

Response to Comments Concerning the Notice of Intent to Modify a Listing by the Labor Code Mechanism: Alcoholic Beverages as Causing Cancer under Proposition 65

Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
November 23, 2018

On August 3, 2018, the Office of Environmental Health Hazard Assessment (OEHHA) issued a Notice of Intent to Modify the Listing¹ of “Ethanol in Alcoholic Beverages” as known to the state to cause cancer to “Alcoholic Beverages” under Proposition 65². The notice initiated a 30-day public comment period that closed on September 4, 2018. This document responds to relevant comments received on the notice.

The process by which OEHHA lists chemicals and substances via the Labor Code listing mechanism is set out in regulation at Title 27, Cal. Code of Regs., section 25904³. Section 25904 outlines OEHHA’s procedures for Labor Code listings and incorporates court decisions interpreting the Proposition 65 statute as it applies to Labor Code listings⁴. In accordance with that regulation, OEHHA provided an opportunity for the public to comment on whether the proposed modification to the listing met the requirements pursuant to Health and Safety Code section 25249.8(a) and Labor Code section 6382(b)(1).

OEHHA received comments from:

- The North American Meat Institute
- Casey Miles (2 comments)
- Karen Robinson-Stark
- Two anonymous commenters

¹ California Regulatory Notice Register, 2018, No. 31-Z, pp. 1241-1243. Available at: <https://oal.ca.gov/wp-content/uploads/sites/166/2018/08/31z-2018.pdf>

² The Safe Drinking Water and Toxic Enforcement Act of 1986 (codified at Health and Safety Code section 25249.5 *et seq.*) hereinafter referred to as Proposition 65 or the Act.

³ All further references are to sections of Title 27, Cal. Code of Regs unless otherwise stated.

⁴ Specifically, Section 25904 excludes from listing any chemicals or substances classified by the International Agency for Research on Cancer (IARC) as Group 2B based on limited evidence of carcinogenicity in experimental animals as required by *Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment*, (2012) 210 Cal. App. 4th 1082. Additionally, in the Second Interim Order of the *Sierra Club v. Schwarzenegger (Brown)* case (Case No. RG07356881), the court ordered OEHHA to list chemicals when IARC concludes there is sufficient evidence of carcinogenicity in humans or animals, regardless of whether the final IARC Monograph on the substance or chemical has been published. See also, *California Chamber of Commerce v Schwarzenegger et al.*, (2011) 196 Cal. App 4th, 233 clarifying that Labor Code listings are ministerial acts required by statute.

All of the comments, other than those submitted by the North American Meat Institute, addressed issues that OEHHA could not consider in the context of a Labor Code listing. For example, some commenters stated their opinions about Proposition 65, explained the anticipated effect of the modification of the listing, asked rhetorical questions, or discussed the scientific basis for the decision by the International Agency for Research on Cancer (IARC) to identify alcoholic beverages as a Group 1 known human carcinogen. As required by Title 27, Cal. Code of Regs., section 25904(c), responses are provided for comments that are directly related to the IARC identification of alcoholic beverages as a Group 1 known human carcinogen. Lack of a response to a given comment does not mean OEHHA agrees with it.

North American Meat Institute comments

- 1. Comment:** Commenter generally objects to Labor Code listings of chemicals related to food. OEHHA offers no explanation or reasoning as to what beverages would be covered by the new listing that are not covered by the old listing, making the need for this change unexplained and unsubstantiated.

Response: Health and Safety Code section 25249.8(a) requires the listing of “substances identified by reference in Labor Code Section 6382(b)(1) and those substances identified additionally by reference in Labor Code Section 6382(d)”. This includes substances identified as human carcinogens by IARC. A substance can include a chemical mixture such as alcoholic beverages. Nothing in this language or the implementing regulations in Title 27, Cal. Code of Regulations, section 25904, excludes the listing of chemicals or substances related to food. Proposition 65 requires broadening the “ethanol in alcoholic beverages” listing in order to conform to the current broader designation by IARC.

- 2. Comment:** Proposition 65 governs and regulates "chemicals" such as ethanol. It does not and should not regulate "substances" that are not well-defined chemicals. "Alcoholic beverages" is a category of substances that includes beverages that contain alcohols other than ethanol, such as methanol. There is no indication that the International Agency for Research on Cancer ("IARC") intended to include beverages other than those that contain ethanol in its cancer classification.

Response: The IARC Monograph states:

"This monograph focuses on the main beverage categories of beer, wine and spirits unless there is a specific reason to examine some subcategory, e.g. alcopops or flavoured alcoholic beverages. These categories are, however, not as clear-cut as they may seem. There are several beverages that are a combination of two types (e.g. fortified wines, in which spirits are added to wine). The categorization above is based on production methods and raw materials, and not on the ethanol content of the beverages. (IARC, 2010, page 41)

Further, the California Business and Professions Code section § 23004, defines “alcoholic beverage” as follows:

“Alcoholic beverage” includes alcohol, spirits, liquor, wine, beer, and every liquid or solid containing alcohol, spirits, wine, or beer, and which contains one-half of 1 percent or more of alcohol by volume and which is fit for beverage purposes either alone or when diluted, mixed, or combined with other substances.”

As noted in the previous response, Proposition 65 expressly refers to “substances” in the context of Labor Code listings. IARC’s explanation of the scope of the Monograph sufficiently identifies the types of substances included in the designation of “alcoholic beverages”. Further, the modified listing of alcoholic beverages is not unique. “Alcoholic beverages, when associated with alcohol abuse” was listed under Proposition 65 as known to cause cancer in 1988. A number of other substances have also been listed, including aloe vera non-decolorized whole leaf extract, areca nut, bracken fern, Chinese-style salted fish, tobacco smoke and marijuana smoke.

- 3. Comment:** Alcoholic beverages do not give rise to workplace exposures. Thus, they should not be listed via the Labor Code listing mechanism.

Response: There is nothing in the relevant law or regulations that limits the Labor Code listing mechanism to chemicals used in the workplace. OEHHA has a ministerial duty to list chemicals via this mechanism. See *California Chamber of Commerce v. Brown* (2011)196 Cal.App.4th 233, 259:

“We ...conclude[e] the Labor Code reference method set forth in subdivision (a) of section 25249.8 is to be used in revising the Proposition 65 list, and the three listing methods set forth in subdivision (b) are additional means by which changes can be made to the list. This construction ensures the Proposition 65 list of chemicals “known to the state to cause cancer or reproductive toxicity” always includes “at a minimum” those substances identified by reference to Labor Code section 6382, subdivisions (b)(1) and (d)...”

- 4. Comment:** The Director of Industrial Relations has not listed alcoholic beverages pursuant to the Labor Code, which is further evidence that alcoholic beverages cannot and should not be listed pursuant to the Labor Code listing mechanism.

Response: There is no direct relationship between the Director’s list and Proposition 65. The law only incorporates two small subsections of the Labor Code that in turn identify sources OEHHA *must use* in adding chemicals and substances to the Proposition 65 list. In the *Sierra Club v Brown* case (San Francisco County Superior Court case No. RG07356881, Second Interim Order, July 2010), Judge Freedman entered the following order, which is still binding on OEHHA:

“The Court agrees with Plaintiffs that Defendants' practice cannot be reconciled with the clear language of Labor Code §6382, subdivision (b)(I), which is phrased in terms of "substances listed ... by [IARC]," with no reference to monographs. Under *AFL-CIO v. Deukmejian* (1989) 212 Cal.App.3d 425, *OEHHA has a mandatory duty to list any chemical for which IARC has concluded there is "sufficient" evidence of cancer in humans or animals.*”(emphasis added)

The commenter has not provided any authority for the assertion that OEHHA can only list chemicals that the Director of Industrial Relations has placed on his or her list, and this assertion is contrary to the plain text of Section 25249.8(a), which contains no such restriction.

Since alcoholic beverage are “substances” within the meaning of Section 25249.8(a), and since IARC concluded there is sufficient evidence that they cause carcinogenicity in humans or animals, OEHHA has a mandatory duty to list them. (*AFL-CIO v. Deukmejian* (1989) 212 Cal.App.3d 425, [under Labor Code listing mechanism, OEHHA must list any chemical for which IARC has found “sufficient” evidence of carcinogenicity in humans or animals].)

- 5. Comment:** Changing the listing in the manner OEHHA proposes would substantially complicate the process for identifying a no significant risk level ("NSRL").

Response: As indicated in the previous response, OEHHA has a mandatory duty to list chemicals and substances identified as human or animal carcinogens by IARC. There is no legal basis for OEHHA not to update a listing meeting those criteria because of concerns over any resulting NSRL.

It is not clear why a business would need to determine an NSRL for these products since there are already warnings being provided for them throughout California and the United States. In any event, businesses could still calculate a No Significant Risk Level for alcoholic beverages as a chemical mixture, using the guidance provided in the regulations.

- 6. Comment:** The most accurate reading of IARC Monograph 100E is that IARC is concerned with the presence of ethanol, not with methanol or other components of alcoholic beverages.

Response: IARC Monograph 100E focuses considerable attention on ethanol, and discusses the role of ethanol as a mechanism in the carcinogenicity of alcoholic beverages. The monograph retains its earlier finding in Monograph 96 that ethanol in alcoholic beverages is carcinogenic to humans. However, IARC⁵ also makes the larger finding that alcoholic beverages are carcinogenic to humans, classifying them

⁵ IARC List of Classifications, Volumes 1-122, available at: <https://monographs.iarc.fr/list-of-classifications-volumes/>

as a Group 1 carcinogen and providing as a reference Monograph Volumes 44, 96 and 100E.

IARC could have limited this identification to only certain chemicals in alcoholic beverages, but it did not. In this case, IARC clearly concluded that “alcoholic beverages” are a human carcinogen. As discussed in the response to Comment 1, IARC’s conclusions require modification of the Proposition 65 list to broaden the listing to alcoholic beverages pursuant to Health and Safety Code section 25249.8(a) and Labor Code section 6382(b)(1).