

# Client Alert

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## Another Major Earthquake: California Creates Big Fissures in Proposition 65 Regulations – Proposals Could Shatter Defenses

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In the midst of making Proposition 65's longstanding warning regulations far more onerous, and vexatious litigation far more likely, California's Office of Environmental Health Hazard Assessment (OEHHA) has unveiled still more new proposals that would undermine some of the few defenses available under the Act. The proposals include a potential change to OEHHA's longstanding Proposition 65 "safe harbor" level for lead and several major changes in the way the extent of exposure is calculated and how the "naturally occurring" exemption for foods is determined.

A common thread in many of these proposals is the plaintiff bar's opposition to enforcement of Proposition 65 being based upon the science proven up in our most recent Proposition 65 victory in the courts. That suit, *Environmental Law Foundation v. Beech-Nut Corporation, et al.*, 325 Cal.App.4th 307 (2015), sought to require birth defect warnings due to trace levels of lead in fruit juice, packaged fruit, and fruit- and vegetable-containing baby foods. Both the trial court and a unanimous Court of Appeal found in favor of our clients, holding that no warnings were required. The California Supreme Court recently denied review. Among other things, the trial and appellate courts found that it was scientifically appropriate to average contaminant levels in multiple product samples even when drawn from multiple lots. The courts also found that it was scientifically appropriate to average levels of product use over multiple days to estimate exposure levels.

OEHHA's new proposals essentially seek to nullify the important *Beech-Nut* precedents and will make it *even more difficult* for businesses to defend Proposition 65 claims about lead and the nearly 300 other chemicals listed for reproductive effects, especially those that may be present as trace contaminants in food products. OEHHA's proposals include the following four elements:

**1. Revised Safe Harbor for Lead and Other Chemicals.** OEHHA proposes to repeal the current safe harbor level for lead (the Maximum Allowable Dose Level or MADL). In its place, OEHHA proposes multiple levels that depend on the frequency of exposure, from exposure once per day to once every 116 or more days. OEHHA asserts that the once-per-day figure should be *reduced* from 0.5 to 0.2 micrograms/day and that the existing 0.5 microgram/day level should instead apply only to exposures that occur no more than once every third day. For exposures that would occur only once every 6 to 9 days, the lead safe harbor figure would rise to 1.0 microgram/day and to higher amounts as exposure intervals become more infrequent. Plaintiffs' groups contend that the lead safe harbor should be an order of magnitude lower at 0.03 micrograms per single day and do not want any alternative levels based on frequency of exposure over time. Despite its proposal for lead, *as to all other chemicals listed for reproductive effects*, without offering any scientific rationale, OEHHA proposes to eliminate any consideration of the frequency of exposure when safe harbor levels are applied.

# Client Alert

**2. Naturally Occurring Allowances for Lead and Arsenic in Some Foods.** In a bid to placate California agriculture that will likely be hotly contested by plaintiffs' groups and perhaps commodity producers from other states and abroad, OEHHA proposes to adopt several specific naturally occurring allowances for lead and arsenic (but not other chemicals such as cadmium) in some types of food ingredients/products commonly grown in California. The allowances for arsenic are 60 ppb and 130 ppb for white and brown rice respectively. For lead, they are 8.8 ppb for raw leafy vegetables and 6.2 ppb for raw non-leafy vegetables, fruit, meat, seafood, eggs, and fresh milk. The agency purportedly bases its proposal on data regarding background levels of lead in soil in California as well as rates of uptake by relevant plants. It is unclear from OEHHA's proposal whether the new allowances are also intended to reflect "the lowest level currently feasible," the definition of which was a hotly contested topic of litigation in *Beech-Nut*.

**3. Averaging of Product Samples.** OEHHA further proposes to expressly prohibit averaging lead or other contaminant levels across different lots of a food product in the final form it will be purchased by a consumer. This proposal expressly rejects the holdings of the *Beech-Nut* courts, which found that such averaging was reasonable and scientifically appropriate. It would instead require that the level of a contaminant in a lot of food be determined by "representative sampling" from within a particular lot. OEHHA also would define a "lot" on a production basis, apparently by reference to date or production codes, which could significantly increase the amount of testing required.

**4. Average Rate of Exposure.** Finally, OEHHA proposes to dictate that, as to any Proposition 65-listed chemical (lead or otherwise), the "average rate of exposure" must always be calculated based on the arithmetic mean and not a geometric mean or some other measure of the central tendency of a data set. OEHHA's proposal, offered with no justification, flies directly in the face of sound science, the prior position of the California Attorney General's office, and the decision of the trial court in *Beech-Nut*.

OEHHA has scheduled public hearings to further discuss its new proposals on October 14 and 19, 2015, in Sacramento. It is also inviting written public comment on the lead safe harbor issue until October 28, 2015, and on the averaging issues until November 2, 2015.

Morrison & Foerster has long been the leading law firm representing businesses in matters concerning Proposition 65, be they regulatory, litigation, enforcement, or compliance-oriented. We have more partners with more Proposition 65 experience than any other law firm, and they have participated in more rulemakings and litigated more cases under this unique statute than anyone else.

If we can be of assistance, please contact any of us:

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