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Calif. Prop 65 Proposals Are Bad Policy

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The California Office of Environmental Health Hazard Assessment, or OEHHA, has issued a proposed rule-making package that, if adopted, will change two critical statutory interpretations that food companies have successfully used to establish a key affirmative defense under the state's Proposition 65 law. The two provisions at issue, discussed below, specifically concern how a business can establish that the level of exposure to a chemical listed for reproductive effects is below the threshold — also known as the "maximum allowable dose level," or MADL — that triggers a Proposition 65 warning.

One proposed change, to be codified in Section 25821(a) of the Proposition 65 regulations, would prohibit food producers from averaging test results obtained from different manufacturers or even different manufacturing facilities in determining the relevant "level in question" (i.e., concentration level of a chemical in a product). The practical effect of such a regulation would be to require many food manufacturers to expand their chemical contaminant testing programs dramatically if they wish to preserve their right to even mount a "no significant risk defense" to a Proposition 65 claim made against them in the future.

The other, to be codified in Section 25821(c) of the regulations, would require companies to always use an arithmetic mean in determining the reasonably anticipated rate of intake (i.e., average consumption) of a food product. The practical import of this rule change would be to preclude companies from introducing scientific testimony that other superior statistical measures of central tendency better characterize the amount of a food average consumers eat.

Both changes are designed to undercut the First District California Court of Appeal published decision in Environmental Law Foundation v. Beech-Nut Nutrition Corp., et al.[1] In that precedent-setting decision, a unanimous panel of the California Court of Appeal affirmed the trial court's defense judgment that Proposition 65 birth defect and reproductive harm warnings were not required due to trace levels of lead in 100 percent fruit juice, packaged fruits and baby foods. Both the trial and appellate courts found that the level of lead exposure from the fruit, juice, and baby food products was below the associated Proposition 65 MADL for lead and, hence, sustained a major victory for sound science.

In Beech-Nut, expert witnesses for the defense used the "geometric mean" to calculate the average rate of intake of the food products at issue. The geometric mean is a statistical tool intended to correct heavily skewed data sets and regularly employed by scientists from the U.S. Environmental Protection Agency and the vast majority of academia. The experts provided persuasive evidence that the geometric mean is superior to the arithmetic mean that OEHHA now seeks to make mandatory because the consumption data for the products was otherwise artificially skewed by a few individuals with atypically high consumption rates. The testifying experts also showed that averaging test data on the level of lead in the food products across different ingredient sources and manufacturing facilities was representative because the trace levels of lead at issue reflected what consumers would be exposed to in the marketplace and were generally consistent with those observed over several decades by the U.S. Food & Drug Administration.

On this record, both the trial court and the court of appeal concluded that averaging test results across different suppliers and facilities and using the "geometric mean" were both elements of a "legally appropriate" exposure methodology for determining whether warnings for lead are under Proposition 65. Although it was a published decision and may therefore be cited as precedent, Proposition 65 plaintiffs and OEHHA disagreed with the court of appeal's analysis from the outset. Since its issuance in 2015, they have sought to undermine it both by litigation and regulation, including attacks on Proposition 65's longstanding MADL for lead (subsequently upheld by another unanimous court of appeal panel) and on the equally long-standing "extent of exposure" rules that have been part of Proposition 65's regulations since 1989.

For example, in the fall of 2015, OEHHA superseded its previously announced Proposition 65 rule-making priorities and requested public comment on a set of "pre-regulatory" proposals on potential changes to the long-standing Proposition 65 regulations that have never been mentioned prior to the court of appeal decision in Beech-Nut. In addition to proposing to mandate use of the arithmetic mean for extent of exposure calculations as it again does now, OEHHA then proposed to preclude averaging test results between lots of food products produced at various times, even within the same facilities, and to dramatically reduce the published MADL for lead relative to foods eaten daily or every other day. (Indeed, for foods consumed on a daily basis, the MADL for lead would have been reset at 0.2 micrograms/day under OEHHA's 2015 pre-regulatory proposals, a 60 percent reduction.) Although it is now proposing to formally advance two related rule changes, OEHHA has yet to respond to the plethora of public comments and substantial scientific evidence it received in response to its pre-regulatory proposals.

Likewise, earlier in 2015, lawyers who typically represent two of the most active Proposition 65 plaintiff's organizations sought a writ of mandate from the Alameda County California Superior Court to effectively depublish the 0.5 microgram/day MADL for lead that has been in the regulations since the chemical was first listed, on which the Beech-Nut defendants had relied. The trial court initially allowed this challenge to this regulation to proceed notwithstanding the fact that it was untimely given that the regulation had been published by the state as a final rule almost 30 years ago and been relied on by both plaintiffs and defendants in numerous cases and settlements since. However, when it got to the merits, the trial court subsequently ruled against the plaintiff, concluding that there was an adequate scientific foundation for the 0.5 microgram/day level all along. That decision was upheld by another unanimous First District California Court of Appeal decision earlier this year.[2]

OEHHA's currently proposed rule-making continues the agency's attack on the scientific principles that were relied on by the experts and courts in Beech-Nut, attributing the court of appeal's "incorrect conclusion" to a purported "lack of clarity" in the existing regulations. The agency's current proposals represent significant change to long-standing regulations that have stood the test of time and been relied upon by industry for both compliance and defense purposes. It reflects an apparent ideological conclusion that isolating sources and using the simple arithmetic mean is preferable — even with skewed data sets — because the result more conservatively represents the potential for the highest one-time aberrational exposures that a consumer may confront on a particular given day. This is bad science and bad policy.

OEHHA will hold a public hearing on its proposals on Nov. 19, 2018, at 10 a.m. and will accept written public comments until Nov. 26, 2018.

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Disclosure: Morrison & Foerster represented the defendants in Environmental Law Foundation v. Beech-Nut Nutrition Corp., et al. in both the trial and appellate courts.

[1] Environmental Law Foundation v. Beech-Nut Nutrition Corp., et al. (2015) 235 Cal.App.4th 307.

[2] Mateel Environmental Justice Foundation v. Office of Environmental Health Hazard Assessment (2018) 24 Cal.App.5th 220.