



April 4, 2014

Via e-mail to P65Public.Comments@oehha.ca.gov

Ms. Monet Vela
Office of Environmental Health Hazard Assessment (OEHHA)
1001 I Street
Sacramento, CA 95812

RE: Comments on Proposed Rulemaking, Title 27 California Code of Regulations, Proposed Section 25904 Listings by Reference to the California Labor Code [01/27/14]

Dear Ms. Vela:

On behalf of National Federation of Independent Business/CA and Western Growers, please find these comments to the Proposed Rulemaking, Title 27 California Code of Regulations, Proposed Section 25904 Listings by Reference to the California Labor Code, issued by the Office of Environmental Health Hazard Assessment (OEHHA) on January 27, 2014. Our organizations represent thousands of independent businesses and farmers operating in California, where compliance with Proposition 65 is a significant part of doing business, with the attendant risks, costs and uncertainties. It is of tremendous importance to our members that OEHHA administer Proposition 65 with fairness, integrity and faithfulness to the law. These comments are offered in the spirit of seeking an appropriate and well-written regulatory scheme governing Proposition 65 listings under the Labor Code.

On July 31, 2013, we provided comments on the earlier Pre-regulatory Conceptual Proposal, issued by OEHHA on May 17, 2013, which was the subject of a June 17, 2013 Labor Code Workshop. We re-iterate those comments here, calling for the clarity and certainty of the Labor Code listing mechanism under Proposition 65 consistent with court decisions and a sound reading of the Proposition 65 statute. While the current proposal, particularly as explained in the Initial Statement of Reasons, goes some distance to provide needed clarity and certainty, we

nonetheless believe a grammatical flaw in the language of the draft regulation leads to a reading inconsistent with the court decisions and requires correction. In this letter, we suggest certain key improvements to the language suggested by OEHHA. The recommendations below reflect our view that the court decisions apply broadly to all OEHHA listing actions and are not limited to any particular narrow category of chemical or substance.

Initially, it should be noted that the courts have now uniformly articulated that OEHHA shall only list chemicals “by reference” under Labor Code section 6382(b)(1) and 6382(d) when there is sufficient evidence that the chemical is known to cause cancer or reproductive toxicity. See *AFL-CIO v. Deukmejian*, 212 Cal. App. 3d 425, 438 (1989). In *SIRC v. OEHHA*, (2012) 210 Cal.App.4th 182, both the trial court and the Third District Court of Appeal, in an opinion amended Nov. 15, 2012, clarified that that OEHHA may not list a chemical as causing cancer under Prop 65 under the Labor Code mechanism solely on the basis of its identification by an outside group, such as IARC or NTP, incorporating it by reference under the Labor Code, where the referenced identification is based on less than sufficient evidence of carcinogenicity in humans or animals. Any regulation addressing the incorporation “by reference” of chemicals for listing under Proposition 65 must clearly and accurately state the standard of evidence applicable to the incorporated chemicals.

In fact, Proposition 65 requires the listing only of *known* carcinogens and reproductive toxicants. The courts have made clear that “for the purpose of interpreting the IARC monographs, ‘sufficient evidence’ of carcinogenicity is the equivalent of ‘known’ carcinogenicity.” See *SIRC v. OEHHA*, relying on *AFL-CIO v. Deukmejian*, 212 Cal.App.3d at 434, fn. 3. OEHHA has already defined “sufficient evidence” of causing cancer or reproductive toxicity for these purposes. See Chemicals Formally Identified by Authoritative Bodies, Title 27, California Code of Regulations, § 25306(e), (f), (g). These definitions are drawn from the same scientific bodies that provide the listings of carcinogens and reproductive toxicants used to populate the Prop 65 list and which are available for updating and revising the listings. With these principles in mind, we examine the current proposed regulation.

I. The proposed regulation incorrectly and misleadingly suggests that all the chemicals identified by IARC in Groups 1, 2 and 3 are based on sufficient animal or human evidence.

Much as we explained in our earlier comments in response to the May 17, 2013 Pre-regulatory Conceptual Proposal, OEHHA has used a flawed grammatical construction in its proposal that effectively recognizes all Group 2B chemicals as having sufficient evidence of carcinogenicity for the purposes of listing under the Labor Code mechanism. This flies in the face of the SIRC decision and OEHHA's own Notice on the matter. The current proposal is only slightly different from the 2013 proposal. We shall discuss only the current proposal here.

In its proposed addition of a new regulatory section, 27 C.C.R. section 25904, OEHHA has drafted the following:

- (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)

In the Initial State of Reasons ("ISR") accompanying the proposed regulation, OEHHA clearly acknowledges the *SIRC* decision, stating that "chemicals listing [sic] via the Labor Code method must be based on sufficient animal or human evidence. Therefore, the phrase 'based on sufficient animal or human evidence' was added to the proposed regulatory language." ISR, p. 8.

The problem in the drafting, however, is that the phrase "*based on sufficient animal or human evidence*" is a dangling participial phrase, followed, not preceded, by the word "*as*." Then the entire collection of phrases is followed by a, b, and c, the respective IARC Groups. This leads to a reading that all the chemicals in Groups 1, 2 and 3 are those that are based on sufficient animal or human evidence, contrary to the law, the ISR and OEHHA's obvious intent. Actually, two problems appear. The sentence uses the participial phrase parenthetically, but it likely modifies "A chemical," not the past participle "is identified." Arguably, it is wrongly placed to modify "IARC Monographs series," which makes little sense, as the Monographs series are not based on

sufficient animal or human evidence—only the chemicals listed in the Monographs series are, or are not, so based.

Secondly, the whole paragraph properly hangs on the single subordinating conjunction “if.” A proper sentence with a subordinating conjunction has two clauses, one main clause and one subordinate, or dependent, clause. The main clause is “The chemical shall be included,” and the dependent clause is “if it is identified” by IARC, etc., “as” one of the groups. As written, the conjunction only relates to the identification by IARC as within Group 1, 2 or 3. The parenthetical “based on sufficient . . . evidence as” points directly at the Groups, not the conditional identification by IARC.

We can assume OEHHA meant this construction to mean “[and if it is] based on sufficient . . . evidence.” Because the “based on sufficient . . . evidence” phrase *adds* to the IARC identification requirement, it should say so. There are *two* requirements here. The chemical must be identified (1) “as” within one of the identified groups, and (2) “as” “based on sufficient . . . evidence.”

A better construction would be as follows (*changes in italics*):

- (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), *as* based on sufficient animal or human evidence, *and within one of the following*:
 - a. Carcinogenic to humans (Group 1)
 - b. Probably carcinogenic to humans (Group 2A)
 - c. Possibly carcinogenic to humans (Group 2B)

Simply shifting the “as” to place the word before the phrase “based on sufficient . . . evidence” accomplishes the connection of the identification to the sufficiency of the evidence.

As we suggested in our July 31, 2013 letter, this regulation need not even recite the respective groupings within the IARC Monographs series. Consistent with the court decisions and OEHHA’s own interpretation and the explanation provided in the ISR, the following is as effective in summarizing the law and providing guidance to both OEHHA and the regulated community (*changes in italics*):

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), *as based on sufficient animal or human evidence that it causes cancer.*

We believe that a simple, grammatically correct re-writing of the proposed regulation, section (a)(1), as noted above, will effectuate the intent of OEHHA and properly memorialize the rulings of the courts.

II. The proposed regulation fails to provide any meaning to what constitutes “within the scope” of Federal Hazard Communications Standard for purposes of listing chemicals under Labor Code section 6382(d).

Labor Code section 6382(d) requires OEHHA to list those chemicals “within the scope” of the Hazard Communication Standard adopted by the federal Occupational Safety and Health Administration (OSHA). OSHA’s regulations, including the HCS, are found in Title 29 of the Code of Federal Regulations, section 1910.1200. Effective May 2012, OSHA amended the HCS, which amendment we believe has significant consequences as to the viability of Labor Code section 6382(d). Previously, the HCS provided that chemical manufacturers, importers and employers evaluating chemicals “shall treat the following sources as establishing that a chemical is a carcinogen or potential carcinogen for hazard communication purposes:” (1) the National Toxicology Program (NTP), “Annual Report on Carcinogens;” and, (2) the IARC Monographs. As written before the 2012 amendment, it seemed relatively clear how to apply the mandate of including chemicals “within the scope” of the HCS. Carcinogens identified as such (subject to the courts’ rulings that there must be sufficient evidence of human or animal carcinogenicity) would be “within the scope” of the HCS, and thus the subject of listing under the Labor Code mechanism.

The May 2012 amendments to the HCS (“HCS 2012”), however, removed the language that chemical manufacturers, importers and employers “shall treat” the NTP or IARC as sources to establish that a chemical is a carcinogen. HCS 2012 now permits, but does not require, a manufacturer, importer or employer to treat chemicals designated on IARC and NTP as

carcinogens, based on a weight of the evidence analysis. The manufacturer's determination is for the purpose of accurately identifying the chemicals for the required safety data sheets ("SDS"). However, the body of the HCS that once required a treatment of IARC and NTP as sources *establishing* the carcinogenicity of certain chemicals no longer mandates that treatment. Accordingly, the manufacturer's determinations for the SDS's cannot constitute being "within the scope" of the HCS.

OEHHA, in its Initial Statement of Reasons, concludes that the mandatory requirement to produce the SDS somehow makes mandatory the classification of a carcinogen from the IARC or NTP listings as well, and thus it is "within the scope" of the HCS. This seems doubtful, as it is not a plain reading of the HCS 2012. As it stands, the Initial Statement of Reasons re-writes the federal regulation, and the proposed text of the OEHHA regulation reflects a pre-2012 regime, providing no guidance or worse, incorrect direction to the regulated community. As suggested below, there is a way to resolve the issue.

HCS 2012 does mandate inclusion of carcinogens listed in its subpart Z,¹ and that could serve as the basis for a regulatory reference clarifying the meaning of "within the scope," wholly apart from the IARC or NTP. The Initial State of Reasons and the proposed text of the regulation could be revised to reflect this, and thereby provide essential guidance. The proposed text could read as follows (changes in italics):

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

We believe, in the majority of cases, if a chemical is listed as a carcinogen in the IARC

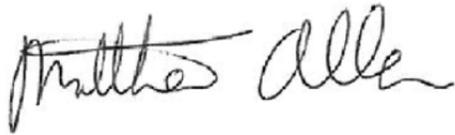
¹ Appendix A to the 2012 HCS provides manufacturers *may* treat IARC and NTP classifications as establishing that a chemical is a carcinogen or potential carcinogen. It also provides that "[w]here OSHA has included cancer as a health hazard to be considered by classifiers for a chemical covered by 29 CFR part 1910, Subpart Z, Toxic and Hazardous Substances, chemical manufacturers, importers, and employers shall classify the chemical as a carcinogen."

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Monograph series, and it is based on sufficient evidence of human or animal evidence, it will likely qualify under both Labor Code sections for listing under Proposition 65. What is important is that the proposed regulations accurately reflect the rulings of the courts and set forth language, procedures and policy that are clear, direct and logical.

We look forward to answering any questions concerning these comments and will be pleased to provide additional background or information as needed.

Sincerely,

A handwritten signature in black ink that reads "Matthew Allen". The signature is written in a cursive style with a long horizontal stroke at the end.

Matthew Allen
Western Growers Association

Sincerely,

A handwritten signature in black ink that reads "Ken DeVore". The signature is written in a cursive style with a large "K" and "D" and a long horizontal stroke at the end.

Ken DeVore
Legislative Director, NFIB/CA