

MEMORANDUM

From: Martin Hahn
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Re: OEHHA Proposes Significant Amendment on Determining the Daily Intake of Listed Chemicals as Causing Reproductive Toxicity

Last week, the California Office of Environmental Health Hazard Assessment (OEHHA), the lead agency that implements California's Proposition 65, proposed an amendment to the existing regulation requiring: (1) the average concentration of a listed chemical as causing reproductive toxicity (e.g., lead) be based on products from the same manufacturing facility; and (2) the dietary exposure to a listed chemical as causing reproductive toxicity be calculated using the arithmetic mean. ^{1/} If adopted, the proposed changes would overrule the court decision in *Environmental Law Foundation v Beechnut Nutrition Corp* on how to determine the daily intake of listed chemicals as causing reproductive toxicity. ^{2/} The change could impose additional testing requirements on the industry and could create a more rigid standard for falling within a safe harbor. We encourage food companies to evaluate whether the proposed changes would adversely impact their current Proposition 65 compliance positions.

Comments to the proposed regulation are due by November 19, 2018. In addition, a public hearing on the proposed amendment would be scheduled on request. To request a hearing, OEHHA needs to be notified no later than November 5, 2018.

Below, we discuss the proposed amendment in more details.

Background

By way of background, under California's Proposition 65, businesses are required to provide a "clear and reasonable" warning before knowingly and intentionally exposing anyone in California to a listed chemical on the Proposition 65 list. ^{3/} However, if the company can establish that the level of the listed chemical in a given product would result in a daily intake level that is within a "safe harbor," such a product is exempt from the warning requirements. ^{4/} The daily intake level is determined by

^{1/} A press release on the proposed amendment is available at:

<https://oehha.ca.gov/proposition-65/cnr/proposed-amendment-sections-25821a-and-c-level-exposure-chemicals-causing>.

^{2/} *Environmental Law Foundation v Beechnut Nutrition Corp. et al.*, (2015) 235 Cal.App.4th 307.

^{3/} Cal. Health & Safety Code § 25249.6.

^{4/} Cal. Health & Safety Code § 25249.10.

multiplying the “level of question” (a concentration of a chemical in the product) with the reasonably anticipated rate of exposure.

Under the existing regulation 27 CCR §25821, as well as the court’s interpretation of the regulation in *Environmental Law Foundation v Beechnut Nutrition Corp*, for purposes of assessing the daily intake of chemicals listed as causing reproductive toxicity, companies are allowed to use the average concentration of the listed chemical in products produced over significant time periods, geographic locations and producers, as well as the use of the geometric mean when calculating individual exposures to the chemical. The court in the *Beechnut* decision recognized that using geometric means, as opposed to arithmetic means, could help avoid the average intake data being “skewed” by a few outliers – consumer who consumed very high levels and do not represent average users. The current practice ensures the daily intake derived is “the reasonably anticipated rate of intake or exposure for average users of the consumer product...” ^{5/}

OEHHA’s Proposed Amendments

I. Section 25821(a) Average "Level of Concern"

The proposed action would amend Title 27, California Code of Regulations section 25821(a) by adding the following limitation to the existing provision:

“For purposes of this section, where a business presents evidence for the “level in question” of a listed chemical in a food product based on the average of multiple samples of that food, the level in questions may not be calculated by averaging the concentration of the chemical in food products from different manufacturers or producers, or that were manufactured in different manufacturing facilities from the product at issue.”

In its Initial Statement of Reasons, OEHHA noted that the amounts of listed chemicals in food products can vary significantly based on when and where the food was grown, processed, or packaged. As such, calculations of the concentration of a chemical in a food product for purposes of determining whether a warning is required should reflect an exposure that a consumer might reasonably receive from a product purchased at a specific time and place in California. OEHHA reasoned that if the concentration of a listed reproductive toxicant is high in one sample and low in another sample taken from a different location, averaging those concentrations could produce exposure estimates that bear little resemblance to the actual exposure an individual would experience from consumption of a particular product. Accordingly, the OEHHA’s proposed amendment would not allow the use of average concentrations of the chemical in food products from different manufacturers or producers or from products manufactured in different facilities.

The current practice of determining average concentration of chemicals in products from different manufacturers and facilities ensures the results are representative of the products that are available to Californian residents. The proposed amendment would force the industry to collect data from each facility that is producing products that could end up in the Californian market.

II. Section 25821(c) Geometric Intake

The proposed action would modify Section 25821(c)(2) to clarify that the reasonably anticipated rate of intake or exposure from a consumer product to a chemical listed as causing reproductive toxicity “is calculated as the arithmetic mean of the rate of intake or exposure for users of the product.” In its Initial Statement of Reasons, OEHHA noted that some consumers may use or consume a relatively large amount of a product, while other consumers may use the product in much smaller amounts.

^{5/} See 27 CCR Section 25821 (c)(2).

The existing regulation is silent about whether an average consumer's intake is to be characterized by the geometric mean, the median level, some other percentile, or the arithmetic mean. OEHHA reasoned that, because Proposition 65 is intended to warn Californians of significant exposure to listed chemicals, a determination of the exposures to a chemical in a food or consumer product should be based on the full range of exposures experienced by Californians. OEHHA concluded that the arithmetic mean is the most appropriate way of measuring the intake because it accounts for consumption levels at both the low and the high end of the range, weighing the intake of each consumer equally.

Consumer behavior necessarily varies and the anticipated rate of exposure for average users was adopted originally, in part, to avoid warnings based solely on occasional consumption at the highest levels. 6/ In the *Beechnut* case, during which the court ruled geometric means were allowed for intake assessment, the defendants' expert reasoned geometric means can help avoid the average intake data being "skewed" by a few outliers – consumers who ate a very high amount and do not represent how an average Californian consumer would consume the products. The court sided with the defendants and accepted the use of geometric means. OEHHA's proposal would overturn this important finding in the *Beechnut* case. We find this interpretation troubling and arguably inconsistent with OEHHA's own regulation that requires the level of exposure be calculated using "the reasonably anticipated rate of intake or exposure for average users of the consumer product..." 7/ Treating the few very high intake data points as equal with the other data points will not yield the reasonably anticipated rate of intake of exposure for average users.

The proposed amendment would set stricter criteria for Proposition 65 assessments. While we recognize the difference between the geometric and arithmetic means may amount to only a few grams in many instances, the use of the higher values could be the difference between compliance or non-compliance. Further, while the proposed amendment only relates to reproductive toxicants, not the listed chemicals as carcinogens (e.g., acrylamide), given the similar wordings of the Proposition 65 regulations on the reproductive toxicants and carcinogens, we are concerned the same interpretation may also be applied to the carcinogens on determining the daily intake, if the current proposal is adopted. We encourage companies to review the proposal and consider submitting comments.

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We will continue to monitor all developments on Proposition 65 regulation and litigation. Please contact us if you have any questions.

6/ June 1989 Final Statement of Reasons, pages 84-85, available at: <https://oehha.ca.gov/media/downloads/cnr/art78fsrjune1989.pdf>.

7/ See 27 CCR Section 25821 (c)(2).