

**Proposed Amendments to Sections 25821(a) and (c)
(Title 27, California Code of Regulations):
Level of Exposure to Chemicals Causing
Reproductive Toxicity**

Public Hearing on Rulemaking
Office of Environmental Health Hazard Assessment
Oakland, California
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OEHHHA

SCIENCE FOR A HEALTHY CALIFORNIA

Background

- Implementing regulations adopted nearly 30 years ago
- Courts have had some difficulty interpreting regulations
- Need for clarity and consistency

Calculating Levels of Exposure

- Proposition 65 requires businesses to provide a warning for exposure to a listed chemical unless the level of exposure is below a specified amount (for reproductive toxicants, $1/1000^{\text{th}}$ of the No Observable Effect Level).
 - The level of exposure to a listed chemical is determined by multiplying the “level in question” (concentration of a chemical in a given medium) times the reasonably anticipated rate of exposure for an individual to a given medium.
 - For exposures to consumer products, the level of exposure is calculated using the reasonably anticipated rate of intake or exposure for average users of the product.

Section 25821. Level of Exposure to Chemicals Causing Reproductive Toxicity

Areas identified for clarification

- Proposition 65 statute and regulations [Section 25821(a)] do not specify procedures for determining the “level in question”.
- Proposition 65 statute and regulations [Section 25821(c)(2)] are not specific about how the intake or exposure of an average consumer is determined.

Proposed Amendments to Section 25821(a)

For purposes of the Act, “level in question” means the chemical concentration of a listed chemical for the exposure in question. The exposure in question includes the exposure for which the person in the course of doing business is responsible, and does not include exposure to a listed chemical from any other source or product. 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 question 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.



Proposed Amendments to Section 25821(c)(2)

For exposures to consumer products, the level of exposure shall be calculated using the reasonably anticipated rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population. This rate of intake or exposure is calculated as the arithmetic mean of the rate of intake or exposure for users of the product. The rate of intake or exposure shall be based on data for use of a general category or categories of consumer products, such as the United States Department of Agriculture Home Economic Research Report, Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion, where such data are available.



Proposed amendment to 25821(a)

- Provides specific parameters for measuring the concentration of a listed reproductive toxicant in a food product.
- Where a business can show that averaging the concentration of a chemical in a given food product is appropriate, the “level in question” may not be calculated by:
 - Averaging the concentration of the chemical in food products from *different manufacturers or producers*
 - Averaging the concentration of the chemical in food products that were *manufactured in different manufacturing facilities* from the product at issue.
- Helps to ensure that the “level in question” is representative of the food products an individual would typically be exposed to when purchasing and consuming a product in California.



Proposed amendment to 25821(c)(2)

- Identifies the arithmetic mean of measured intake rates or exposures as the average value of intake or exposure for users of a consumer product.
- The arithmetic mean
 - Takes into account the magnitudes of all measured values, weighting all values equally
 - Does not discount exposures near the high end of the range
 - Is an estimate of the expected (i.e., average) magnitude of intake or exposure
- Helps to ensure that the average value of intake or exposure for users of a consumer product is based on the full range of exposures experienced by Californians.

