

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

NOTICE OF PROPOSED RULEMAKING

TITLE 22, CALIFORNIA CODE OF REGULATIONS,  
AMENDMENTS TO SECTION 12601:  
CLEAR AND REASONABLE WARNINGS

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to amend Title 22, California Code of Regulations, Section 12601 to add new "Safe Harbor" provisions specific to warnings for acrylamide exposures from food.

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, at the 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 at the following address 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 may be sent by mail or by facsimile and should be 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

Comments may also be transmitted via email ([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

Inquiries concerning the substance and processing of the action described in this notice may be directed to Susan Luong, in writing at the address given above, or by telephone at (916) 445-6900. Ms. Cynthia Oshita is a back-up 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, 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 an 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). Implementing regulations were adopted in Title 22, California Code of Regulations, Section 12601, to interpret and make specific the "clear and reasonable" warning requirement.

The existing regulations establish criteria and prescribe specific messages and methods for consumer product, occupational and environmental exposure warnings that are deemed by OEHHA to be in compliance with the "clear and reasonable" warning requirement specified in the Act. Under the existing criteria, a warning is "clear" if it clearly communicates that the chemical in question is known to the State to cause cancer, or birth defects or other reproductive harm, and "reasonable" if the method employed to transmit the message is reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure.

The proposed amendment to Section 12601 would add provisions to the regulation specifically for the purpose of giving warnings for exposures to the chemical acrylamide in foods. In April 2002, acrylamide was discovered to be present in starchy foods cooked or heat processed at high temperatures. Given the pervasiveness of the chemical in many common foods and the public health necessity of encouraging people to consume a balanced diet, OEHHA determined that the development of a specific “safe harbor” warning for acrylamide in foods would provide assistance to the regulated community to help them comply with the Act and would provide the public with a more balanced and appropriate warning message for exposures to this chemical in foods. The proposed regulation also expressly provides that a warning for acrylamide in foods may be provided at the point of sale of the food product and need not be included on package labels for each individual product.

#### AUTHORITY

Health and Safety Code section 25249.12.

#### REFERENCE

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

#### IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS

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 costs or savings to local agencies or school districts will result from the proposed regulatory action because Proposition 65 does not impose any duty on local agencies or school districts.

#### 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 because state agencies are not subject to the warning or discharge provisions of the Act.

#### 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 on directly affected businesses, including the ability of California businesses to compete with businesses in other states. The proposed regulation is intended to assist regulated businesses in providing clear and reasonable warnings for acrylamide exposures from foods and thereby comply with the requirements of the Act.

## 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 with 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 regulatory action will assist small businesses subject to the Act in determining whether or not a given warning satisfies the “clear and reasonable” warning criteria specified in the Act.

## CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5(a)(13), OEHHA must determine that no reasonable alternative considered by the office, or that has otherwise been identified and brought to the attention of the office 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 information upon which the regulation is based, and the text of the regulation. A copy of the initial statement of reasons and a copy of the text of the regulation is available upon request from OEHHA’s Proposition 65 Implementation

Program at the address and telephone number indicated above. These documents are 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 are also 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 is also 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