

INITIAL STATEMENT OF REASONS
TITLE 22, CALIFORNIA CODE OF REGULATIONS

SECTION 12601. CLEAR AND REASONABLE WARNINGS

The Safe Drinking Water and Toxic Enforcement Act of 1986¹ (hereinafter 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 the State to cause cancer or reproductive toxicity without first giving a clear and reasonable warning to such individual (Health and Safety Code section 25249.6). Implementing regulations were adopted in Title 22, of the California Code of Regulations, Section 12601² to interpret and make specific the “clear and reasonable” warning requirement.

Section 12601 establishes general criteria for “clear and reasonable” warnings. It also prescribes specific messages and methods for consumer product, occupational, and environmental exposure warnings that have been determined by OEHHA to comply with the “clear and reasonable” warning requirement specified in the Act. Persons using these “safe harbor” messages and methods are assured that such warnings are in compliance with the Act. The regulation does not preclude the use of any other warning method or message that can be demonstrated to provide a clear and reasonable warning.

A warning is considered “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 is “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. Warnings for exposures to chemicals listed under the Act are required to be given without qualification before an exposure above the specified risk level occurs.

Section 12601

The proposed amendments to Section 12601 would add provisions to the regulation specifically for the purpose of giving warnings for exposures to acrylamide in foods. In April 2002, acrylamide was discovered to be present in many starchy foods cooked or processed at high temperatures including fried potatoes, potato chips, crackers, cookies, coffee, breads and cereals. 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 assist the regulated community to comply with the Act and would provide the public with a more balanced and appropriate warning message. The proposed amendments also provide that a warning for acrylamide in foods may be posted at the point of sale or point of display of the affected food products and need not be included on package labels for each individual product.

¹ Health and Safety Code section 25249.5 et seq.

² All further references are to Title 22 of the California Code of Regulations, unless otherwise indicated.

Specifically, the proposed amendments would add subsection (b)(1)(E) to Section 12601. The new subsection provides that warnings for acrylamide in foods that are sold primarily for consumption off-premises (i.e. at grocery or convenience stores) may be provided by posting warning notices at each point of sale, or point of display of the product within the store. This provision is similar to the existing subsection (b)(1)(D) establishing “safe harbor” warnings for alcoholic beverages. The new subsection further provides that for businesses such as restaurants, the new warning being established for acrylamide in foods may be posted or in the alternative, the restaurant may use the warning provided in the existing subsection (b)(4)(C).

The amendments provide specific language that must be included in the warning for acrylamide exposures from food. This language is designed to provide a balanced message to consumers concerning the presence of acrylamide in foods. The warning language specifies the cooking methods that are known to cause acrylamide to form in foods, specifies cooking methods that are not known to cause acrylamide to be formed in foods, provides the current advice available from the U.S. Food and Drug Administration (FDA) concerning eating a balanced diet, and provides references to the FDA and OEHHA web sites so that interested consumers can easily locate more information. OEHHA believes that the proposed warning language will provide the necessary clear and reasonable warning required by Proposition 65, while not unduly alarming or confusing consumers. Given the fact that many different types of foods contain acrylamide in amounts in excess of the no significant risk level (NSRL,) providing the warning notice at the point of sale or the point of display may help reduce consumer confusion and will also ensure that the warning notice does not interfere with any mandatory labeling requirements for food that may be imposed by the FDA or other regulatory agencies.

Due to the ubiquitous nature of this chemical in foods, OEHHA has determined that it would not be feasible or practical to list every type of food that might cause an exposure to acrylamide in the warning notice.

The proposed amendments to Section 12601 further provide that all warnings given pursuant to the new subsection must be clearly visible to consumers, that retail establishments are free to supplement the warning notice with other information, and that the warning language provided in the new subsection may be used for individual product labels if the manufacturer chooses to include it on the product packaging or the warning language provided in the existing regulations may be used on individual products. Proposition 65 does not require warning labels on individual food products. Thus the proposed regulation provides the maximum level of flexibility for regulated businesses as they determine what is the most efficient and cost effective method to use in communicating the required warning. OEHHA believes that supplementing the warning notice with additional information such as lists of foods that contain acrylamide would be advisable. Retailers may wish to download information from the OEHHA or FDA web sites for distribution to customers.

In addition a nonsubstantive change is made in Section 12601(b)(4)(C) to reflect the current citation reference for Health and Safety Code section 27521(a) which was renumbered to section 113785(a).

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS.

OEHHA conducted an extensive public process to develop a work plan for addressing issues related to the discovery of acrylamide in foods. Based on the information received through that process from the general public, the regulated community, the FDA and review of the existing scientific information available concerning acrylamide, OEHHA has developed these proposed regulations establishing a special “safe harbor” warning for acrylamide exposures in foods. OEHHA particularly focused on information available on the FDA web site (WWW.FDA.GOV) concerning acrylamide levels in foods. The current FDA advice concerning the finding of acrylamide in foods is included in the proposed warning. OEHHA also developed a document entitled “Characterization of Acrylamide Intake from Certain Foods” which is included in the rulemaking file and was relied on for the development of the proposed warning regulation that integrates information from FDA as well as the U.S. Department of Agriculture concerning average food consumption rates.

REASONABLE ALTERNATIVES TO THE REGULATION AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES.

OEHHA is not aware of any reasonable and legally feasible alternatives to the proposed regulatory action other than taking no action at all. This regulation does not have mandatory effect on regulated businesses and is offered instead as a service to those businesses to assist them in complying with the “clear and reasonable” warning requirement of the Act.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESSES.

OEHHA has not identified any alternatives that would lessen any adverse impact on small businesses. For the reasons stated below, OEHHA believes there should be no adverse impact on small business, or any business, related to these proposed regulations.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON ANY BUSINESS.

The proposed regulatory 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. The proposed amendment does not impose any mandatory requirement upon private persons or business. In fact, the proposed regulatory action is intended to make it easier for affected businesses to comply with Proposition 65 warning requirements by providing specific provisions in the “safe harbor” warning regulations for acrylamide exposures from foods that can be used by businesses if they choose to do so.

DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS CONTAINED IN THE CODE OF FEDERAL REGULATIONS.

Proposition 65 is a California law that has no federal counterpart. OEHHA is not aware of any federal laws or regulations specifically prescribing the method, form or content for warnings regarding exposures to known carcinogens in foods. Thus, OEHHA believe there is no duplication of, or conflict with, federal law or regulations. OEHHA has communicated with staff at the FDA in an effort to avoid conflict with or duplication of any federal law concerning acrylamide in foods. FDA is considering its official position concerning the proposed regulations. However, the FDA has not cited, and OEHHA is not aware of, any federal law or regulation that specifically governs warnings for acrylamide in food that would directly conflict with or preempt the “safe harbor” warning regulations being proposed in this notice. Additionally, the federal Food and Drug Administration and Modernization Act of 1997 (Pub.L. No. 105-110, 111 Stat. 2296, section 379r(a)), exempts Proposition 65 from the statutes express preemption of state laws governing labeling and other requirements relating to food and drug products. Therefore, OEHHA is proceeding with this proposal to adopt “safe harbor” warning regulations for acrylamide in foods.