

UPDATE: OEHHA EXTENDS PUBLIC COMMENT PERIOD FOR MULTIPLE AMENDMENTS TO PROPOSITION 65 REGULATIONS

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We previously reported that the Office of Environmental Health Hazard Assessment (“OEHHA”), the state agency responsible for implementing Proposition 65 (which requires businesses to warn consumers when the level of exposure from a consumer product exceeds a specific amount for a given chemical), is considering adopting a regulation that would establish background levels for certain chemicals, i.e., lead and arsenic, that are naturally present in unprocessed food. Our previous blog discussing the proposed regulation and its importance can be found here (<http://bicklawgroup.com/oehha-considering-regulation-establishing-background-levels-for-naturally-occurring-chemicals-in-food-including-lead>).

OEHHA’s pre-regulatory workshop for this potential new regulation remains scheduled for **October 14, 2015, from 1:00 p.m. to 4:00 p.m.** in the Coastal Hearing Room at the CalEPA Headquarters building at 1001 I Street in Sacramento. On September 23, 2015, however, OEHHA announced that the deadline to submit written comments on the proposed regulation has been extended from October 25, 2015 to **5:00 p.m. on November 12, 2015.**

On a related note, OEHHA also is considering adopting amendments to existing regulations in Section 25821 of the regulatory code (Title 27 of the California Code of Regulations) concerning determining the level of exposure to chemicals causing reproductive toxicity. OEHHA believes certain provisions of the existing regulation lack clarity because they do not specify procedures for calculating the concentration of a listed chemical, or “level in question,” in a food product.

In particular, OEHHA explains that Section 25821(a) – which defines the “level in question” as the chemical concentration of a listed chemical for the exposure in question – has been interpreted to allow for averaging of samples from various lots of food products that were gathered over extended periods of time and geographic areas. OEHHA further explains that Proposition 65 is focused on providing warnings for individual exposures to listed chemicals that occur via specific products or locations and that, because chemical concentrations can vary from lot to lot, it is inconsistent with this purpose to average concentrations of a listed chemical in food products that are manufactured in different locations or time periods. Therefore, the possible regulatory action would clarify that the concentration of a listed reproductive toxicant in a food product must be determined on the basis of a single lot of a product in the form it would likely be sold to the end-consumer and may not be averaged across lots from different locations, manufacturing runs, or time periods of production.

The proposed amendment would define a lot as that quantity of a food product having uniform characteristics and quality that is generated by one producer during a single production run, on a single processing line. While the definition of “lot” varies by product, regulatory agency, and location in the supply chain, OEHHA states that this definition is consistent with definitions and concepts used by the U.S. EPA, the California Department of Public Health, and the European Commission.

The possible amendment would not technically require food manufacturers to engage in any product testing but would provide guidance for how they could use existing quality control testing to address any duty they may have to provide Proposition 65 warnings. OEHHA

believes that food manufacturers should be able to feasibly incorporate Proposition 65 considerations into their existing quality control programs because OEHHA's approach to defining a lot is consistent with the methods used by U.S. FDA and the European Commission for the sampling of foodstuffs to test for a variety of adulterants and/or contaminants.

Finally, OEHHA also is considering a proposed regulatory amendment to clarify the method for calculating exposure for an average consumer to reproductive toxicants in a product. OEHHA has proposed a modification to Section 25821(c)(2) to specify that exposure of an average consumer shall be calculated by an arithmetic mean of daily intake or exposure for product users. The agency says the regulation as currently written does not clearly define how to determine average consumer exposure. The proposed change would specify that an arithmetic mean is the "appropriate metric," rather than a geometric mean, median value, or other calculation.

OEHHA contends that lack of clarity on the above issue can lead to incorrect determinations that product-related exposures are exempt from Proposition 65 warnings pursuant to Health and Safety Code section 24549.10(c) (which exempts exposures that will have no observable effect assuming exposure at one thousand (1000) times the level in question for substances known to the state to cause reproductive toxicity). OEHHA further contends that the geometric mean is not the appropriate metric for identifying average consumption levels of a food or consumer product because it underweights the rate of exposure of those people who consume significantly more of a food or product than more typical consumers. In most cases, use of the geometric mean will produce a lower average consumption amount than the arithmetic mean, which weights all the values for intake rate equally and does not discount exposure of people consuming nearer to the higher end of the range. OEHHA believes it is appropriate to weigh all individual consumers equally and, therefore, the reasonably anticipated rate of exposure for purposes of Proposition 65 should be calculated as the arithmetic mean.

Workshops on these proposed amendments to Section 25821 will be held on **October 19, 2015**, in the Auditorium in the Elihu Harris state building at 1515 Clay Street in Oakland, California. The workshop addressing subsection 25821(c) will be held at **10:00 a.m.** followed by the workshop on subsection 25821(a) from **1:00 p.m. to 4:00 p.m.** Interested parties are encouraged to attend the workshop and participate in the discussion. OEHHA has extended the deadline to submit written comments on the proposed modifications to Section 25821 from November 2, 2015, to **November 17, 2015, at 5:00 p.m.**

All written comments, including those regarding the proposed regulation to establish background levels for naturally occurring chemicals in food products, should be directed to:

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For further information, please visit http://www.oehha.ca.gov/prop65/CRNR_notices/index.html.