VINYL ACETATE COUNCIL

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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:

The Vinyl Acetate Council (VAC) appreciates this opportunity to submit comments in response to the January 27, 2014 Notice on the Proposed Rulemaking, Title 27 California Code of Regulations, Proposed Section 25904 Listings by Reference to the California Labor Code. The VAC represents the major North American manufacturers and users/processors of vinyl acetate monomer (VAM) and VAM based polymers. The VAC has a particular interest in this regulation, as one of the key court decisions that now guides listing under the Labor Code mechanism was applicable to vinyl acetate.

As OEHHA is well aware, Proposition 65 enacted California Health and Safety Code section 25249.8(a) that instructs OEHHA to publish a list of chemicals known to the state to cause cancer or reproductive toxicity. That statute requires OEHHA to include on the list, substances "identified by reference in Labor Code Section 6382(b)(1) and those substances identified additionally by reference in Labor Code Section 6382(d)." The focus of this comment letter is on Section 6382, subdivision (b)(1), which refers to "[s]ubstances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC)."

IARC's activities of relevance to the Labor Code listing process are the development of Monographs that classify various chemicals into categories based on their different levels of evidence of carcinogenicity. Historically, the most problematic category for the purposes of listing under the Labor Code, has been IARC "Group 2B - possibly carcinogenic to humans." This category is typically assigned when there is limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals, or in other combinations that still demonstrate inadequate evidence of carcinogenicity in humans.

IARC defines the meaning of "sufficient evidence of carcinogenicity" resting on the causal relationship between the agent and the incidence of cancer (Preamble to the IARC

Monographs, para. B.6(a,(b)). These definitions are generally followed by OEHHA in its regulations governing other mechanisms for the listing of chemicals under Proposition 65. See Chemicals Formally Identified by Authoritative Bodies, Title 27, California Code of Regulations, § 25306(e), (f), (g).

In light of the California Court of Appeal, Third Appellate District decision, there is a need to apply a sufficiency of the evidence standard to all chemicals and in the case of carcinogens, to list only those chemicals known to cause cancer, and "for the purpose of interpreting the IARC monographs, 'sufficient evidence' of carcinogenicity is the equivalent of 'known' carcinogenicity." *See Styrene Information and Research Center [SIRC] v. Office of Environmental Health Hazard Assessment* (2012) 210 Cal.App.4th 182, relying on AFL-CIO v. Deukmejian (1989) 212 Cal.App.3d 425, 434, fn. 3. VAC was pleased to see that in response to the *SIRC* decision, on January 4, 2013, OEHHA announced it was withdrawing certain Group 2B chemicals (including VAM) previously noticed for listing under the Labor Code mechanism, as those chemicals had been identified by IARC with "less than sufficient evidence" of human or animal carcinogenicity.

This current proposal is intended to follow the *SIRC* decision and to codify by regulation the requirement that there be sufficient animal or human evidence before listing under the Labor Code mechanism. While the *SIRC* decision focused on the Labor Code section 6382(d) mechanism for listing, it is clear the decision applies equally to section 6382(b)(1). Both the court decision and OEHHA's Initial State of Reasons appear to agree that listing under the Labor Code must be based on sufficient animal or human evidence. Nonetheless, VAC is concerned that proposed regulatory section, 27 CCR, section 25904(a)(1), could be interpreted to suggest that all chemicals classified by IARC in either Group 1, 2A or 2B are assumed to be "based on sufficient animal or human evidence" and as such warrant listing under Prop 65.

The current proposed language states:

(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)

To ensure that there is no misunderstanding, rather than put the emphasis on the different IARC Groups, VAC recommends modifying the provision to emphasize that it is not the IARC classification itself that matters, but that IARC's conclusion on the specific chemical be based on sufficient animal or human evidence. We believe this can be achieved, with a simpler language as follows:

(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 carcinogenic based on sufficient animal or human evidence.

Please consider this suggestion as you proceed with this rulemaking. Do not hesitate to contact us with any questions or concerns.

Sincerely,

Robert J. Fensterheim, MPH
Executive Director