
PRE-REGULATORY DRAFT – FOR DISCUSSION PURPOSES ONLY
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
PROPOSITION 65

**POSSIBLE AMENDMENTS TO SECTION 25821(c), LEVEL OF EXPOSURE TO
CHEMICALS CAUSING REPRODUCTIVE TOXICITY**

CALCULATING INTAKE OF THE AVERAGE CONSUMER OF A PRODUCT

**Office of Environmental Health Hazard Assessment
California Environmental Protection Agency**

August 28, 2015

The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Proposition 65 (hereinafter referred to as "the Act"), was enacted as a ballot initiative on November 4, 1986¹. The Act requires businesses to provide a warning prior to causing an exposure to a chemical listed as known to the state to cause cancer or reproductive toxicity. The Act also prohibits the discharge of listed chemicals to sources of drinking water. OEHHA, within the California Environmental Protection Agency, is the lead state entity responsible for the implementation of Proposition 65², and has the authority to adopt and amend regulations to further the purposes of the Act³.

The Act requires warning consumers when the level of exposure from a consumer product exceeds a specific amount for a given chemical. For purposes of Section 25249.10(c) of the Act, the level of exposure to a listed chemical shall be determined by multiplying the level in question (stated in terms of a 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 shall be calculated using the reasonably anticipated rate of intake or exposure for average users of the consumer product.

This possible regulatory action would amend Section 25821(c)(2) to clarify that the reasonably anticipated rate of intake or exposure to a listed chemical must be calculated as the arithmetic mean of daily intake or exposure for product users.

¹ The Safe Drinking Water and Toxic Enforcement Act of 1986. Health and Safety Code section 25249.5 *et seq.*

² Health and Safety Code section 25249.12 and Cal. Code of Regs., Title 27, section 25102(o).

³ Health and Safety Code, section 25249.12(a).

Section 25821(c).

The Act and existing implementing regulations are not specific about how the intake or exposure of an average consumer is to be determined. Lack of clarity on the above question can lead to incorrect determinations that product-related exposures are exempt from Proposition 65 warnings pursuant to Health and Safety Code 24549.10(c).

The possible regulatory action would amend Subsections 25821(c)(2) of the existing regulation to clarify how rates of intake and exposure are calculated for consumer product exposures. This amendment would clarify OEHHA's intent concerning the correct method for calculating the level of exposure to a listed chemical. The language in Section 25821(c)(2) would be amended to specify that the *arithmetic mean* of the intake or exposure level among consumer product users must be used to calculate the rate of intake or exposure for users of a consumer product.

Intakes or exposures vary for different product consumers, and can be represented by a distribution of values. The existing regulation is not clear about whether an average consumer is to be characterized by the geometric mean, the median level, some other percentile, or the arithmetic mean of consumer intakes. Clarifying that the arithmetic mean of the intake or exposure level for users of a consumer product is the appropriate approach helps the responsible business to correctly determine the rate of intake or exposure for average users of the consumer product and decide whether a warning is required for a given exposure.

Intake rates or exposures of a population of consumers naturally have a range from low to high. For example, some consumers may use or consume a large amount of a certain product on a given day, while other consumers may use considerably less. The range can be characterized by a distribution from lowest to highest exposures with the use of the familiar "bell-shaped" curve or a skewed curve indicating that some consumers use the product at much higher rates than others. For food intake rates, the distribution is most often skewed to the right as discussed in OEHHA, 2012⁴, especially Chapters 7 and 9. In other words, for many food products, a relatively small number of people consume the product at significantly higher amounts than other consumers of the product.

The geometric mean is often used for averaging very different types of measurements.

⁴ OEHHA (2012) Air Toxics Hot Spots Risk Assessment Guidelines. Technical Support Document for Exposure Assessment and Stochastic Analysis. Office of Environmental Health Hazard Assessment. Available at: http://www.oehha.ca.gov/air/hot_spots/tsd082712.html

(The geometric mean is calculated by multiplying the measurements together and then taking the nth root of the product, where “n” equals the number of measurements that were multiplied together.) The geometric mean could be acceptable for a rating system that scores products based on two or more criteria, such as price, availability and sales data. However, the geometric mean is not the appropriate metric for identifying average consumption levels of a food or consumer product. A single consistent measurement – e.g., amount of a food product eaten or ounces of a consumer product used on the day consumed – is used to calculate the average consumption amount.

This supports the use of the familiar arithmetic mean (calculated by adding measurements and then dividing by the number of measurements that were added) as the appropriate metric for identifying average consumption of a product by people using the product.

The geometric mean 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 exposures of people consuming nearer to the higher end of the range. OEHHA believes it is appropriate to weigh all individual consumers equally. Thus, the reasonably anticipated rate of exposure for purposes of Proposition 65 should be calculated as the arithmetic mean.

INPUT ON THE POSSIBLE CLARIFICATION

OEHHA is seeking public input concerning this potential clarification of the existing regulation. Based on public input during the public workshop and in written comments, OEHHA will determine whether to proceed with a formal rulemaking. The formal rulemaking proposal could change substantially from this pre-regulatory proposal. Stakeholders are encouraged to participate in all aspects of the rulemaking process.