



MANUFACTURER'S LAWSUIT SPOTLIGHTS SUBSTANCE LISTINGS UNDER CALIFORNIA'S PROP 65

by

Ann G. Grimaldi

About six months from now, Californians may start seeing Proposition 65 warnings on automotive parts, wall coverings, food plastic wraps and even shower curtains. Why? They all can contain di-isodecyl phthalate (“DIDP”), a chemical that the California Office of Environmental Health Hazard Assessment (“OEHHA”) listed on April 20, 2007 as a reproductive toxin under the California Safe Water and Toxic Enforcement Act, commonly referred to as Proposition 65. On June 7, 2007, Exxon Mobil Corporation, the only U.S. manufacturer of DIDP, asserted a legal challenge to the listing. Filed in Los Angeles County Superior Court, Exxon Mobil’s lawsuit¹ asserts that OEHHA has violated its own regulations pertaining to the listing of chemicals under Proposition 65. Exxon Mobil urges the court to declare that the listing is unlawful and to order OEHHA to rescind the listing. This lawsuit will test OEHHA’s listing procedure generally, as well as the scientific basis for listing DIDP. Should the lawsuit fail, a substantial ripple effect will result, at least in the form of Proposition 65 warnings on commonly used products where no warnings are actually necessary, and in the form of manufacturers seeking to reformulate those products – perhaps substituting less-studied chemicals.

Phthalates like DIDP are used ubiquitously as plasticizers to soften poly vinyl chloride and other plastics. Di(2-ethylhexyl)phthalate (“DEHP”), for example, is used in intravenous tubing, to make the tubing soft and flexible. Regulators around the world increasingly are scrutinizing phthalates, primarily because of potential reproductive effects caused by this class of chemicals. In fact, the EU has banned DEHP and two other phthalates from all children’s toys and childcare items, and has banned DIDP and other phthalates in children’s toys and childcare items that children can put in their mouths. Under a newly enacted law, California will impose a similar ban.

Perhaps it’s not surprising, then, that OEHHA also has occupied itself with phthalates. Since December 2005, OEHHA has listed butyl benzyl phthalate (“BBP”), di-n-butyl phthalate (“DBP”) and di-n-hexyl phthalate (“DnHP”), in addition to DIDP. OEHHA listed DEHP as a reproductive toxicant in 2003. Perhaps it’s not surprising, too, that industry would resist the listing of such widely used chemicals.

¹*Exxon Mobil Corp. v. Office of Environmental Health Hazard Assessment, et al.*, Los Angeles County Superior Court Case No. BS109343.

Here, Exxon Mobil’s legal challenge flows from the regulatory framework pursuant to which OEHHA makes listing decisions. The Proposition 65 implementing regulations establish two committees of outside experts, the Carcinogen Identification Committee (“CIC”) and the Developmental and Reproductive Toxicant Committee (“DART”). CAL. CODE REGS., tit. 22, § 12301. Among the duties of each Committee is the responsibility to “identify bodies which are considered to be authoritative and which have formally identified” carcinogens and reproductive toxicants. *Id.* at § 12305(a)(2), (b)(2). With respect to identification of chemicals that cause reproductive harm, DART has identified a number of authoritative bodies, including the National Toxicology Program’s Center for Evaluation of Risks to Human Reproduction (“NTP-CERHR”). *Id.* at § 12306(l), (m).

Under Proposition 65, OEHHA may list a chemical when an authoritative body formally identifies the chemical as causing cancer and/or reproductive toxicity. *Id.* at § 12306. This listing mechanism, usually referred to as the “authoritative body listing” mechanism, is a streamlined listing process. It acknowledges that it would be unnecessarily duplicative for the CIC or DART to render an opinion regarding the health effects of a chemical under another section of the Proposition 65 regulations, where an identified authoritative body already has rendered its own opinion on the matter using essentially the same scientific criteria.

The authoritative body listing mechanism involves a collaborative interaction between OEHHA and (depending on the health endpoint at issue for the chemical to be listed) the relevant Committee, where each in turn determines whether the statutory criteria for the particular proposed listing are satisfied. First, OEHHA must determine whether the candidate chemical has been formally identified by an authoritative body in a list, report or other document, and whether the authoritative body specifically and accurately identifies the chemical in that document. *Id.* at § 12306(d) and (d)(2). Next, the agency must determine that the authoritative body concluded that the chemical at issue “causes” the health effect of concern, as measured against specified criteria. *Id.* at § 12306(e), (g). Finally, the regulations require OEHHA to conclude that the chemical does *not* cause the health endpoint at issue, if scientifically valid data which were not considered by the authoritative body clearly establish that the chemical does not satisfy the criteria for “causing” the health effect of concern. *Id.* at § 12306(f), (h).

If the listing is to go forward, OEHHA must publish in the California Regulatory Notice Register and provide to the CIC or DART a notice that identifies the chemical as the subject of intended listing and the authoritative body whose statement caused the chemical to be proposed for listing. *Id.* at § 12306(i). The notice allows members of the public opportunity to comment and submit evidence why a chemical should not be listed; it also permits the Committees, as the State’s qualified experts, to render their respective opinions as to whether there is sufficient evidence to add the chemical to the Proposition 65 list. OEHHA may list the chemical only after considering and responding to the comments of the CIC or DART.

One of the fundamental questions presented in Exxon Mobil’s lawsuit is: What does it really mean to “cause” the relevant health effect under the authoritative body listing mechanism? Here, an expert panel assembled by the NTP-CERHR published a report titled “NTP-CERHR Expert Panel Report on Di-Isodecyl Phthalate” (the “Report”), following an extensive review of existing studies on the chemical. The Report concluded that there was “minimal concern” for DIDP’s potential to cause reproductive toxicity effects. The expert panel based its conclusion on (among other things) various animal studies, which showed a causal relationship between the chemical and reproductive effects – but only at doses and routes of exposure wholly irrelevant to humans. Put another way, the causal effect, as to humans, was purely hypothetical.

NTP-CERHR reviewed the Report and echoed the expert panel’s conclusion of “minimal concern.”

further finding that there was “negligible concern” for reproductive harm and that “DIDP will not adversely affect human reproduction.” The Report ultimately was incorporated into the April 2003 NTP-CERHR Monograph.

OEHHA proposed DIDP for listing in 2005, relying exclusively on the NTP-CERHR Monograph. Exxon Mobil objected to the proposed listing, providing additional information regarding DIDP’s physical characteristics that the NTP-CERHR expert panel did not consider. According to Exxon Mobil, other data presented to OEHHA also established that, even if DIDP were present in food at 1000 times its water solubility limit, the maximum theoretical amount of DIDP that can enter the human body is still at least 19 thousand-fold below the no observable adverse effect level (“NOAEL”) established by the animal studies reviewed by the NTP-CERHR expert panel. Other data provided to OEHHA showed that the maximum exposure to DIDP through other routes was 19 million times below the NOAEL, according to Exxon Mobil. Based on these and other data, Exxon Mobil asserted to OEHHA that there is no biologically plausible basis to conclude that DIDP “causes” reproductive harm within the meaning of the Proposition 65 regulatory scheme, and that therefore the proposed listing should not go forward.

OEHHA rejected Exxon Mobil’s arguments. Among other things, the agency responded that it is authorized to list chemicals solely on the basis of animal effects under the authoritative body mechanism, even where the authoritative body “does not discuss potential effects on human development.” OEHHA also stated that it is authorized to measure the basis for the authoritative body’s conclusion against the criteria, as articulated in Section 12306(g)(2) of the regulations, for determining that the association between the chemical and reproductive harm is biologically plausible.² Exxon Mobil disputes each of these assertions, and others, and counters that OEHHA has exceeded its authority.

Setting aside disputes over regulatory authority and other issues raised by Exxon Mobil’s lawsuit, it certainly seems odd to conclude that a chemical “causes” reproductive harm when what the authoritative body actually said was that the risk of such harm is “negligible” and of “minimal concern” to humans. No toxicologist, or any expert, speaks in absolutes. It would be most unexpected for a toxicologist to conclude that a chemical can *never* cause harm. The nearest an expert can come to such an expansive statement is what the NTP-CERHR expert panel said. Yet, OEHHA listed DIDP solely on the basis of the expert panel’s conclusion.

California voters passed Proposition 65 to, among other things, assist members of the public in making informed decisions about the products they use. Defending a Proposition 65 lawsuit is an expensive endeavor. Its plaintiff-friendly nature, combined with substantial civil penalties and significant monetary rewards for plaintiffs, creates incentives for businesses to provide warnings on products even where no

²Section 12306(g) provides that a chemical is formally identified “as causing reproductive toxicity” when one of the following criteria has been satisfied:

- (1) Studies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity, or
- (2) Studies in experimental animals indicate that there are sufficient data, taking into account the adequacy of the experimental design and other parameters such as, but not limited to, route of administration, frequency and duration of exposure, numbers of test animals, choice of species, choice of dosage levels, and consideration of maternal toxicity, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible.

CAL. CODE REGS., tit. 22, § 12306(g).

warnings are really needed. OEHHA's listing of DIDP perpetuates this over-warning phenomenon, initiating a cascade of requirements that ultimately could lead to Proposition 65 warnings on products, including even shower curtains, in the absence of any real risk to health. Such a result is entirely inconsistent with the law's goal.

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