

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

**SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
PROPOSITION 65**

**NOTICE OF PROPOSED RULEMAKING
TITLE 27, CALIFORNIA CODE OF REGULATIONS**

**PROPOSED AMENDMENT TO SECTIONS 25821(a) AND (c)
LEVEL OF EXPOSURE TO CHEMICALS CAUSING REPRODUCTIVE TOXICITY:
CALCULATING INTAKE BY THE AVERAGE CONSUMER OF A PRODUCT**

October 5, 2018

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to amend Title 27, Cal. Code of Regulations, Section 25821, subsections (a) and (c)(2), Level of Exposure to Chemicals Causing Reproductive Toxicity. This proposed regulatory action would amend subsection (a) to clarify that where a business presents evidence for the “level in question” of a chemical listed as causing reproductive toxicity 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 facilities from the product at issue. The proposed regulatory actions would also modify subsection (c)(2) to clarify that, when determining whether exposure to a reproductive toxicant in a consumer product requires a warning, that the reasonably anticipated rate of intake or exposure from consumer products to a chemical listed as causing reproductive toxicity be calculated as the arithmetic mean of the rate of intake or exposure for product users.

PUBLIC PROCEEDINGS

In order to be considered, **OEHHA must receive comments by 5:00 p.m. on November 19, 2018**, the designated close of the written comment period. All comments will be posted on the OEHHA website at the close of the public comment period.

The public is encouraged to submit written information electronically, rather than in paper form. Comments may be submitted electronically through our website at <https://oehha.ca.gov/comments>. Comments submitted in paper form can be mailed, faxed, or delivered in person to the address below.

Monet Vela
Office of Environmental Health Hazard Assessment
1001 I Street, 23rd Floor
P. O. Box 4010
Sacramento, California 95812-4010

Telephone: 916-323-2517

Fax: 916-323-2610

E-mail comments may be sent to P65Public.Comments@oehha.ca.gov ([link sends e-mail](#)). Please include "Calculating Intake" in the subject line when submitting emailed comments.

Please be aware that OEHHA is subject to the California Public Records Act and other laws that require the release of certain information upon request. If you provide comments, please be aware that your name, address and e-mail may be available to third parties.

A public hearing on this proposed regulatory amendment will be scheduled on request. To request a hearing, send an e-mail to Monet Vela at monet.vela@oehha.ca.gov or to the address listed above by no later than **November 5, 2018**. OEHHA will mail a notice of the hearing to the requester and interested parties on the Proposition 65 mailing list for regulatory public hearings. The notice will also be posted on the OEHHA web site at least ten days before the public hearing date. The notice will provide the date, time, and location of the hearing.

CONTACT

Please direct inquiries concerning the proposed regulatory action described in this notice to Monet Vela at (916) 323-2517, or by e-mail to monet.vela@oehha.ca.gov. Mario Fernandez is a back-up contact person for inquiries concerning processing of this action and is available at (916) 323-2635 or mario.fernandez@oehha.ca.gov.

AUTHORITY

Health and Safety Code section 25249.12

REFERENCE

Health and Safety Code sections 25249.5, 25249.6, 25249.9, 25249.10, 25249.11 and 25249.12

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

BACKGROUND

OEHHA is the state entity responsible for the implementation of Proposition 65¹. Proposition 65 prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the state to cause cancer or reproductive toxicity, without first giving clear and reasonable warning to such individual². The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into any source of drinking water³. Warnings are not required and the discharge prohibition does not apply when exposures are insignificant⁴. The Act requires a warning for a consumer when the level of exposure from a consumer product exceeds a specific amount for a given chemical. OEHHA has the authority to adopt and modify regulations as necessary to implement and further the purposes of Proposition 65⁵.

For purposes of Section 25249.10(c) of the Act, Title 27, Cal. Code of Regulations, Section 25821 requires that the level of exposure to a chemical listed as causing reproductive toxicity 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 is calculated using the reasonably anticipated rate of intake or exposure from a product for average users of the consumer product. This proposed action would amend Section 25821(a) to clarify that where a business presents evidence for the “level in question” of a chemical listed as causing reproductive toxicity 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 food products that were manufactured in different facilities. This proposed action would also amend Section 25821(c)(2) to clarify that for exposures to chemicals listed as causing reproductive toxicity from consumer products, the reasonably anticipated rate of intake or exposure to the chemical must be calculated as the arithmetic mean of the rate of intake or exposure for product users.

¹ The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 *et seq.*, commonly referred to as “Proposition 65”. Hereafter referred to as “Proposition 65” or “the Act”.

² Health and Safety Code section 25249.6

³ Health and Safety Code section 25249.5

⁴ Health and Safety Code sections 25249.9 and 25249.10

⁵ Health and Safety Code section 25249.12.

SPECIFIC BENEFITS OF THE PROPOSED REGULATION

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

Section 25821(a) does not specify procedures for determining the concentration of a listed chemical, or the “level in question”, in a food product. Lack of clarity on this issue has led to the incorrect conclusion that the existing regulations allow averaging of the measured concentrations of a listed chemical in a food product across products manufactured by different manufacturers, and from manufacturing facilities in different states and countries. This proposed regulatory action would amend Section 25821 to clarify that the level in question in a food product 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 facilities from the product at issue. In addition, the proposed regulatory action would amend Section 25821(c)(2) of the existing regulation to clarify how rates of intake and exposure are calculated for consumer product exposures. The existing regulation is not clear 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 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 properly decide whether a warning is required for a given exposure.

NO INCONSISTENCY OR INCOMPATIBILITY WITH EXISTING REGULATIONS

After conducting an evaluation for any related regulations in this area, OEHHA has determined that these are the only regulations dealing with calculating the levels of exposure to Proposition 65 chemicals listed as causing reproductive toxicity. Therefore, the proposed amendment is neither inconsistent nor incompatible with other existing state regulations. The regulatory amendment will not change the existing mandatory requirements on those businesses or state or local agencies, and does not address compliance with any other law or regulation.

LOCAL MANDATE/FISCAL IMPACT

Because Proposition 65 by its terms⁶ does not apply to local agencies or school districts, OEHHA has determined the proposed regulatory action would not impose a mandate on local agencies or school districts; nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. OEHHA has also determined that no nondiscretionary costs or

⁶ See Health and Safety Code section 25249.11(b).

savings to local agencies, state agencies, or school districts will result from the proposed regulatory action, nor will there be any costs or savings in federal funding to the state because of the proposed regulatory action.

EFFECT ON HOUSING COSTS

OEHHA has initially determined that the proposed regulatory action will have no effect on housing costs because it does not impose any new mandatory requirements on any business.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

The proposed regulatory action provides compliance assistance to businesses subject to the Act by clarifying an existing regulation and does not impose any mandatory requirements on those businesses. OEHHA has therefore made an initial determination that the adoption of this action will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

RESULTS OF ECONOMIC IMPACT ANALYSIS (Gov. Code section 11346.3(b))

OEHHA finds there will be no economic impact related to the clarifying regulatory amendment. The amendment does not impose any costs because it merely clarifies how the level of exposure of a listed chemical in a food product be calculated and specifies 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.

Creation or Elimination of Jobs within the State of California

The proposed regulatory action will not impact the creation or elimination of jobs within California. The action merely clarifies how the level of exposure to a listed chemical in a food product be calculated and specifies 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.

Creation of New Businesses or Elimination of Existing Businesses within the State of California

The proposed regulatory action will not impact the creation of new businesses or the elimination of existing businesses within California. The action simply clarifies how the level of exposure to a listed chemical in a food product be calculated and specifies 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.

The Expansion of Businesses Currently Doing Business within the State

OEHHA will not have a major impact on the expansion of businesses currently doing business within the state. The proposed action provides clarification on how the level of exposure to a listed chemical in a food product be calculated and specifies 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.

Benefits of the Proposed Regulation

Affected businesses will likely benefit from the proposed regulatory action because the amendment clarifies existing regulation and provides guidance for businesses that choose to determine the anticipated exposure level for users of a consumer product in order to take advantage of established safe harbor levels. This amendment will add more certainty in assessing whether reproductive toxicants in a consumer product result in exposures that require a warning under Proposition 65. The amendment will contribute to public health and safety by providing additional guidance to businesses about how to calculate the level of exposure of a chemical listed as causing reproductive toxicity in a food product for purposes of determining whether a warning is required under the Act, and thus benefit California residents by ensuring that warnings are provided for significant exposures to reproductive toxicants, thereby improving the public's ability to make informed decisions concerning the foods and consumer products they may choose to purchase.

CONSIDERATION OF ALTERNATIVES

Pursuant to Government Code section 11346.5(a)(13), OEHHA must determine that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to the attention of OEHHA, would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

EFFECT ON SMALL BUSINESSES

The proposed regulatory action will not adversely impact very small businesses because Proposition 65 is limited by its terms to businesses with 10 or more employees⁷.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS

OEHHA is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed

⁷ Health and Safety Code section 25249.11(b)

regulatory action. The action does not impose any new requirements upon private persons or business.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATIONS

OEHHA has prepared and has available for public review an Initial Statement of Reasons for the proposed regulation, all the information upon which the regulation is based, and the text of the proposed regulation. These documents are available on OEHHA's web site at www.oehha.ca.gov.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

The full text of any proposed regulation that is changed or modified from the express terms of this proposed action will be made available at least 15 days prior to the date on which OEHHA adopts the resulting regulation. Notice of the comment period on the revised proposed regulation and the full text will be mailed to individuals who testified or submitted oral or written comments at the public hearing, whose comments were received by OEHHA during the public comment period, and anyone who requests notification from OEHHA of the availability of such change. Copies of the notice and the changed regulation will also be available on the OEHHA Web site at www.oehha.ca.gov.

AVAILABILITY OF THE FINAL STATEMENT OF REASONS

A copy of the Final Statement of Reasons may be obtained, when it becomes available, from Monet Vela at the e-mail or telephone number indicated above. The Final Statement of Reasons will also be available on OEHHA's web site at www.oehha.ca.gov.

OFFICE OF ENVIRONMENTAL
HEALTH HAZARD ASSESSMENT

Allan Hirsch
Chief Deputy Director

Dated: October 5, 2018