

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
SAFE HARBOR WARNINGS FOR ACRYLAMIDE EXPOSURE FROM FOOD
PROPOSED AMENDMENT TO
SUBSECTION 25607.2(b)
FOOD EXPOSURE WARNINGS - CONTENT

April 5, 2024

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes amend Article 6 of Title 27 of the California Code of Regulations, section 25607.2.¹ This proposed rulemaking would amend subsection (b) to provide an additional safe harbor warning option, for businesses that cause significant exposures to acrylamide in food products.² This would be in addition to the applicable safe harbor warnings that already apply to such exposures under existing law. The warning content and methods provided in the safe harbor regulations are deemed “clear and reasonable” by OEHHA for purposes of the Act.

PUBLIC COMMENTS

To be considered, **OEHHA must receive comments by May 20, 2024**, the designated close of the written comment period. All written comments will be posted on the OEHHA website at the close of the public comment period.

OEHHA strongly recommends that the public submit written information electronically, rather than in paper form. Comments may be submitted electronically through our

¹ All further references are to sections of Title 27, Cal. Code of Regs., unless indicated otherwise.

² A current rulemaking noticed on October 27, 2023, Office of Administrative Law file no. 2023-1017-03, would also amend section 25607.2. In that proposal, existing subsection (b) would be renumbered to (c). If that rulemaking is finalized before this proposal, that non-substantive change will affect the numbering of this proposal.

website at <https://oehha.ca.gov/comments>. In the alternative, comments can be mailed to the address below.

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Office of Environmental Health Hazard Assessment
1001 I Street, 23rd Floor
P. O. Box 4010
Sacramento, California 95812-4010
Telephone: 916-323-2517

OEHHA encourages all commenters to submit their comments in a format compliant with the accessibility requirements of the Americans with Disabilities Act, so that they can be read using screen reader technology and those with visual impairments are able to listen to them.

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.

PUBLIC PROCEEDINGS

A public hearing on these proposed regulatory amendments will only be scheduled upon 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 **May 6, 2024**. If one is scheduled, 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 instructions for participating in 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. Corey Friedman is a back-up contact person for inquiries concerning processing of this action and is available at (916) 323-2635 or corey.friedman@oehha.ca.gov.

AUTHORITY

Health and Safety Code section 25249.12.

REFERENCE

Health and Safety Code sections 25249.6 and 25249.11.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

BACKGROUND AND SUMMARY OF EXISTING LAWS

OEHHA is the lead agency that implements Proposition 65 and has the authority to promulgate and amend regulations to further the purposes of the Act.³ The Act requires businesses to provide a clear and reasonable warning before they cause an exposure to a chemical listed as known to the state to cause cancer or reproductive toxicity.⁴ The Act also prohibits the discharge of listed chemicals to sources of drinking water.⁵ The proposed amendment would adopt new safe harbor warning content for exposure to acrylamide from food.

Under Proposition 65, when a product exposes a consumer to a cancer-causing chemical, a business must first provide a “clear and reasonable” warning (Health & Safety Code §25249.6), unless the level of exposure does not pose significant risk. To reduce the burden on businesses, they may rely upon the safe harbor warnings promulgated by OEHA, which are presumptively clear and reasonable. (27 CCR § 25601.) The safe harbor warnings are not required by law, and businesses may develop their own “clear and reasonable” warnings. However, many businesses use the safe harbor warnings to avoid the risk of litigation over whether a given warning is “clear and reasonable.”

Existing safe harbor warnings applicable to such exposures would still be available for businesses. These warnings may be found in the existing section 25607.2(a) [general warning for food exposures] and 25607.2(b) [warning for food exposures to acrylamide].

AMENDMENTS

The text of the proposed amendment is included with this Notice. In that document, any additions to the text are indicated in underline and any deletions in ~~cross-out~~.

Amendment to 25607.2(b): The first sentence of subsection (b) is amended to indicate that companies availing themselves of the acrylamide-specific safe harbor warning may comply with either subpart (1) or the newly proposed (2). Subsection (b)(1) in this proposal contains the existing safe harbor language, and subsection (b)(2) provides the new proposed warning options added by this rulemaking.

³ Health and Safety Code section 25249.5 et seq., The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as “Proposition 65,” hereafter referred to as “Proposition 65” or “the Act.”

⁴ Health and Safety Code section 25249.6.

⁵ Health and Safety Code section 25249.5.

A current rulemaking noticed on October 27, 2023, Office of Administrative Law file no. 2023-1017-03, would also amend section 25607.2. In that proposal, existing subsection (b) would be renumbered to (c). If that rulemaking is finalized before this proposal, that non-substantive change will affect the numbering of this proposal.

Amendment to 25607.2(b)(1): The existing acrylamide-specific safe harbor language is amended to allow the signal words “CA Warning and “Warning” in addition to “California Warning.” This subsection has also been amended to make the existing warning part of a single subsection, for ease of comparison with the new warning option in proposed subsection (b)(2). Non-substantive amendments to allow the existing safe harbor warning for acrylamide in food to be described in (b)(1) and the proposed warning in (b)(2).

New subsection 25607.2(b)(2): This is the proposed addition, which creates a new, additional safe harbor warning for acrylamide in foods. The proposal would add the following text:

(2) The words “**WARNING:**” or “**CA WARNING**” or “**CALIFORNIA WARNING:**” in all capital letters and bold print, followed by the language in subsections (A) and (B). Optional language in subsection (C) may be added. “United States” may be abbreviated as “US” and the words “Environmental Protection Agency” as “EPA”.

(A) The words, “Consuming this product can expose you to acrylamide,” or the words “Consuming this product can expose you to acrylamide, a chemical formed in some foods during cooking or processing at high temperatures.”

(B) At least one of the following sentences:

(i) “The International Agency for Research on Cancer has found that acrylamide is probably carcinogenic to humans.”

(ii) “The United States Environmental Protection Agency has found that acrylamide is likely to be carcinogenic to humans.”

(iii) “The United States National Toxicology Program has found that acrylamide is reasonably anticipated to cause cancer in humans.”

(C) The content in (A) and (B) may be followed by one or more of the following sentences:

(i) “Acrylamide has been found to cause cancer in laboratory animals.”

(ii) “Many factors affect your cancer risk, including the frequency and amount of the chemical consumed.”

(iii) “For more information including ways to reduce your exposure, see www.P65Warnings.ca.gov/acrylamide.”

OBJECTIVES AND SPECIFIC BENEFITS OF THE PROPOSED REGULATIONS

A district court issued a preliminary injunction against enforcement of the Proposition 65 warning for acrylamide in food in *CA Chamber of Commerce v. Becerra* (E.Dist.Cal. 2021) 529 F.Supp.3d 1099. The preliminary injunction, which addressed warning language materially different than both existing, acrylamide-specific safe harbor warning regulations and the amendments proposed in this rulemaking, was upheld by the Ninth Circuit in *CA Chamber of Commerce v. Council for Education and Research on Toxics* (9th Cir. 2022) 29 F.4th 468. OEHHA drafted the existing tailored warning regulation accordingly. That regulation, which added subsection (b) to section 25607.2, became effective on January 1, 2023. The case is continuing, and the question of the constitutionality of the current acrylamide warning content has not yet been resolved.

On November 7, 2023, the Ninth Circuit provided additional guidance regarding Proposition 65 and compelled commercial speech under the First Amendment in *National Association of Wheat Growers v. Becerra* (9th Cir. 2023) 85 F.4th 1263. Although OEHHA believes that the existing safe harbor warning for acrylamide in food complies with the First Amendment, OEHHA has determined that providing additional options for safe harbor warnings will further the right-to-know provisions of the Act while ensuring that the warning remains “(1) purely factual, (2) noncontroversial, and (3) not unjustified or unduly burdensome.”⁶ The proposal also provides businesses with increased flexibility.

NO INCONSISTENCY OR INCOMPATIBILITY WITH EXISTING REGULATIONS

OEHHA has conducted an evaluation and has determined that Article 6 is the only regulation concerning Proposition 65 safe harbor warnings. Therefore, the proposed regulatory action is neither inconsistent nor incompatible with any other existing state regulations. The action does not change the existing mandatory requirements on businesses subject to Proposition 65, state or local agencies and does not address compliance with any other law or regulation.

⁶ *American Beverage Assoc. v. City and County of San Francisco* (9th Cir. 2023) 916 F.3d 749, 756.

LOCAL MANDATE/FISCAL IMPACT

Because Proposition 65 by its terms 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.⁷ OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action, nor will there be any costs or savings to the state or in federal funding to the state because of the proposed regulatory action.

NO INCORPORATION BY REFERENCE

No forms or other documents are incorporated by reference.

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

No business will be required to change its warnings, or add new warnings, due to the safe harbor warning proposal. Businesses are not legally required to use the proposed safe harbor warning content and may use other “clear and reasonable” warnings on consumer products. These include the existing safe harbor warnings applicable to acrylamide in food. Under this proposal, businesses can retain use of those warnings while keeping the safe harbor protection. This proposal only creates another safe harbor option; it does not mandate that businesses use that option.

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))

Creation or Elimination of Jobs within the State of California

The proposed regulatory action will not impact the creation or elimination of jobs within the State of California. The proposed regulation will help businesses comply with the

⁷ See Health and Safety Code section 25249.11(b).

requirements of Proposition 65 by providing an additional, nonmandatory safe harbor warning for acrylamide in food. As stated above, businesses are not required to take any action based on this rulemaking.

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 proposed regulation will help businesses comply with the requirements of Proposition 65 by providing an additional, nonmandatory safe harbor warning for acrylamide in food. As stated above, businesses are not required to take any action based on this rulemaking.

The Expansion of Businesses Currently Doing Business within the State

OEHHA does not anticipate any major impact on the expansion of businesses currently doing business within the state. The proposed regulation will help businesses comply with the requirements of Proposition 65 by providing an additional, nonmandatory safe harbor warning for acrylamide in food. As stated above, businesses are not required to take any action based on this rulemaking.

Benefits of the Proposed Regulation

Making it more straight-forward for businesses to comply with the “clear and reasonable” warning requirement of the Act promotes compliance. Greater compliance furthers the right-to-know purposes of the statute and therefore promotes public health and safety.

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 mandatory requirements upon private persons or businesses.

Effect on Small Business

The proposed regulatory action will not adversely impact small businesses. As stated above, small businesses will not be required to take any action as a result of this

rulemaking. Additionally, Proposition 65 is limited by its terms to businesses with 10 or more employees.⁸

REASONABLE ALTERNATIVES TO THE REGULATION AND THE AGENCY'S REASONS FOR REJECTING THOSE 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 Proposition 65 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.

The following alternatives were considered:

Alternative 1: OEHHA considered drafting a new safe harbor warning tailored to acrylamide in food which would replace the existing warning. This was rejected because businesses which prefer to continue using the existing safe harbor language are still providing adequate information to consumers and should therefore be allowed to continue. This alternative would be no more effective at carrying out the agency's purpose, and no more cost-effective, than the current proposal. This alternative would be more burdensome on businesses than the current proposal.

Alternative 2: OEHHA also considered whether the new safe harbor warning should simply state the full text, without providing a variety of options for businesses to select. OEHHA rejected this alternative because it determined that it was appropriate to give businesses the flexibility of multiple options, so they can select the safe harbor language that best suits their needs. This alternative would be no more effective at carrying out the agency's purpose, and no more cost-effective, than the current proposal. This alternative would be more burdensome on businesses than the current proposal.

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, 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/Proposition-65.

⁸ Health and Safety Code section 25249.11(b).

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/Proposition-65.

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/Proposition-65.