

**Proposition 65**

**Final Statement of Reasons**

**Safe Harbor Warning for Acrylamide Exposure from Food**

**Title 27, California Code of Regulations**

**Chapter 1, Article 6, Subarticle 2.**

**Proposed Amendments to**

**Section 25607.2**

**Food Exposure Warnings — Content**

**August 22, 2024**

**California Environmental Protection Agency**

**Office of Environmental Health Hazard Assessment**

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## General Information

### Overview of the Regulation

This is the Final Statement of Reasons (FSOR) for the proposed amendments to section 25607.2(b),<sup>1</sup> within Title 27 of the California Code of Regulations.<sup>2</sup> The proposal provides an additional safe harbor warning option for products that cause significant exposures to acrylamide from food products. This would be in addition to the safe harbor warnings that already apply to such exposures under the existing regulations: the general warnings for food (full length and “short-form”), and the current safe harbor warning for acrylamide exposures from food. The warning content and methods provided in the safe harbor regulations are deemed “clear and reasonable” by the Office of Environmental Health Hazard Assessment (OEHHA) for purposes of the Act. (27 Cal. Code Regs. § 25601(a).)

### Process and Timeline

On April 5, 2024, OEHHA published the Notice of Proposed Rulemaking and Initial Statement of Reasons (ISOR) for this action, initiating a public comment period that closed on May 20, 2024. Additionally, the Notice announced that a public hearing would be held upon request. No request was made, and no hearing was held.

OEHHA received two written comments during the public comment period. OEHHA’s responses are included in this Final Statement of Reasons (FSOR).

After careful consideration of those comments, OEHHA has determined modifications are not needed to the original rulemaking proposal.

## **Update of Initial Statement of Reasons and Informative Digest**

As authorized by Government Code section 11346.9(d), OEHHA incorporates by reference the ISOR and the Notice of Proposed Rulemaking. There are no changes or additions to those documents.

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<sup>1</sup> 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.

<sup>2</sup> All further citations are to sections of Title 27 of the California Code of Regulations, unless otherwise stated.

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## Summary of and Response to Comments

Written comments were received on the proposed rulemaking from the following:

- California Chamber of Commerce and a coalition of 16 other entities
- Richard Segal

Relevant comments are summarized and responded to below. OEHHA's responses to the relevant comments are incorporated within this FSOR. Some comments submitted do not constitute "an objection or recommendation directed at the proposed action or the procedures followed in this rulemaking action, or the reasons for making no change." (Govt. Code § 11346.9(a)(3).) OEHHA is not required under the Administrative Procedure Act to respond to those comments, although it may choose to do so. The absence of responses to such comments should not be construed to mean that OEHHA in any way agrees or disagrees with them.

**Comment 1 (California Chamber of Commerce and Coalition):** The commenters oppose the proposal, stating that it is "a radical departure from OEHHA's long-standing approach to safe harbor warnings."

**Response to Comment 1:** To the extent the commenters believe that there has been a single approach to safe harbor warnings in the past, the commenters are incorrect. OEHHA has promulgated different safe harbor warning content, and different methods of warning consumers, for a variety of reasons. OEHHA regularly considers the factual circumstances around a particular chemical or set of products, and whether it is appropriate to deviate from existing safe harbor requirements. As a result, some safe harbor warnings are chemical-specific, location-specific, and/or product-specific. Indeed, interested parties can request that OEHHA adopt "a specific product, chemical, or area exposure warning," if OEHHA does not do so on its own initiative. (Section 25600(c).) In recent years, OEHHA has also allowed safe harbor protections for consumer products using either a full warning, or, to save space, a "short-form" warning with fewer characters. (Section 25603(b).)

This proposed safe harbor warning is different from previous chemical/product-specific safe harbor warnings insofar as it is the first such warning with a Notice of Rulemaking issued after *National Association of Wheat Growers v. Bonta* (9th Cir. 2023) 85 F.4th 1263. That decision was issued in November 2023, less than six months before the Notice for the current rulemaking was published. *National Association of Wheat Growers* analyzed Proposition 65 safe harbor warnings for the chemical glyphosate, under the First Amendment. This proposal follows court guidance on businesses' First

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Amendment rights, promotes compliance by offering businesses enhanced flexibility and safe harbor protection from litigation, and ensures that consumers receive valuable, factual information about acrylamide.

No changes were made to the proposed regulation based on this comment.

**Comment 2 (California Chamber of Commerce and Coalition):** The commenters note that “acrylamide at high doses is known to cause cancer in laboratory animals” but assert that “[no one] knows that dietary acrylamide causes cancer in humans.” The commenters state that the proposed warning conveys a message to consumers that acrylamide increases the risk of cancer but assert that there is “robust” evidence that “acrylamide in food and beverages is not known to increase consumers’ risk of cancer.” The commenters cite various sources in support of their argument that acrylamide in food and beverages does not cause cancer in humans.

**Response to Comment 2:**

To the extent the commenters suggest that acrylamide in food is not a cause of cancer, the comment is outside the scope of this rulemaking. OEHHA added acrylamide to the Proposition 65 list for cancer in 1990. This rulemaking is designed to propose a new safe harbor warning; there are separate provisions for reconsidering and de-listing chemicals, unrelated to this rulemaking. (See section 25306(j).) Similarly, commenters’ contention that acrylamide does not affect cancer risk is outside the scope of this rulemaking. This proposal only provides safe harbor protections for additional warning text; it does not affect whether or not a warning is required.

Nonetheless, to provide background information about the chemical at issue in this rulemaking, OEHHA discussed the carcinogenicity of acrylamide in its Initial Statement of Reasons [ISOR]. That document described the carcinogenicity findings of the International Agency for Research on Cancer (IARC), the U.S. Environmental Protection Agency (US EPA), and the U.S. National Toxicology Program. The ISOR also cited supporting documents and regulations from the World Health Organization; the United Nations’ Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives; and the governments of Australia, New Zealand, Canada, France, Germany, and the United Kingdom.

For the convenience of the reader, the ISOR stated as follows [citations omitted]:

Due to concerns over the potential carcinogenic risks to humans from consuming foods with high levels of acrylamide, several governmental agencies and international organizations

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recommend ways to reduce formation of acrylamide in food production, or advise that acrylamide be reduced.

- The US Food and Drug Administration
  - *Guidance for Industry: Acrylamide in Foods* “to help growers, manufacturers, and food service operators reduce acrylamide levels in certain foods.”
- The European Union:
  - A regulation, in 2017, establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food.
- The United Nations’ FAO (Food and Agriculture Organization) - WHO (World Health Organization) Codex Alimentarius:
  - “Code of Practice for the Reduction of Acrylamide in Foods” (CAC/RCP 67- 2009) “to provide national and local authorities, manufacturers and other relevant bodies with guidance to prevent and reduce formation of acrylamide in potato products and cereal products.”
- The United Nations’ Joint FAO/WHO Expert Committee on Food Additives (JECFA):
  - “work to reduce exposure to acrylamide in food by minimizing its concentrations should continue.”
  - “information on the occurrence of acrylamide in food consumed in developing countries would be useful to conduct a dietary exposure assessment and consider appropriate mitigation strategies to minimize acrylamide concentrations in food.”

To the extent the commenters’ concerns are related to the specific warning text included in this proposal, they ignore the full body of evidence that has led to broad scientific concern about acrylamide in food. There is widespread international understanding on this issue. For example:

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## European Union: The European Foods Safety Agency (EFSA)

“EFSA’s experts agree with previous evaluations that acrylamide in food potentially increases the risk of developing cancer for consumers in all age groups. While this applies to all consumers, on a body weight basis, children are the most exposed age group.”<sup>3</sup>

## United Kingdom: Food Standards Agency

“Laboratory tests show that acrylamide in the diet causes cancer in animals. Scientists agree that acrylamide in food has the potential to cause cancer in humans as well. We recommend that the amount of acrylamide we all consume is reduced, as a precaution.”<sup>4</sup>

## Norway: Norwegian Scientific Committee for Food Safety (VKM)

“VKM is of the opinion that the conclusion reached by EFSA's risk assessment of acrylamide, which states that acrylamide in food potentially increases the risk of developing cancer for consumers in all age groups, also applies to Norwegians.”<sup>5</sup>

## France: ANSES (French acronym for the National Agency of Food Safety, Environment and Work)

“The TDS [total diet study] data revealed that the levels of exposure of the French population are still too close to the doses recognized as carcinogenic in animals. Therefore, exposure to acrylamide through food remains a public health concern and initiatives aiming to reduce exposure should be pursued.”<sup>6</sup>

That acrylamide poses a risk of cancer when consumed in food is consistent with the understanding of experts in governmental agencies and public health institutions worldwide.

The commenters appear to believe that Californians should not be alerted before exposure to a carcinogen unless there is complete consensus amongst all scientists

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<sup>3</sup> European Food Safety Authority, Acrylamide (site rev. 2024), FAQ section available at: <https://www.efsa.europa.eu/en/topics/topic/acrylamide#faq>.

<sup>4</sup> United Kingdom Food Standards Agency, Acrylamide (April 26, 2022), available at <https://www.food.gov.uk/safety-hygiene/acrylamide>.

<sup>5</sup> Vitenskapskomiteen for mattrygghet [Norwegian Scientific for Food Safety], Risk Assessment of Dietary Exposure to Acrylamide in the Norwegian Population (Dec. 17, 2015) VKM Report 2015:32, available at <https://vkm.no/download/18.2994e95b15cc5450716151db/1498142208319/40af783860.pdf>.

<sup>6</sup> Agence Nationale de Sécurité Sanitaire de l’Alimentation, Acrylamide in Foods (Jan. 17, 2013), available at <https://www.anses.fr/en/content/acrylamide-foods>.

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and medical professionals. However, this both defeats the right-to-know purposes of Proposition 65—which gives Californians the ability to evaluate their own exposures—and also misunderstands the scientific process, which does not require total unanimity. The fact that individuals or entities may express a desire for additional evidence about a given chemical does not invalidate a generally accepted recognition of that chemical’s carcinogenicity. A good example of this is actually cited by the commenters, namely a webpage of the American Cancer Society addressing acrylamide in food. That website states that epidemiological studies—as opposed to the other types of evidence supporting human carcinogenicity—do not support increased risk for some cancers (“the most common types of cancer”) and that the results of “ongoing studies” are still needed.<sup>7</sup> But the same site also emphasizes that the American Cancer Society “**does not determine if something causes cancer** [bold in original]” and expressly refers to IARC, the National Toxicological Program, and the US EPA as “respected organizations” regarding the carcinogenicity of acrylamide.<sup>8</sup> These are the same three organizations, and the same three findings, that are quoted in the proposed safe harbor warning.<sup>9</sup>

To the extent that the commenters are suggesting that some unspecified part of the proposed warning language is incorrect or misleading, please see response to Comment 5.

No changes were made to the proposed regulation based on this comment.

### Comment 3

The commenters oppose the proposal because the U.S. Food and Drug Administration (FDA) does not require warnings for exposures to acrylamide; the FDA opposed such warnings for whole grain food; and acrylamide in food must be safe, according to the

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<sup>7</sup> Epidemiological evidence is not the only type of evidence that can demonstrate carcinogenicity in humans, nor is it without uncertainties. The other entity referenced by the commenters, the National Cancer Institute, acknowledged the limitations of the existing epidemiologic studies: “One reason for the inconsistent findings from human studies may be the difficulty in determining a person’s acrylamide intake based on their reported diet.”

<sup>8</sup> According to the website referenced by the commenters, the site was last updated February 11, 2019. Available at: <https://www.cancer.org/cancer/risk-prevention/chemicals/acrylamide.html>.

<sup>9</sup> Similarly, another organization noted by the commenters, the National Cancer Institute, specifically names the U.S. National Toxicology Program and IARC as the entities that decide which exposures can cause cancer in humans. “Environmental Carcinogens and Cancer Risk,” available at <https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/carcinogens>, last updated April 6, 2023.



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commenters, because coffee is a significant source of acrylamide but does not cause cancer, as recognized by an OEHHA regulation which was supported by the FDA.

### **Response to Comment 3:**

FDA labeling has different purposes than Proposition 65 warnings. The fact that the FDA does not require disclosure of a given chemical on food labels does not preclude OEHHA from creating a safe harbor Proposition 65 warning. Furthermore, as noted in the ISOR, the FDA has recommended methods that companies can use to reduce acrylamide in food products.

Regarding whole-grain foods, the commenters suggest that an acrylamide warning might discourage people from consuming healthy foods. The commenters have not identified any particular whole-grain product which both benefits consumers' health and would also require a Proposition 65 warning for acrylamide, so OEHHA cannot respond to the commenters' concerns. Many food products that contain acrylamide do not require a Proposition 65 warning for that chemical; see Response to Comment 9.

The ISOR provides the scientific basis for the regulation concerning coffee, which excludes from the Proposition 65 warning requirements exposures to *any* listed carcinogens in coffee inherent to the roasting or brewing process, not just acrylamide.<sup>10</sup> (Section 25704.) The fact that coffee does not cause cancer is not evidence that acrylamide—or any one of the many other chemicals contained in coffee—is not a human carcinogen. Coffee is a “unique and complex chemical mixture of numerous compounds.”<sup>11</sup> As stated in the ISOR, there is “a rich mix of cancer-preventative agents in brewed coffee” and extensive evidence, specific to coffee, showing it may *reduce* the risk of certain cancers. This evidence from studies of coffee does not apply to acrylamide—or other listed chemicals—when they occur in other foods.

To the extent this comment is intended to argue that acrylamide in food should not require any Proposition 65 warning because the chemical is not carcinogenic in humans, the comment is outside the scope of this rulemaking. See Response to Comment 2.

No changes were made to the proposed regulation based on this comment.

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<sup>10</sup> This applies to chemicals listed for cancer on or before March 19, 2019. (Section 25704.)

<sup>11</sup> Initial Statement of Reasons for section 25704 (June 2018), p. 4, available at: <https://oehha.ca.gov/media/downloads/cnr/coffeeisor061418.pdf>.

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**Comment 4 (California Chamber of Commerce and Coalition):** The commenters contend that this proposal is a “litigation tactic.” The commenters describe litigation involving Proposition 65 warnings for glyphosate and acrylamide exposures. The commenters state that, in the latter litigation, the California Chamber of Commerce planned to make a motion for summary judgment at the time the Notice for this proposal was published. The commenters assert that OEHHA is the client of the California Attorney General and should not propose a new safe harbor warning for acrylamide.

**Response to Comment 4:**

See Response to Comment 1. The opinion in *National Association of Wheat Growers v. Bonta* (9th Cir. 2023) 85 F.4th 1263 was issued in November 2023, less than six months before the Notice for the current rulemaking was published. It was appropriate for OEHHA to take that decision into consideration when developing this proposed rulemaking.

Existing litigation regarding Proposition 65 warnings for exposure to acrylamide in food was acknowledged by OEHHA in the ISOR.<sup>12</sup> OEHHA is not a party to that litigation and is not being represented by the Office of the Attorney General (OAG) in that case.<sup>13</sup> Rather, the Attorney General is the defendant in that matter.

OEHHA declines to delay or withdraw this rulemaking because of existing litigation.

No changes were made to the proposed regulation based on this comment.

**Comment 5 (California Chamber of Commerce and Coalition):** The commenters argue that the proposal violates the First Amendment.

**Response to Comment 5:** Although OEHHA believes that the existing safe harbor warning for acrylamide in food comports with the First Amendment, OEHHA has also evaluated the application of recent First Amendment caselaw to the current proposal. OEHHA has determined that the additional safe harbor warning in this proposal is purely factual; noncontroversial; does not mislead; and is neither unjustified nor unduly burdensome. (*American Beverage Assoc. v. City and County of San Francisco* (9th Cir. 2023) 916 F.3d 749, 756; *National Association of Wheat Growers v. Bonta* (9th Cir.

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<sup>12</sup> The case proceeding in the Eastern District, No. 2:19-cv-02019-DJC-JDP, is a continuation of the case considered in *California Chamber of Commerce v. Becerra* (E.D. Cal. 2021) 529 F.Supp.3d 1099 and *California Chamber of Commerce v. Council for Education and Research on Toxics* (9th Cir. 2022) 51 F.4th 1182.

<sup>13</sup> The OAG has represented OEHHA in other, unrelated lawsuits.

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2023) 85 F.4th 1263; *CTIA – The Wireless Assoc. v. City of Berkeley, California* (9th Cir. 2019) 928 F.3d 832).

The commenters have not specified any particular language within the proposed warning that they believe to be inaccurate, misleading, or controversial, and they do not contend that the warning is unduly burdensome. Rather, they state that the warning is similar to one rejected in *Association of Wheat Growers*, which found that there was a controversy about the carcinogenicity of glyphosate based largely on the fact that “the Environmental Protection Agency (EPA) has concluded that glyphosate does not pose a cancer hazard or risk to humans.” (*National Association of Wheat Growers v. Bonta, supra*, at p. 1270.)

The commenters make this argument even though acrylamide was found by the US EPA to be “likely to be carcinogenic in humans.” Furthermore, the proposed warning varies significantly from the language addressed in *National Wheat Growers*.

No changes were made to the proposed regulation based on this comment.

**Comment 6 (California Chamber of Commerce and Coalition):** The commenters object to the fact that the proposal allows many different options for businesses and states that this is not good policy because consumers will be confused by different warnings, and because this is different from past safe harbor warnings. The commenters also state that there is no basis for the rulemaking because “OEHHA does not know how consumers will react” to the various options.

**Response to Comment 6:** OEHHA disagrees with the commenters’ position that businesses should have fewer options, or that consumers will be confused by the proposed warning.

Each of the options available to businesses through this proposal is factually accurate and will provide consumers with important information about exposures to acrylamide, whenever such exposures are high enough to pose a significant risk. Giving businesses the opportunity to select their preferred safe harbor warning language thus does not diminish the right-to-know and public health purposes of Proposition 65. Rather, providing options offers businesses increased flexibility, which promotes compliance. As stated in the ISOR, businesses can “decid[e] whether to prioritize brevity or to include additional context.”

To the extent the commenters are suggesting that OEHHA is required to conduct a study for each proposed safe harbor warning to evaluate consumer responses, that is not required by the Administrative Procedure Act or any other law or regulation. Furthermore, although there is value in consistency as a general matter, Proposition 65 and its implementing regulations have long allowed businesses to use different safe

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harbor warnings, when appropriate, tailored to their specific circumstances. The safe harbor warnings set forth in sections 25602 *et seq.* are presumptively “clear and reasonable” as required by Proposition 65, but they are not required by law, and businesses may develop their own “clear and reasonable” warnings. Even among the existing safe harbor regulations, OEHHA has promulgated a variety of different warnings that are product-, location-, and/or chemical-specific. OEHHA also allows the use of “short-form” warnings in lieu of full-length warnings (Section 25603(b)), and court settlements sometimes result in different warning language, as noted by the commenters. (See Response to Comment 7.)

No changes were made to the proposed regulation based on this comment.

**Comment 7 (California Chamber of Commerce and Coalition):** The commenters describe the proposed warning as requiring one or more of four sentences and state that the proposed safe harbor warning differs from warnings agreed to by companies when settling Proposition 65 claims. The commenters also contend that the proposal deviates from the OAG guidelines for settlements between defendants and private enforcers. In particular, the commenters cited an Attorney General regulation which discourages use of the adverb ‘may’ in connection with statements about whether the chemical causes cancer or reproductive toxicity.<sup>14</sup> The commenters both assert that a warning that describes a chemical as “known to cause” cancer would be unconstitutional and also object to the fact that the proposal uses language other than that phrase.

**Response to Comment 7:**

Companies that have agreed to other warning language as part of a settlement are not required to use the proposed language, first because this proposal is only a new option and not mandatory, and second because existing regulations state that “[a] person that is a party to a court-ordered settlement or final judgment establishing a warning method or content is deemed to be providing a “clear and reasonable” warning for that exposure ...if the warning complies with the order or judgment.” (Section 25600(e)).

The proposal does not use the word “may” to describe carcinogenicity. It uses statements from authoritative bodies identified by statute and accurately quotes the findings of those entities. This language is factually correct and conveys important information to consumers.

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<sup>14</sup> That regulation is not binding on litigants or the courts. (Code Regs. tit. 11, sec. 3200, 3202(b).)

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OEHHA has used the findings of other entities regarding acrylamide to describe the chemical's potential effect on consumers. OEHHA disagrees with the commenters that it is obligated to use the phrase "known to cause" within the proposed warning. Nothing in the statute requires any specific language to be used in the warning itself.

Finally, the commenters are incorrect that the proposal requires businesses to use one or more of four options, including the sentence "Acrylamide has been found to cause cancer in laboratory animals." The proposal requires the warning to state the determination of IARC, the US EPA, or the U.S. National Toxicology Program. The sentence about animal studies *may* be used as part of a warning, for businesses that would like to provide more context to consumers, but it is not required. That sentence reflects the fact that studies of laboratory animals were the basis of the U.S. National Toxicology Program determination and the primary basis of the determinations by IARC and the US EPA. All three entities found sufficient evidence of carcinogenicity in animals. This does not imply that studies of acrylamide in animals are the only evidence of potential carcinogenicity in humans.<sup>15</sup> Nor does it mean that IARC, the US EPA, and the U.S. National Toxicology Program were unaware of supporting evidence from mechanistic studies at the time of their hazard determinations.<sup>16</sup>

No changes were made to the proposed regulation based on this comment.

**Comment 8 (California Chamber of Commerce and Coalition):** The commenters stated that OEHHA has no expertise in risk communication and should hire an expert to determine the proposed safe harbor warning's effect on consumers. The commenters expressed concern that average Californians cannot understand Proposition 65 warnings because of their limited literacy.

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<sup>15</sup> For instance, an updated review by EFSA in 2022 concluded "that dietary exposure to AA [acrylamide] has the potential to result in formation of GA [glycidamide] adducts and GA-related mutations." The additional studies reviewed in 2022 "extend the information assessed by the CONTAM Panel in its Opinion on the risks to human health related to the presence of AA in food (EFSA CONTAM Panel, 2015), and support its conclusions." European Food Safety Authority, Assessment of the Genotoxicity of Acrylamide (May 5, 2022 [approved March 29, 2022]) EFSA Journal vol. 20, issue 5, available at: <https://www.efsa.europa.eu/en/efsajournal/pub/7293>; See: European Food Safety Authority, Scientific Opinion on Acrylamide in Food (June 4, 2025 [adopted April 30, 2015]) EFSA Journal vol. 13, issue 6, available at <https://www.efsa.europa.eu/en/efsajournal/pub/4104>.

<sup>16</sup> US EPA (2010) and IARC (1994) explicitly considered supporting evidence related to the genotoxicity of acrylamide. Being genotoxic is a key characteristic of carcinogens. U.S. Environmental Protection Agency, *Toxicological Review of Acrylamide in Support of Summary Information on the Integrated Risk Information System (IRIS)* (2010); International Agency for Research on Cancer, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Vol. 60, Some Industrial Chemicals (1994), p. 425, available at <https://publications.iarc.fr/78>.

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**Response to Comment 8:** OEHHA notes the commenters' suggestion regarding outside experts. However, OEHHA has extensive experience with Proposition 65, for which it is the lead agency, as well as with science communication more broadly. The proposed safe harbor warning communicates health information to consumers while prioritizing strict factual accuracy.

OEHHA does not agree with the commenters that Californians are unable to read or understand Proposition 65 warnings and should thus not be informed of exposures to listed chemicals. Proposition 65, a right-to-know law, was enacted directly by California voters as an initiative. Thus, Californians wished to know about significant exposures to chemicals added to the Proposition 65 list for cancer or reproductive harm and presumably believed themselves capable of understanding such information. The commenters provide no evidence to the contrary. The commenters have not indicated any particular word or phrase within the proposed warning that they believe Californians will be unable to comprehend.

No changes were made to the proposed regulation based on this comment.

**Comment 9: (California Chamber of Commerce and Coalition):** The commenters expressed concern that “ubiquitous” warnings could be dangerous, referencing an amicus brief and a February 2020 article titled “Guidance on the Application of Human Factors to Consumer Products.”

**Response to Comment 9:** To the extent the commenters are concerned that there will be too many warnings related to acrylamide, OEHHA disagrees. The number of warnings required by Proposition 65 for exposures to acrylamide will not increase because of the proposed regulation. The proposal has no effect on the number of products which require a warning.

As described in the ISOR, this proposal applies to a limited number of food products. The acrylamide formed in food from cooking and heat processing is not subject to a Proposition 65 warning as long as it is reduced to the lowest level currently feasible using the methods specified in existing regulations. (Section 25506(a).) The commenters do not state whether they represent manufacturers who decline to use such methods. But even if they do, a number of the commenters' products are still not subject to a warning if the acrylamide is below certain specified concentration limits.<sup>17</sup>

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<sup>17</sup> As described in the ISOR, even if a manufacturer cannot establish that it has reduced acrylamide to the lowest currently feasible level, OEHHA has promulgated concentration levels for acrylamide for a variety of foods for which acrylamide is commonly present. (Section 25506(d).) Those food products do not

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In support of their argument, the commenters quoted “Guidance on the Application of Human Factors to Consumer Products” from the U.S. Consumer Product Safety Commission’s Division of Human Factors and the Risk Assessment Division of the Canadian Consumer and Hazardous Products Safety Directorate. That document, like the cited amicus brief, was not submitted with the public comment, but OEHHA was able to locate it online. The guidance document did not address Proposition 65 or any other government-mandated right-to-know requirements; rather, the document was intended “to help consumer product manufacturers integrate human factors principles” because “product-related injuries can be prevented by better design.”

No changes were made to the proposed regulation based on this comment.

### **Comment 10 (Richard Segal)**

The commenter stated that acrylamide is dangerous, there are alternative cooking techniques that avoid acrylamide, and research into the hazards of acrylamide has been suppressed.

**Response to Comment 10:** This comment is outside the scope of this rulemaking. However, OEHHA notes that the commenter is correct that acrylamide in food can be reduced by various techniques.

No changes were made to the proposed regulation based on this comment.

## **Local Mandate Determination**

OEHHA has determined this regulatory action will not impose a mandate on local agencies or school districts, nor will it require reimbursement by the State pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code. Local agencies and school districts are exempt from Proposition 65.

OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from this regulatory action.

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require a warning, as long as the average and maximum concentrations of acrylamide are at or below the given thresholds. Acrylamide in coffee “created by and inherent in the processes of roasting coffee beans or brewing coffee” also does not require a warning, as noted above, because of evidence specific to coffee consumption. (Section 25704.)

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## **Alternatives Determination**

In accordance with Government Code section 11346.9(a)(4), OEHHA has considered available alternatives. OEHHA has determined that no alternative it considered, or that was otherwise identified and brought to its attention, would be (a) more effective in carrying out the agency's purpose; (b) as effective and less burdensome to affected private persons than the adopted regulation; or (c) more cost effective to affected private persons and equally effective in implementing the statutory policy. The consideration of alternatives included those discussed in the ISOR.

The only alternative proposed by public comment was withdrawal of the proposal.

### **Alternatives that Would Lessen the Adverse Economic Impact on Small Business Determination**

There were no alternatives proposed that would lessen any adverse economic impact on small businesses as defined in Government Code section 11342.610 that were rejected by OEHHA. The proposed regulatory action will not adversely impact small businesses. 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. Businesses are not required to take any action based on this rulemaking.

Additionally, Proposition 65 does not apply to all small businesses, since it is limited by its terms to businesses with 10 or more employees.<sup>18</sup>

### **Non-duplication Statement**

Proposition 65 is a California law that has no federal or state counterpart. OEHHA has determined that the regulation does not duplicate and will not conflict with federal law or regulations. OEHHA has further determined that the regulation does not serve the same purpose as a state or federal statute or another regulation.

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<sup>18</sup> Health and Safety Code section 25249.11(b).