation for making no change. In response OEHHA has updated the FSOR, OEHHA has carefully reviewed and more specifically summarized and responded to all the relevant comments received in all five public comment periods as part of the rulemaking record for this proposed regulation. In the updated FSOR, OEHHA has provided summaries and explanations for all comments and provided specific explanations for suggested changes that were not made.

1.1. Economic Impact Assessment and Major Regulation

OAL stated that OEHHA did not adequately respond to a comment opining that the Economic Impact Analysis (EIA) is incorrect. In the FSOR included as part of OEHHA's resubmission, OEHHA has responded to the comment regarding the EIA.

1.2. Other comments

OAL stated that OEHHA did not adequately respond to comments and recommendations that were rejected. Additionally, OAL noted that OEHHA made certain changes to the regulation that were not completely explained in the FSOR. In response to this comment, OEHHA in this updated ISOR has summarized all the comments to this regulatory proposal, and has specifically provided explanations for all changes to the regulation.

2. Documents Relied Upon

OAL stated that the disk containing electronic versions of the documents relied on was unreadable and directed that OEHHA resubmit a viewable version of the documents relied on. Additionally, OAL identified two documents that must be included if relied on, the "side-by-side" of the 2012 amendments to the HCS and a Notice of Entry Order signed by Judge Freedman with POS attached (Sierra Club v. Brown). The Entry Order was reviewed but not relied upon; therefore no additional 15-day notice is required.[11] A 15-day notice of augmentation of record was published on February 27, 2015 providing the public notice and an opportunity to inspect the Preamble to the IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, and recent changes (effective May 2012) to the federal HCS regulations. As part of the resubmission, OEHHA has included an updated, viewable disk containing an electronic version of all documents relied on.

3. Authority and Reference Citations

OAL commented on the requirement for authority and reference citations for the regulatory provisions. In the February 23, 2015 modified regulatory text, OEHHA has been updated to include authority and reference citations.

4. Underline/Strikeouts

OAL commented that OEHHA is required to use underline or italics to denote additions and strikeout to indicate deletions from the California Code of Regulations. The changes to the proposed regulatory text were presented as follows to denote additions and deletions from the originally proposed regulatory text. The June 2014 additions to the initially proposed regulatory text (January 2014) are indicated by underline, thus: <u>added language</u>; deletions from the regulatory text are indicated by strikethrough, thus: ~~deleted language~~. The September 2014 additions to the regulatory text are indicated by double

[11] Similarly, the Stipulation for Entry of Partial Consent Judgment and Order Thereon for the *Sierra* case was reviewed, but not relied on by OEHHA.

underline, thus: added language; deletions from the regulatory text are indicated by double strikethrough, thus: ~~deleted language~~. The February 2015 additions to the regulatory text are indicated by italics and underline, thus: *added language*; deletions from the modified regulatory text are indicated by italics and strikethrough, thus: ~~*deleted language*~~. The May 2015 additions to the regulatory text are indicated by italics and double underline, thus: *added language*; deletions from the modified regulatory text are indicated by italics and double strikethrough, thus ~~*deleted language*~~.

Additionally, OEHHA has submitted a final proposed version of the regulation to OAL as part of the resubmission. This document is in full underline because the regulation is newly proposed, i.e., it is not an amendment to an existing regulation.

ALTERNATIVES DETERMINATION

In accordance with Government Code section 11346.9(a)(7), OEHHA has considered available alternatives to determine whether any alternative would be more effective in carrying out the purpose for which the regulations were proposed. OEHHA has also considered whether an alternative existed that would be as effective as, and less burdensome to, affected private persons than the proposed action. OEHHA has determined that no alternative considered would be more effective, or as effective and less burdensome to affected persons, than the proposed regulation because the regulation provides clarity and transparency regarding the process OEHHA uses to add chemicals to the proposition 65 list based on the Labor Code mechanism.

LOCAL MANDATE DETERMINATION

OEHHA has determined this regulatory action will not impose a mandate on local agencies or school districts nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. Local agencies and school districts are exempt from Proposition 65. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from this regulatory action. This regulation simply clarifies the process OEHHA currently uses to list chemicals under Proposition 65 by reference to the California Labor Code.