

July 10, 2009

BY E-MAIL TO: coshita@oehha.ca.gov

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment (OEHHA)
P.O. Box 4010, MS-19B
Sacramento, California 95812-4010

In Re: Requests for Comments on Chemicals Proposed for Listing by the Labor Code Mechanism (carcinogens and reproductive toxins) published by OEHHA ("Agency") in the June 12, 2009 California Regulatory Notice Register

Dear Ms. Oshita:

On behalf of NPCA/FSCT, I am providing these comments of the Chemicals Proposed for Listing by the Labor Code Mechanism (carcinogens and reproductive toxins) that were published by OEHHA in the June 12, 2009 California Regulatory Notice Register.

NPCA/FSCT is a voluntary, nonprofit trade association representing some 300 paint and coatings manufacturers, raw materials suppliers and distributors plus several thousand professional members from throughout the country. As the preeminent organization representing the paint and coatings industry in the United States – some 95% of all coatings sold are manufactured by NPCA/FSCT member companies – NPCA/FSCT's primary role is to serve as ally and advocate on legislative, regulatory and judicial issues at the federal, state and local levels. In addition, NPCA/FSCT provides members with such services as research and technical information, statistical management information, professional development programs, legal guidance, and community service project support. (NPCA/FSCT requested, on July 3, 2009, that the 90-day comment period be extended, along with others, due to the complexities of this important proposed listing – a request denied July 2, 2009, via a form response, which attests to the Agency's general inflexible "mandatory ministerial duty," referencing two court rulings as its specific charge, while acknowledging that these are under appeal, and may be the subject of a motion for a stay of the listing process, by one of the parties.)

The proposed listing of a number of the chemicals identified in the notice raises serious procedural, legal and practical issues. In particular, we question whether the chemicals identified in the announcement meet the requirements specified in Health and Safety Code section 25249.8 to be identified as a chemical "known to the State to cause cancer or reproductive harm."

Labor Code Section 6382(b)(1) refers to "[s]ubstances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC)." However, IARC does not publish a list that identifies human or animal carcinogens, per se. IARC's evaluations are more complex and the issues surrounding the proper interpretation of those evaluations are central to

establishing whether in fact IARC determined that a substance should be considered a “human or animal carcinogen.”

In *AFL-CIO et al. v. GEORGE DEUKMEJIAN, as Governor, etc.* 212 Cal.App.3d 425 (1989), the California Court of Appeals established that, for the purpose of interpreting Labor Code Section 6382(b)(1), chemicals are to be listed if determined by IARC to be known human or animal carcinogens *and* that “sufficient evidence” of carcinogenicity is the equivalent of “known” carcinogenicity:

Nonetheless, both sides agree that for the purpose of interpreting the IARC monographs, “sufficient evidence” of carcinogenicity is the equivalent of “known” carcinogenicity.

The Court also recognized that the mere probability that an agent may be carcinogenic is not sufficient for listing:

... the question is not whether a chemical is “probably” carcinogenic to humans, but whether it is in fact a known carcinogen or reproductive toxin. The trial court found, and we agree, that only those chemicals that are known, and not merely suspected, of causing cancer or reproductive toxicity must be on the list. The IARC Group 1 substances, made up of chemicals for which there is sufficient evidence of carcinogenicity to humans, clearly are subject to the Act and were included in defendant's initial list.

Most important, the Court recognized that, with regards to IARC Group 2, only those chemicals that have “sufficient evidence” should be listed, not all IARC Group 2 chemicals:

IARC Group 2 and supplemental category chemicals as to which there is sufficient evidence that exposure causes cancer or reproductive toxicity in animals are also known carcinogens. Just as “sufficient evidence” (fn. 3, supra) with regard to Group 1 chemicals means “known carcinogenicity,” so also it means “known carcinogenicity” in respect to Group 2 and supplemental category chemicals which must therefore be included in the initial list.” (emphasis provided)

This decision by the Court of Appeals argues that it is critically important for OEHHA to assess whether IARC determined that there was *sufficient* evidence before adding a chemical to Proposition 65 based on the Labor Code listing mechanism. For example, IARC concluded that there was not sufficient evidence of carcinogenicity of vinyl acetate in **either** animals or humans, and states the following:

Humans: There is inadequate evidence in humans for the carcinogenicity of vinyl acetate.

Animals: There is limited evidence in experimental animals for the carcinogenicity of vinyl acetate.

This clearly indicates that adding vinyl acetate to Proposition 65 list based on the Labor Code listing mechanism is not appropriate. Were OEHHA to move forward incorporating by reference vinyl acetate and other chemicals that offer *inadequate* or *limited* evidence, the agency would be

abrogating its responsibility to undertake a rigorous science based review for any proposed listing.

At a minimum, OEHHA should defer listing any of the IARC Group 2B chemicals as part of the Labor Code listing mechanism until the appeals of *Sierra Club v. Schwarzenegger* have been resolved. A notice of appeal has been filed in the case, and the underlying legal issues associated with the scope of the Labor Code listing under Health & Safety Code § 25249.8 (a) will impact how the chemicals proposed for listing will ultimately be considered under Proposition 65.

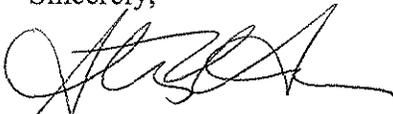
NPCA endorses the California Chamber of Commerce's Coalition comments dated July 2, 2009 which speak to the ongoing legal challenge, and emphasize, inter alia, that the Labor Code Mechanism is not a viable option for adding substances to the Proposition 65 list:

The Labor Code mechanism served its purpose for generating the initial Proposition 65 list, but its proposed new use as a method for continuing to add chemicals to the Proposition 65 list is unwarranted, contrary to good science, and not supported by statute.

We would also like to offer one additional technical comment on the listing of reproductive hazard chemicals identified by the American Conference of Governmental Industrial Hygienists (ACGIH) in its 2009 Threshold Limit Values (TLVs). ACGIH, in referencing a TLV for a reproductive hazard chemical, has undertaken a risk assessment to affirm that there is a human exposure level in the workplace that, if not exceeded, is protective of adverse reproductive outcomes. Exposures encountered in the workplace greatly exceed in intensity (magnitude and duration) those experienced by consumers using formulated products. This distinction is critical for OEHHA to consider in light of the fact that a TLV can be, and is, relied on throughout industry as protective. At a minimum, listing of a reproductive hazard chemical under Prop 65 that has such an established protective exposure level (ACGIH-TLV) should be acknowledged by OEHHA as having, *prima facie*, an established "safe harbor" level.

We strongly encourage OEHHA to consider a technically sound approach on the proposed chemicals for listing using the Labor Code mechanism. Appreciate that the recognition by the public, and those regulated alike, of all those Proposition 65 listings which are based on sound science, with sufficient evidence on the record as carcinogenic and/or reproductive toxicants, is essential for its to accomplish its statutory purpose; public trust and confidence in the regulatory regime as a whole is undermined drastically when *any* listing occurs which is insufficiently based as a result of a rush to scientific judgment and/or by corresponding rote Agency fiat.

Sincerely,



Stephen R. Sides
Vice President

Science, Technology and Environmental Policy
National Paint and Coatings Association, Inc.