

Environmental ADVISORY

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California Court Rejects Challenge to Listing of 4-MEI Pursuant to Proposition 65; Industry May Have an Obligation to Reformulate Products or Provide Warnings if Products Contain Certain Levels of 4-MEI by January 2012

A California court recently ruled that the California Office of Environmental Health Hazard Assessment within the California Environmental Protection Agency (OEHHA) properly added the chemical 4-methylimidazole (4-MEI) to the list of chemicals known to California to cause cancer. The listing, effective as of January 7, 2011, was made pursuant to the Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65").¹ As a result of the court's ruling, companies that utilize 4-MEI in products that include pharmaceuticals, dyes and pigments, or that manufacture foods that create 4-MEI through the heating or fermenting processes, may need to either reformulate their products or provide clear and reasonable warnings to the public if those products expose consumers to certain levels of 4-MEI. The warning obligation becomes effective on January 7, 2012.

The Listing of 4-MEI

Proposition 65 is a California law that requires the governor to publish a list of chemicals known to the state of California to cause cancer and birth defects or other reproductive harm. It is administered by OEHHA. Among other things, Proposition 65 requires that warnings be provided with consumer products that expose persons to listed substances. Proposition 65 is enforced through citizen lawsuits, in addition to lawsuits brought by the attorney general or other government prosecutors.

When California listed 4-MEI under Proposition 65, it also proposed to establish a no significant risk level (NSRL) at 16 micrograms per day. In October 2011, OEHHA modified the proposed NSRL, increasing it to 29 micrograms per day.² Pursuant to Proposition 65, companies selling products containing 4-MEI would be required to provide a "clear and reasonable" warning if the foreseeable use of the product could expose persons to 4-MEI above the NSRL. This warning can be given by a variety of means, such as by labeling a consumer product or by shelf labeling in stores.

4-MEI is fairly ubiquitous and is used in the manufacture of various products, including foods and beverages, pharmaceuticals, dyes, pigments and agricultural products; it is also created in certain foods through the heating or fermenting process. Like acrylamide, which has also been listed under

¹ California Health & Safety Code § 25249.5 *et seq.*

² For an update on the status of the listing of 4-MEI, see http://oehha.ca.gov/prop65/law/100711MEI_NSRL.html. For the text of the revised regulation and technical support document, see http://oehha.ca.gov/prop65/law/pdf_zip/1007114MEI.pdf#page6.

Proposition 65, foods containing 4-MEI as a result of heating or fermenting include coffee, some carbonated beverages, beer and wine, soy sauce, molasses and crackers.

Various Trade Associations Challenge the Listing

In February 2011, various trade associations sued the state of California to challenge the listing of 4-MEI. The basis for the challenge was that OEHHA's listing of 4-MEI was an improper application of Proposition 65's "authoritative body listing mechanism," implemented at 27 CCR Section 25306. This mechanism allows OEHHA to conclude that a chemical is known to California to cause cancer or reproductive toxicity if an "authoritative body" has "formally identified" the chemical as causing cancer or reproductive toxicity. Both "authoritative body" and "formally identified" are defined in Section 25306; in short, Section 25306 allows OEHHA to list a chemical pursuant to Proposition 65 if it has been formally identified as causing cancer by a body considered to be authoritative by the state's qualified experts. Here, OEHHA listed 4-MEI on the basis of conclusions drawn by the National Toxicology Program (NTP) that long-term animal studies conducted by NTP demonstrated that 4-MEI caused lung cancer in male and female mice and provided "clear evidence of carcinogenic activity." The trade associations contended that the NTP Technical Report did not support the listing because it "did not formally identify 4-MEI as causing cancer and did not provide sufficient evidence of carcinogenicity from studies in experimental animals" as required by Section 25306.

On November 21, 2011, the Sacramento County Superior Court ruled that the listing was valid.³ As described below, the court rejected each of the trade associations' arguments and found that OEHHA had acted well within its regulatory authority in relying on the NTP studies to support listing of 4-MEI.

First, the court rejected the trade associations' argument that the NTP Technical Report was inadequate because it failed to extrapolate the results of mice studies to humans, finding that the NTP Technical Report "provides sufficient evidence that the chemical causes cancer for purposes of listing under Proposition 65," because "the relevance of evidence of carcinogenicity from experimental animal studies does not require a specific evaluation to determine the relevance of the evidence" to humans. Indeed, the court evaluated applicable authorities and concluded that "an assessment of the human risk posed by a chemical like 4-MEI is not required for listing when OEHHA properly determines pursuant to Section 25306 that the chemical has been formally identified by an authoritative body as causing cancer on the basis of sufficient evidence of carcinogenicity from animal studies."

Second, the court was unconvinced by the trade associations' argument that the studies summarized in the NTP Technical Report do not constitute "sufficient evidence" of carcinogenicity within the meaning of Section 25603(e)(2). The court found that the NTP Technical Report clearly describes four separate experiments, one each for male and female rats and male and female mice, and that "each of the four experiments is separately summarized, reviewed and evaluated, and a separate conclusion about the strength of the experimental evidence of carcinogenicity is drawn for each

³ See *California League of Food Processors, et al. v. Office of Environmental Health Hazard Assessment, et al.*, Sacramento County Sup. Ct. Case 34-2011-80000784, Ruling on Submitted Matter (Nov. 21, 2011).

experiment.” The court therefore concluded that OEHHA’s interpretation of this evidence is well within the purview of OEHHA’s scientific expertise and does not conflict with applicable statutes.

Third, the court rejected the trade associations’ argument that the NTP Technical Report failed to consider all relevant animal data relating to the carcinogenicity of 4-MEI.

What’s Next For Business

The court’s November 21 ruling validating the listing means that beginning January 7, 2012, businesses that manufacture products containing 4-MEI that expose consumers to the chemical in amounts greater than the NSRL may be required to either reformulate such products or provide reasonable warnings to the public of the carcinogenic properties of those products. While the deadline for industry groups to appeal the court’s ruling has not passed, affected businesses should not count on further litigation staying the effective date of the listing and should be developing a compliance strategy.

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