

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

**NOTICE OF PROPOSED RULEMAKING**

**TITLE 22, CALIFORNIA CODE OF REGULATIONS**

**AMENDMENT TO SECTION 12705.  
SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK**

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment proposes to establish a specific regulatory level posing no significant risk for acrylamide and amend Title 22, California Code of Regulations, Section 12705(b). Upon adoption, this proposed level would supersede the regulatory level for acrylamide established in 1990 in Section 12705(c).

**PUBLIC PROCEEDINGS**

A public hearing will be held on **Tuesday, May 24, 2005**, at which time any person may present statements or arguments orally or in writing relevant to the action described in this notice. The public hearing will commence at 10:00 a.m. in the Byron Sher Auditorium, California Environmental Protection Agency Building, 1001 I Street, 2<sup>nd</sup> Floor, Sacramento, California and will last until all business has been conducted, or until 5:00 p.m.

Any written statements or arguments regardless of the form or method of transmission must be received by OEHHA by 5:00 p.m. on **Tuesday, May 24, 2005**, which is hereby designated as the close of the written comment period.

Written comments regarding this proposed action can be sent by mail or by fax addressed to:

Susan Luong  
Office of Environmental Health Hazard Assessment  
Proposition 65 Implementation Program  
P. O. Box 4010  
Sacramento, California 95812-4010  
FAX: (916) 323-8803  
Telephone: (916) 445-6900

Comments sent by courier should be delivered to:

Susan Luong  
Office of Environmental Health Hazard Assessment  
1001 I Street, 19<sup>th</sup> Floor  
Sacramento, California 95814

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Comments may also be transmitted via email addressed to: ([sluong@oehha.ca.gov](mailto:sluong@oehha.ca.gov)).

It is requested but not required that written statements or arguments be submitted in triplicate.

If you have special accommodation or language needs, please contact Susan Luong at (916) 445-6900 or [sluong@oehha.ca.gov](mailto:sluong@oehha.ca.gov) by May 10, 2005. TTY/TDD/Speech-to-Speech users may dial 7-1-1 for the California Relay Service.

## CONTACT

Please direct inquiries concerning the substance and processing of the action described in this notice to Susan Luong, in writing at the address given above, or by telephone at (916) 445-6900. Ms. Cynthia Oshita is a back-up contact person for inquiries concerning processing of this action and is available at the same telephone number.

## INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq. and commonly known as Proposition 65 (hereinafter referred to as 'Proposition 65' or 'the Act'), 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 cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code Section 25249.6). The Act also prohibits such persons 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 (Health and Safety Code Section 25249.5).

For chemicals known to the State to cause cancer, an exemption from the warning requirement and the discharge prohibition is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which he or she is responsible poses no significant risk, or that a discharge to drinking water which otherwise complies with applicable requirements would result in an exposure through drinking water at a level which poses no significant risk (Health and Safety Code Sections 25249.9 and 25249.10). A determination that a level of exposure poses no significant risk of cancer may be made by referencing Title 22, California Code of Regulations sections 12701 to 12721.<sup>1</sup> Section 12701 describes alternative methods for making a determination that a given exposure poses no significant risk. One such method is through the application of a specific regulatory level established for the chemical in question, if one has been established in Section 12705. The levels set in Section 12705(b) supersede the levels established in Section 12709 (Exposure to Trace Elements) and Section 12711 (Levels Based on State or Federal Standards).

This proposed regulation sets forth a no significant risk level (NSRL) for acrylamide that OEHHA proposes to adopt into Section 12705(b). This proposed NSRL would supersede the NSRL for acrylamide which is currently established in Section 12705(c). The proposed NSRL

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<sup>1</sup> All further references are to Title 22 of the California Code of Regulations, unless otherwise indicated.

was developed by OEHHA staff using scientific methods consistent with procedures outlined in Section 12703.

Details on the basis for the proposed number are provided in the reference cited below, which is also included in the rulemaking record. The reference is a risk assessment document prepared by OEHHA describing and summarizing the derivation of the regulatory level listed below. The proposed level described below for inclusion in Section 12705 represents the level of exposure to the chemical which is calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming exposure over a 70-year lifetime ( $10^{-5}$  lifetime risk of cancer).

This proposed regulation adopts the following NSRL into Section 12705(b) for acrylamide, a chemical known to cause cancer:

Chemical	NSRL, in units micrograms per day	Reference
Acrylamide	1.0	OEHHA (2005)

Levels established for carcinogens in Section 12705(b) supersede any existing levels for these carcinogens in Section 12705(c) and Section 12705(d) and this NSRL supercedes the level set for acrylamide in 1990 in Section 12705 (c).

The risk assessment which was used by the Office of Environmental Health Hazard Assessment to determine the stated level is as follows:

Office of Environmental Health Hazard Assessment (OEHHA, 2005). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen Acrylamide. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, March 2005.

#### AUTHORITY

Health and Safety Code Section 25249.12.

#### REFERENCE

Health and Safety Code Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11.

#### IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS

The Office of Environmental Health Hazard Assessment (OEHHA) has determined the proposed regulatory action would not pose 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

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costs or savings to local agencies or school districts will result from the proposed regulatory action.

#### COSTS OR SAVINGS TO STATE AGENCIES

OEHHA has determined that no savings or increased costs to any State agency will result from the proposed regulatory action.

#### EFFECT ON FEDERAL FUNDING TO THE STATE

OEHHA has determined that no costs or savings in federal funding to the State will result from the proposed regulatory action.

#### EFFECT ON HOUSING COSTS

OEHHA has determined that the proposed regulatory action will have no effect on housing costs.

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

OEHHA has made an initial determination that the adoption of the regulation 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. OEHHA believes the proposed amendments to the regulation will provide clarity and certainty for businesses that must comply with Proposition 65.

#### IMPACT ON THE CREATION, ELIMINATION, OR EXPANSION OF JOBS/BUSINESSES

OEHHA has determined that the proposed regulatory action will not have any impact on the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

#### COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

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

#### EFFECT ON SMALL BUSINESSES

OEHHA has determined that the proposed regulation will not impose any requirements on small business. Rather, the proposed regulation will assist small businesses subject to the Act in determining whether or not an exposure for which they are responsible is subject to the warning requirement or discharge prohibition.

#### CONSIDERATION OF ALTERNATIVES

In accordance with 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 or would be as effective and less burdensome to affected private persons than the proposed action.

#### 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 regulation, all the critical information upon which the regulation is based, and the text of the regulation. A copy of the Initial Statement of Reasons, a copy of the text of the regulation and copies of the risk assessment which was used by OEHHA to determine the NSRL is available upon request from OEHHA's Proposition 65 Implementation Program at the address and telephone number indicated above. This document is also posted on OEHHA's Web site at [www.oehha.ca.gov](http://www.oehha.ca.gov).

AVAILABILITY OF CHANGED OR MODIFIED TEXT: The full text of any regulation which is changed or modified from the express terms of the 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 changed regulations 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 who request notification from OEHHA of availability of such change. Copies of the notice and the changed regulation will also be available at the OEHHA's Web site at [www.oehha.ca.gov](http://www.oehha.ca.gov).

#### FINAL STATEMENT OF REASONS

A copy of the Final Statement of Reasons may be obtained, when it becomes available, from OEHHA's Proposition 65 Implementation Program at the address and telephone number indicated above. The Final Statement of Reasons will also be available at the OEHHA's Web site at [www.oehha.ca.gov](http://www.oehha.ca.gov).

OFFICE OF ENVIRONMENTAL  
HEALTH HAZARD ASSESSMENT

Joan E. Denton, Ph.D.  
Director

Dated: April 8, 2005

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