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

POSSIBLE AMENDMENT TO SECTION 25821(a), LEVEL OF EXPOSURE TO
CHEMICALS CAUSING REPRODUCTIVE TOXICITY

MEASURING CONCENTRATIONS OF CHEMICALS IN PRODUCTS

Office of Environmental Health Hazard Assessment
California Environmental Protection Agency

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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.

This possible regulatory action would amend Title 27, Cal. Code of Regs., section 25821(a)⁴ to clarify that, for chemicals known to cause reproductive toxicity, the concentration of a listed chemical 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. Proposition 65 is focused on providing warnings for individual exposures to listed chemicals that occur via specific products or locations⁵. 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. The proposed amendment would clarify that the chemical concentration of a listed reproductive toxicant in a food product may not be averaged across lots from different locations, manufacturing runs or time periods of production.

The Act and implementing regulations in Section 25821 do not specify procedures for determining the concentration of a listed chemical, or "level in question", in a food product. Lack of clarity on this issue has led to the incorrect conclusion that the existing

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).

⁴ All further references are to sections of Title 27, Cal. Code of Regs., unless otherwise indicated

⁵ Health and Safety Code section 25249.6

regulations allow averaging of the measured concentrations of a listed chemical in a food product across lots manufactured in different states and countries, and over extended periods of time⁶. Since chemical concentrations can vary from lot to lot and, for most reproductive toxicants, exposure is to be evaluated for consumption on the day the food product is eaten, it is not consistent with the purposes of the Act to allow averaging across lots. If the concentration of a listed chemical is high in one lot and low in another lot, allowing the concentrations to be averaged over multiple lots could allow food-related exposures to a listed chemical to occur without a the required warning for reproductive toxicity. This is a particular concern if averaging is allowed across lots manufactured in different states and countries, and over extended periods of time. The results of such averaging can bear little resemblance to the actual exposure an individual incurs from consumption of food from an individual lot. Thus, the concentration of a given chemical in a single lot for a product as sold to the end-consumer is the appropriate basis of determining the need for a warning.

However, concentrations of listed chemicals within a single lot may vary, but such variation is not expected to be nearly as large as across lots. Given the impracticality of testing and providing warnings for individual food items, it is appropriate to provide for the use of the average lot concentration in determinations of exposure. Thus a representative sample of the lot or some other scientifically valid method can be used to characterize the average concentration of the lot. If composited samples are used, there should be multiple composited samples collected to allow for determination of variability. Established methods used by the US Food and Drug Administration (US FDA)⁷ may be appropriate for this purpose. The regulation therefore provides that the concentration of the listed chemical in the lot may be determined using a representative sample or other scientifically valid methodology for ensuring the concentration calculated accurately reflects the average concentration of the listed chemical in the lot.

Thus when representative sampling is used it is to be based on a set of samples that is capable of producing valid results with a reasonable margin of error. The sample size must be large enough to provide reliable information that reflects the larger lot, and may be a set of composite samples of similar quantities of incremental samples taken from individual places throughout the lot to appropriately reflect the heterogeneity of the lot.

Consistent with other regulatory agencies and common best practices of food producers and manufacturers, the possible regulatory 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 and regulatory agency and location in the supply chain, the possible amendment's definition is consistent with definitions and concepts used by the US FDA^{8 9}, the California Department of Public Health¹⁰, and the European

⁶ Environmental Law Foundation v Beechnut Nutrition Corp. et al., (2015) 235 Cal.App.4th, 307

⁷ US FDA, 2014 Investigations Operations Manual, Chapter 4, Sampling.

⁸ Title 21, Code of Federal Regulations, Chapter 1, Subchapter 3, Part 210, Section 210.3

Commission¹¹. Lots or batches are small traceable units of manufacture and are the result of:

- uniform manufacturing characteristics.
- production at a single manufacturing facility.
- production during a single production run. Many lots are from production runs less than 24 hours, some may extend over a few days.

The possible amendment would not require food manufacturers to engage in any product testing for purposes of Proposition 65. It would provide guidance for how food manufacturers could use existing quality-control testing to address any responsibilities they may have to provide Proposition 65 warnings. Food manufacturers should be able to feasibly incorporate Proposition 65 concerns into their existing quality-control programs, since OEHHA's approach to defining a lot is consistent with the methods used by US FDA and European Commission for the sampling of foodstuffs to test for a variety of adulterants and/or contaminants.

⁹ Memorandum of Understanding between the Food and Drug Administration Department of Health and Human Services of the United States of America and the National Food Authority of the Republic of the Philippines Concerning Various Food Products Exported to the United States of America

¹⁰ Cal. Code of Regs. Title 17, Section 12435, 12470, 12475

¹¹ Official Journal of the European Union, Commission Regulation (EC) No 333/2007 of 28 March 2007, Laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs, Annex Part A, March 29, 2007