

the Department 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 regulatory action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law. Interested persons are invited to present statements or arguments with respect to any alternatives to the changes proposed at the scheduled hearing or during the written comment period.

#### AVAILABILITY OF PROPOSED TEXT AND INITIAL STATEMENT OF REASONS

The Department has prepared and will make available the text and the Initial Statement of Reasons (ISOR) of the proposed regulations. The rulemaking file for this regulatory action, which contains those items and all information on which the proposal is based (i.e., rulemaking file) is available to the public upon request directed to the Department's contact person. The proposed text, ISOR, and Notice of Proposed Action will also be made available on the Department's website: [www.cdcr.ca.gov](http://www.cdcr.ca.gov).

#### AVAILABILITY OF THE FINAL STATEMENT OF REASONS

Following its preparation, a copy of the Final Statement of Reasons may be obtained from the Department's contact person.

#### AVAILABILITY OF CHANGES TO PROPOSED TEXT

After considering all timely and relevant comments received, the Department may adopt the proposed regulations substantially as described in this Notice. If the Department makes modifications which are sufficiently related to the originally proposed text, it will make the modified text, with the changes clearly indicated, available to the public for at least 15 days before the Department adopts, amends or repeals the regulations as revised. Requests for copies of any modified regulation text should be directed to the contact person indicated in this Notice. The Department will accept written comments on the modified regulations for at least 15 days after the date on which they are made available.

## TITLE 27. OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

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

#### 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

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, 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](mailto: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](mailto: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 website 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](mailto: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](mailto: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 65<sup>1</sup>. 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 individual<sup>2</sup>. 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 water<sup>3</sup>. Warnings are not required and the discharge prohibition does not apply when exposures are insignificant<sup>4</sup>. 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 65<sup>5</sup>.

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 ex-

<sup>1</sup> 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".

<sup>2</sup> Health and Safety Code section 25249.6.

<sup>3</sup> Health and Safety Code section 25249.5.

<sup>4</sup> Health and Safety Code sections 25249.9 and 25249.10.

<sup>5</sup> Health and Safety Code section 25249.12.

posure to the chemical must be calculated as the arithmetic mean of the rate of intake or exposure for product users.

#### **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 terms<sup>6</sup> 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 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.

<sup>6</sup> See Health and Safety Code section 25249.11(b).

**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 employees<sup>7</sup>.

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 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 website at [www.oehha.ca.gov](http://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 peri-

<sup>7</sup> Health and Safety Code section 25249.11(b).

od, 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 website at [www.oehha.ca.gov](http://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 website at [www.oehha.ca.gov](http://www.oehha.ca.gov).

TITLE 27. OFFICE OF  
ENVIRONMENTAL HEALTH  
HAZARD ASSESSMENT

SAFE DRINKING WATER AND TOXIC  
ENFORCEMENT ACT OF 1986  
PROPOSITION 65

AMENDMENT TO SECTION 25805  
SPECIFIC REGULATORY LEVELS:  
CHEMICALS CAUSING  
REPRODUCTIVE TOXICITY

MAXIMUM ALLOWABLE DOSE LEVELS FOR  
*n*-HEXANE, ORAL AND  
INHALATION ROUTES

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to establish two Proposition 65<sup>1</sup> Maximum Allowable Dose Levels (MADLs) for exposure to *n*-hexane by amending Section 25805(b) of Title 27 of the California Code of Regulations. The proposed oral MADL for *n*-hexane is 28,000 micrograms per day and the proposed inhalation MADL for *n*-hexane is 20,000 micrograms per day.

PUBLIC PROCEEDINGS

Any written comments concerning this proposed action, regardless of the form or method of transmission, must be received by OEHHA by 5:00 p.m. on **November 19, 2018**, the designated close of the written comment period. All comments received will be posted on

the OEHHA website at the close of the public comment period.

We encourage you to submit comments in electronic form, rather than in paper form. Comments may be submitted electronically through our website at <https://oehha.ca.gov/comments>. Hard-copy comments may be mailed, faxed, or delivered in person to the appropriate address below.

**Mailing Address:** Ms. Monet Vela  
Office of Environmental Health Hazard Assessment  
P.O. Box 4010, MS-2311F  
Sacramento, California 95812-4010  
Fax: (916) 323-2517

Street Address: 1001 I Street  
Sacramento, California 95814

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. Comments on all regulatory and other actions are routinely posted on our website. By sending us your comments you are waiving any right to privacy you may have in the information you provide. Individual commenters should advise OEHHA when submitting documents to request redaction of home address or personal telephone numbers. Names of commenters will not be redacted.

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](mailto:monet.vela@oehha.ca.gov) or to the address listed above by no later than **November 5, 2018**, which is 15 days before the close of the comment period. OEHHA will send a notice of the hearing to the requester and interested parties on its Proposition 65 email list for regulatory public hearings. The notice will also be posted on the OEHHA website 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, in writing at the address given above, via e-mail to [monet.vela@oehha.ca.gov](mailto:monet.vela@oehha.ca.gov) or (916) 323-2517. Mario Fernandez is the back-up contact. He can be reached at (916) 323-2635 or [mario.fernandez@oehha.ca.gov](mailto:mario.fernandez@oehha.ca.gov).

<sup>1</sup> The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq., referred to herein as "Proposition 65" or "The Act."