



July 31, 2013

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: Labor Code Workshop – June 17, 2013

Dear Ms. Vela:

On behalf of National Federation of Independent Business/CA and Western Growers, please find these comments to the Pre-regulatory Conceptual Proposal: Section 25904 Listings by Reference to the California Labor Code, issued by OEHHA on June 18, 2013. We believe a better solution to the questions concerning the clarity and certainty of the Labor Code listing mechanism under Proposition 65 would be legislation that confirms the holdings of the California courts.

Nonetheless, if OEHHA pursues the regulatory concept presented at the June 17 workshop, we believe certain key improvements to the language suggested by OEHHA are required. 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.

- I. The regulation should require a listing of a substance identified by reference under the Labor Code only IF the finding is based on sufficient evidence that the substance is known to cause cancer or a reproductive toxicity.**

The conceptual proposal for a Labor Code mechanism regulation, to be added in Title 27, California Code of Regulations (CCR), is drafted with an ambiguity in proposed section 25904(a)(3) and (4), that must be corrected if the proposal is to be consistent with the court decisions. Currently, the proposed subsections state:

(3) A chemical shall be included on the list if it is identified in the latest edition of the National Toxicology Program Report on Carcinogens based on sufficient animal or human evidence as:

- a. A human carcinogen
- b. A potential human carcinogen

(4) 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 both subsections (3) and (4), the proposed language allows a reading that an identification in either the National Toxicology Program (NTP) Report on Carcinogens or the International Agency for Research on Cancer (IARC) is *assumed* to be based on sufficient animal or human evidence. The language should make clear, as the courts have articulated it, that the listing should occur *only if* the identification in the NTP or IARC is based on sufficient animal or human evidence that the substance is known to cause cancer. Indeed, proposed subsection (a)(1) of the conceptual regulation gets it right relating to the Department of Industrial Relations Hazardous Substances List (HSL) contained in Title 8, California Code of Regulations, section 339. There the proposal states that a chemical will be included on the list

. . . if a basis for the chemical being placed on the Director's List is that the chemical causes cancer or reproductive or developmental toxicity based on sufficient animal or human evidence. (Italics added).

While the HSL proposal perhaps overuses the word “basis,” or “based,” the key point is that the chemical is listed only if there is sufficient animal or human evidence that the chemical causes cancer or reproductive toxicity. Subsections (3) and (4) should employ the same articulation relating listing *only if* the identification in the NTP or IARC is based on sufficient evidence.

Ms. Monet Vela
Office of Environmental Health Hazard Assessment (OEHHA)
1001 I Street
Sacramento, CA 95812
July 31, 2013
Page 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.

As early as 1989, the courts have articulated that OEHHA shall only list chemicals where the Labor Code reference provides 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*, 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*. Proposition 65 requires listing of known carcinogens and reproductive toxicants. Clearly, the “based on sufficient animal or human evidence” clause should be the conditional basis of the conceptual proposal, and it would more accurately reflect the courts’ rulings if it were to state:

(3) A chemical shall be included on the list if it is identified in the latest edition of the National Toxicology Program Report on Carcinogens *as* based on sufficient animal or human evidence *that it causes cancer.* ~~as:~~

- ~~a. A human carcinogen~~
- ~~b. A potential human carcinogen~~

(4) 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.* ~~as:~~

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

Ms. Monet Vela
Office of Environmental Health Hazard Assessment (OEHHA)
1001 I Street
Sacramento, CA 95812
July 31, 2013
Page 4

II. The proposed regulation should delete references to the categories of substances identified in the NTP and IARC.

The proposed conceptual regulation, in subsections (a)(3) and (4) identifies certain categories of carcinogens within the NTP and IARC. Proposition 65 does not make these distinctions. The law requires OEHHA to list the chemicals when they are “known” to cause cancer without regard to how another body has categorized it. The Third District Court of Appeal made it clear in *SIRC v. OEHHA*:

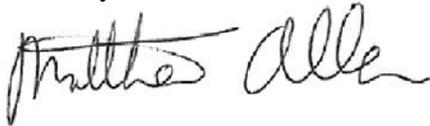
. . . the reference to Labor Code section 6382 in Health and Safety Code section 25249.8, subdivision (a), must be read in conjunction with the prior language requiring the Governor to publish a list of chemicals “known to the state to cause cancer or reproductive toxicity.” Because chemicals may be included in IARC Group 2B based on less than sufficient evidence of carcinogenicity in either humans or experimental animals, they may not qualify for Proposition 65 listing on that basis alone.

The court’s ruling emphasizes the core requirement of Prop 65 without regard to the category assigned a chemical by the IARC. The same is true for classifications provided by the NTP. The imperative for OEHHA is to list chemicals “known to the state to cause cancer or reproductive toxicity” when there is sufficient evidence of carcinogenicity in either humans or experimental animals. When incorporating an identified substance by reference through the Labor Code, the same standard applies for OEHHA to utilize: the carcinogenicity or reproductive toxicity of a chemical must be based on sufficient evidence.

Ms. Monet Vela
Office of Environmental Health Hazard Assessment (OEHHA)
1001 I Street
Sacramento, CA 95812
July 31, 2013
Page 5

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 large, sweeping initial "M".

Matthew Allen
Western Growers Association

Sincerely,

A handwritten signature in black ink that reads "John Kabateck". The signature is written in a cursive style with a large, sweeping initial "J".

John Kabateck
Executive Director, NFIB/CA