

Proposition 65

Final Statement of Reasons

**Title 27, California Code of Regulations
Amendments to Article 6:**

**Safe Harbor Clear and Reasonable Warnings
for Acrylamide Exposures from Food**

Subsection 25607.2(b)

September 16, 2022



**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 for the Office of Environmental Health Hazard Assessment's (OEHHA) proposal to add a subsection to section 25607.2, Article 6, Title 27 of the California Code of Regulations¹ that provides safe harbor warning content for exposures to Proposition 65-listed chemicals in foods, which includes beverages², that require warnings. OEHHA proposes to adopt as Section 25607.2, subsection (b), a non-mandatory, safe harbor warning option for businesses that cause significant exposures to acrylamide in foods. The content of the proposed warning is intended to provide additional information to individuals who may be exposed to acrylamide in foods to help them make better-informed decisions about those exposures. This non-mandatory safe harbor warning, once adopted in section 25607.2, would provide warning content that is deemed to be "clear and reasonable"³ for purposes of compliance with Proposition 65⁴.

The proposed warning consists of multiple parts that draw from existing OEHHA safe harbor warnings for food exposures: signal words, the name of a listed chemical to which a consumer may be exposed, and the URL where consumers can access more information about the chemical, including ways to reduce their exposure. Consistent with the other provisions of the regulations related to food exposures, no warning symbol is required.

The safe harbor warning that OEHHA proposes to adopt in subsection 25607.2, subsection (b) is displayed below:

CALIFORNIA WARNING: Consuming this product can expose you to acrylamide, a probable human carcinogen formed in some foods during cooking or processing at high temperatures. Many factors affect your cancer risk, including the frequency and amount of the chemical consumed. For more information including ways to reduce your exposure, see www.P65Warnings.ca.gov/acrylamide

¹ All further citations are to sections of Title 27 of the California Code of Regulations, unless otherwise stated.

² Section 25600.1, subsection (g).

³ Section 25600, subdivision (a).

⁴ Health and Safety Code section 25249.6.

Process and Timeline

The Notice of Proposed Rulemaking, the proposed regulatory text, and the Initial Statement of Reasons (ISOR) were posted on the OEHHA website on September 17, 2021. The Notice of Proposed Rulemaking for this action was published in the California Regulatory Notice Register⁵ on September 24, 2021. The public comment period closed on November 8, 2021. No public hearing was requested or held.

OEHHA is providing responses to relevant comments submitted during the rulemaking process in this Final Statement of Reasons (FSOR). OEHHA received some written comments during the comment period that were not relevant or related to the proposed action. These comments do not constitute an objection or recommendation specifically directed at the proposed action, or the procedures followed in this rulemaking action. Accordingly, OEHHA is not required under the Administrative Procedure Act⁶ to respond to such comments in this FSOR. The absence of responses to such comments should not be construed to mean that OEHHA in any way agrees or disagrees with them.

Public Commenters

The following entities and individuals submitted written comments on the proposed warning content for exposures to acrylamide in foods during the comment period:

Commenter	Designation
American Bakers Association	ABA
Anonymous	Anon
Center for Environmental Health	CEH
California Chamber of Commerce, Consumer Brands Association, and 19 other signatories ⁷	Coalition

⁵ California Regulatory Notice Register, Notice File Number Z2021-0914-07.

⁶ Government Code section 11340 et seq.

⁷ California Chamber of Commerce and Consumer Brands Association and 19 other signatories include: American Bakers Association, American Beverage Association, American Chemistry Council, American Frozen Food Institute, California Attractions and Parks Association, California Farm Bureau Federation, California Food Producers, California Retailers Association, Chemical Fabrics and Film Association, Consumer Healthcare Products Association, Del Monte Foods, Inc., Flexible Packaging Association, Frozen Potato Products Institute, International Dairy Foods Association, International Food Additives

China WTO/TBT National Notification & Enquiry Center / The People's Republic of China	PRC ⁸
David Steinman	DSteinman
Healthy Living Foundation	HLF
North American Association of Food Equipment Manufacturers	NAFEM
Penny Newman	PNewman
Aida Poulsen, Poulsen Law PC	APoulsen

Summary of Public Comments and OEHHA's Responses

Content of Proposed Warning

Comment 1 (CEH): The alternative safe harbor warning language for acrylamide exposure from food strikes a delicate balance between providing a clear and reasonable warning to the public while also avoiding potential legal challenges.

CEH states that the proposed alternative warning language provides more information to consumers on the cooking processes that form acrylamide, making it clear that acrylamide is not an additive, and that consumers can take steps to reduce their exposure by limiting their intake of certain foods. The additional information will allow consumers to make more informed decisions regarding their exposure to acrylamide from food. CEH supports the adoption of the amendments.

Response: OEHHA acknowledges the CEH comment, and its support for this proposal.

Council, Juice Products Association, National Confectioners Association, Peanut and Tree Nut Processors Association, and SNAC International – collectively referred to as the Coalition.

⁸ This comment was received on December 30, 2021. The comment requests that the deadline to comment be postponed to January 1, 2022, because the Notification from the World Trade Organization (WTO) to its members was issued on November 2, 2021 and requested comments by November 8, 2021. The comment reasons that, following the “transparency principle” of the WTO Agreement on Technical Barriers to Trade, members should be given adequate time to comment. OEHHA declined to extend the comment period beyond the dates prescribed by the APA but, in light of the unique circumstances, OEHHA included this comment in the FSOR and provided the same degree of analysis and weight to this comment as all the other comments.

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

Required Warning Content

Comment 2 (Coalition): The Coalition states that OEHHA and the California Attorney General’s Office previously insisted that a Proposition 65 warning must unequivocally state that the chemical is “known to the state to cause” cancer and/or birth defects or other reproductive harm to satisfy the statutory mandate of a “clear and reasonable” warning. Quoting *Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910, 918, they also state that “the California Supreme Court has held that the warning must communicate that the chemical is “known to the state of California to cause [cancer]”, or words to that effect.” All OEHHA’s safe harbor warnings use this longstanding formulation of “known to the state to cause”. The proposed rulemaking violates this longstanding standard and does so without acknowledging OEHHA’s change in policy and reversal of its prior legal position and the potential inconsistency with the Attorney General’s regulations “or the unwavering and longstanding legal interpretation of both OEHHA and the Attorney General”.

Response: The commenters are incorrect. OEHHA has the statutory authority to adopt regulations that further the purposes of the statute. The statute does not require any specific warning content. The warning simply must be “clear and reasonable”. In fact, OEHHA has adopted tailored safe harbor warnings in Article 6, such as for alcoholic beverages,⁹ occupational exposure warnings,¹⁰ and prescription drug warnings,¹¹ that do not include the phrase “known to the State of California to cause . . .”. OEHHA continues to propose specific and understandable warnings tailored to the chemicals and exposures for which the warning is proposed. Further, OEHHA recently adopted safe harbor warnings for cannabis smoke and THC (delta-9-tetrahydrocannabinol)¹² and glyphosate¹³ that do not include the phrase “known to the State of California to cause . . .”.

⁹ Section 25607.4. Alcoholic Beverage Exposure Warnings: **⚠ WARNING:** Drinking distilled spirits, beer, coolers, wine and other alcoholic beverages may increase cancer risk, and, during pregnancy, can cause birth defects. For more information go to www.P65Warnings.ca.gov/alcohol.

¹⁰ Section 25606(a), OSHA Hazard Communications Standard complies with warning requirement.

¹¹ Section 25607.7, FDA package inserts comply with the warning requirement.

¹² Sections 25607.39, 25607.41, 25607.43, 25607.45, 25607.47; effective October 1, 2022.

¹³ Section 25607.49; effective January 1, 2023.

*Dowhal v. SmithKline Beecham Consumer Healthcare*¹⁴ was a decision in a private enforcement action on the question whether, based on the facts of that case, the Proposition 65 warning for nicotine exposures could be included on a product label for an over-the-counter nicotine patch with an existing warning approved by FDA that did not comply with Proposition 65. The court found that a Proposition 65 warning on the label was preempted because the Proposition 65 warning conflicted with the FDA purpose of encouraging pregnant women to stop smoking. FDA was concerned that pregnant women would continue to smoke, rather than use the nicotine patches, if a Proposition 65 warning were on the product label. The court discussed the Proposition 65 regulations and the content of the warnings as they existed in 2004.¹⁵ The court did not find that OEHHA had to include “known to the State of California to cause” or any other language in its warning regulations.

As the commenters note, the warning regulations discussed in the *Dowhal* case were repealed and replaced in 2016. The new warning regulations included changes to the safe harbor warning content. OEHHA has continued to propose and adopt tailored safe harbor warnings in the regulations (Section 25607 et seq.), some of which do not include the “known to the State of California to cause” language, as discussed above.

The regulations promulgated by the Attorney General’s Office¹⁶ provide guidance to private parties negotiating Proposition 65 settlements. They do not limit OEHHA’s ability to modify, repeal, or propose new regulations relating to safe harbor warnings, including specifying warning content. The Attorney General’s regulatory guidelines expressly provide as follows:

This guideline provides additional information concerning the Attorney General's interpretation of the statute and *existing regulations* governing clear and reasonable warnings and factors that will be considered in the Attorney General's review of settlements. Nothing in this guideline shall be construed to authorize any warning that does not comply with the statute and regulations, or to preclude any warning that complies with the statute and regulations *or to conflict with regulations adopted by the Office of Environmental Health Hazard Assessment.*

¹⁴ *Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910, 918.

¹⁵Section 25601 (repealed in 2018); *Dowhal v. SmithKline Beecham Consumer Healthcare*, *supra*, 32 Cal. 4th at p. 918 (quoting the regulation); *Environmental Law Foundation v. Wykle Research, Inc.* (2005) 134 Cal.App.4th 60, 66 n.6 (“[T]he method of transmission relates to the reasonableness of the warning, whereas the content of the message relates to its clarity.”).

¹⁶ Title 11, Cal. Code of Regs., sections 3200 – 3205.

This guideline is intended to address some of the types of warnings commonly found in settlements, not to provide comprehensive standards.¹⁷

The warning proposed in this rulemaking is clear, understandable, and accurate without the “known to the State of California to cause . . .” phrase. The proposed warning addresses the court’s concern, articulated in *California Chamber of Commerce v Bonta* (the *CalChamber* case)¹⁸ and discussed in greater detail in Response to Comment 16, with the use of the “known to the State of California to cause . . .” language in the general consumer product safe harbor warning. It does so by providing a more specific statement of the determination by the expert authorities as to acrylamide’s carcinogenicity, along with additional information to consumers who may be exposed to acrylamide in foods.

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

Comment 3 (Coalition): The Coalition states that the proposed regulation does not provide criteria “on which OEHHA will base a future decision to alter its longstanding formulation of the ‘known to the state to cause cancer’ wording.”

Response: The purpose of the proposed regulation is to provide non-mandatory safe harbor warning language for acrylamide exposures from foods. The Coalition has not identified any authority that requires OEHHA to address, within the text of the proposed regulation or the context of this rulemaking process, the use of certain language for future warnings for other chemical exposures. To the extent the Coalition’s comment is aimed at the reasons OEHHA decided not to use the phrase “known to the State of California to cause . . .” in the proposed regulation, that issue is addressed in the ISOR at pages 3-7.

Further, the commenters’ statement concerning OEHHA’s “longstanding formulation” of its safe harbor warning is inaccurate. As discussed in Response to Comment 2, OEHHA has periodically adopted safe harbor warnings that do not use the “known to the State of California to cause . . .” language and continues to do so.

¹⁷ Title 11, Cal. Code of Regs., section 3202 (emphasis added).

¹⁸ Case No. 2:19-cv-2019-ADA JDP, pending in the Eastern District of California. The District Court issued a preliminary injunction and found plaintiff was likely to prevail on the merits of its First Amendment claim. *California Chamber of Commerce v. Becerra*, 529 F.Supp.3d 1099 (E.D. Cal. 2021). The preliminary injunction was appealed by an intervenor as a prior restraint of its First Amendment right to petition. The Ninth Circuit rejected that argument and went on to analyze the basis for the District Court’s issuance of the preliminary injunction. *California Chamber of Commerce v. Council for Education and Research on Toxics*, 29 F.4th 468 (9th Cir. 2022). The Ninth Circuit agreed with the District Court’s application of the law on the facts found by that court. Because the comments received refer to the District Court’s decision, these responses to comments do as well unless otherwise noted.

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

Comment 4 (Coalition): The Coalition states that there are many chemicals on the Proposition 65 list about which there is controversy as to whether they cause the relevant cancer or reproductive toxicity endpoint in humans. But OEHHA has not suggested that the “known to the State of California to cause . . .” warning language in those cases could be modified to convey the scientific knowledge more accurately. The commenters discuss di(2-ethylhexyl)phthalate (DEHP) as an example, and state that it was “determined after trial not to cause cancer in humans” and that this might not have been litigated had OEHHA taken the position that the warning would use the phrase, “known to the state to cause reproductive toxicity [sic] in animals”. They state that the proposed rulemaking provides no policy basis for determining which chemicals are entitled to use language other than “known to the state” or words to that effect.

The Coalition further alleges that OEHHA’s proposal is not a well-considered policy change, but a strategic litigation move made in response to the *CalChamber* litigation.

Response: OEHHA has discretion to develop chemical-specific warnings. OEHHA decided to develop the acrylamide-specific warning that is the subject of this rulemaking to provide a more specific warning option that provides more information to consumers who may be exposed to acrylamide in foods, and to address the concerns articulated by the District Court in the *CalChamber* case. See Response to Comment 16.

Moreover, in support of its broad claim about alleged controversies concerning many listed chemicals, the commenters cite to just one example – DEHP. This chemical is not analogous to acrylamide. The trial court in *Baxter Healthcare Corp. v Denton*¹⁹ found that DEHP poses no significant risk of cancer *from its use in certain medical devices*²⁰ based on the evidence presented in that case. The court did not order OEHHA to de-list the chemical and did not find the safe harbor warning to be inadequate. Whether Baxter would have sued OEHHA if it had been allowed to say the chemical causes cancer “in animals” is speculative and not relevant to this rulemaking.²¹

¹⁹ *Baxter Healthcare Corp. v. Denton* (2004) 120 Cal.App.4th 333.

²⁰ Key evidence cited by the court – 2000 IARC’s reclassification of the chemical from “possibly carcinogenic to humans” to “not classifiable as to its carcinogenicity to humans” due to biological mechanisms - was reversed by IARC in 2011 based on further evidence on biological mechanisms.

²¹ The “State’s Qualified Experts” added DEHP to the Proposition 65 list by finding it was “clearly shown, through scientifically valid testing according to generally accepted principles, to cause cancer”. Section 25305(a)(1). Several Proposition 65 authoritative bodies (Section 25306(l)) classify DEHP as posing a “possible”, “probable”, or “reasonably anticipated” cancer hazard for humans based on its carcinogenicity in animals: (1) National Toxicology Program (NTP): “reasonably anticipated to be a human carcinogen”,

The expert agencies listed in the ISOR (pages 5-7) all agree acrylamide is a carcinogen and suggest ways to reduce human exposures. The warning proposed in this rulemaking is intended to give consumers relevant information to allow them to make informed decisions concerning these exposures. The Coalition has not identified any authority that requires OEHHA to address, within the text of the proposed regulation or the context of this rulemaking process, the use of alternative warning language in future rulemakings establishing safe harbor warnings for other chemical exposures.

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

Comment 5 (Coalition, ABA): The Coalition states that the proposed warning is not a “contextual warning” but instead a “controversy warning.” It informs the consumer that a controversy exists about whether the chemical at issue poses a risk and that there is uncertainty about whether the chemical has been appropriately identified as “known to the state” to cause cancer in humans. The Coalition opposes this form of warning and states that OEHHA does not have the authority to mandate warnings describing unknown harms. It also states that scientific controversy cannot be summarized so succinctly without misleading lay readers and calling on them to rely on their own prejudices and biases in arriving at their own decision about the product.

The Coalition’s support for contextual warnings, particularly those delivered through modern, digital technology, should not be misconstrued as support for warnings of any sort for chemicals that are not known to the State to cause cancer or birth defects or other reproductive harm. Warnings for chemicals that are only suspected, or even considered to be possible or probable carcinogens, are inappropriate because they mislead consumers.

Response: As a threshold matter, OEHHA believes the phrase “controversy warning” is misleading. The carcinogenicity of acrylamide is not controversial from a scientific perspective. The use of the phrase “controversy warning” as coined by the commenter implies otherwise.

NTP, 2021. Report on Carcinogens, Fifteenth Edition, available at: <https://ntp.niehs.nih.gov/go/roc15>; (2) IARC: “possibly carcinogenic to humans”, IARC (2013) IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 101, pages 149-284, available at: <https://publications.iarc.fr/125>; (3) National Institute of Occupational Safety and Health (NIOSH): “DEHP is carcinogenic”, NIOH and NIOSH basis for an occupational health standard: Di(2-ethylhexyl)phthalate, US Department of Health and Human Services, available at: <https://www.cdc.gov/niosh/docs/90-110/pdfs/90-110.pdf?id=10.26616/NIOSH PUB90110>; (4) US EPA: “probable human carcinogen”, Integrated Risk Information System, US EPA National Center for Environmental Assessment, available at: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0014_summary.pdf. These entities have not determined that DEHP does not cause cancer in humans.

The harm caused by acrylamide is not “unknown”. There is broad consensus among governmental regulators and health agencies that acrylamide is a carcinogen. The US EPA, International Agency for Research on Cancer, National Toxicology Program, and National Institute for Occupational Safety and Health all recognize that the chemical is an animal carcinogen. Acrylamide was listed as a carcinogen in 1990 based on findings by the International Agency for Research on Cancer (IARC) and US Environmental Protection Agency (US EPA) that acrylamide is an animal carcinogen. The chemical was listed after the decision in *AFL-CIO v Deukmejian*, which required the Governor to list both animal and human carcinogens under Proposition 65.²²

Findings that a chemical is an animal carcinogen are considered applicable to humans, absent compelling evidence to the contrary.²³ Regarding acrylamide, in addition to animal data, there are extensive data showing that acrylamide exhibits characteristics of carcinogens in mechanistic studies. Indeed, a study²⁴ by researchers from IARC and other leading research institutions cited in the ISOR examined human tumors for the unique mutational signature found with acrylamide exposure and found “an unexpectedly extensive contribution of acrylamide-associated mutagenesis to human cancers”. As noted in the ISOR, findings have been made by several regulatory and health agencies regarding acrylamide’s potential for carcinogenicity in humans, specifically:

- The International Agency for Research on Cancer (IARC):
 - probably carcinogenic to humans²⁵
- The National Toxicology Program (NTP). NTP Report on Carcinogens (RoC):

²² *AFL-CIO v. Deukmejian* (1989) 212 Cal.App.3d 425, requiring the Governor to list both animal and human carcinogens under Proposition 65. The position espoused by the commenter would negate the ruling since the purpose of listing chemicals is to require warnings for significant human exposures to them: “The Act applies to those chemicals which respected scientific agencies have already determined cause cancer or reproductive toxicity in humans *or animals*. Our decision simply enforces the will of the people as so expressed.” (Emphasis added.)

²³ “It is a fundamental tenet of toxicology that the results of properly designed studies in experimental animals are applicable to humans. For example, 29 C.F.R. § 1910.1220, app. A.6.1. (Federal Occupational Safety and Health Administration regulations): this principle applies “unless there is strong evidence that the mechanism for tumor formation is not relevant to humans”. In the case of acrylamide, the genotoxic mechanism of action through its metabolite glycidamide, has been proven to be applicable in humans.” Page 13 of ISOR.

²⁴ Zhivagui M, Ng AWT, Ardin M, Churchwell MI, Pandey M, Renard C, et al. (2019). Experimental and pan-cancer genome analyses reveal widespread contribution of acrylamide exposure to carcinogenesis in humans. *Genome Res* 29(4):521-531. Available from: <https://genome.cshlp.org/content/29/4/521>.

²⁵ <https://publications.iarc.fr/78> and <https://monographs.iarc.who.int/list-of-classifications>.

- reasonably anticipated to be a human carcinogen²⁶
- US Environmental Protection Agency (US EPA):
 - likely to be carcinogenic to humans²⁷
- National Institute of Occupational Safety and Health (NIOSH):
 - potential occupational carcinogen²⁸

Thus, as discussed in detail in the ISOR for this proposed warning, governmental bodies and other authoritative entities recommend ways to, or have adopted regulations to, reduce acrylamide in food.²⁹

The Coalition relies on quotes from the American Cancer Society (ACS) and the National Cancer Institute (NCI), as well as various epidemiological studies cited in an expert report submitted by CalChamber in the *CalChamber* case, to argue that a controversy exists about the carcinogenicity of acrylamide.³⁰ However, none of this evidence, when properly weighed with all the other scientific evidence, establishes the existence of a scientific controversy, or undermines the accuracy of the proposed safe harbor warning.

ACS is not, and does not represent itself as, an expert scientific agency that conducts carcinogenicity determinations.³¹ Rather than reaching its own conclusions about the carcinogenicity of acrylamide, it cites the findings of NTP, US EPA and IARC,³² and provides links to fact sheets by other organizations³³ that discuss concerns about acrylamide exposure or risk and ways to reduce it.

NCI, unlike its federal counterparts at US EPA and NTP, does not perform weight of evidence determinations of carcinogenicity based on the full range of scientific

²⁶ <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/acrylamide.pdf>.

²⁷ https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0286tr.pdf.

²⁸ <https://www.cdc.gov/niosh/topics/cancer/npotocca.html>.

²⁹ See ISOR page 6-7.

³⁰ The Ninth Circuit relied on this information in its opinion affirming the District Court's grant of a preliminary injunction, as discussed in note 18, *supra*. As of the date of this FSOR, a petition for en banc rehearing of that opinion remains pending.

³¹ <https://www.cancer.org/about-us/who-we-are.html>; <https://www.cancer.org/healthy/cancer-causes/chemicals/acrylamide.html> ("In general, the American Cancer Society (ACS) does not determine if something causes cancer (that is, if it is a carcinogen), but we do look to other respected organizations for help with this").

³² <https://www.cancer.org/healthy/cancer-causes/chemicals/acrylamide.html>.

³³ European Food Safety Authority: <https://www.efsa.europa.eu/en/corporate/pub/acrylamide150604> ; Agency for Toxic Substances and Disease Registry.

evidence. NCI reports on chemicals that cause cancer in humans,³⁴ but does not engage in identifying probable human carcinogens based on cancer causation in animals and other lines of scientific evidence. Moreover, as NCI notes, “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”.³⁵ Because of such limitations in the conduct of epidemiological studies for this ubiquitous chemical—including those highlighted in the expert report submitted by CalChamber—the studies’ inconclusiveness does not undermine the authoritative agencies’ finding that acrylamide is a probable human carcinogen. This is discussed in greater detail in the ISOR on pages 16-18.

OEHHA has the authority to adopt regulations that conform with and further the purposes of the statute. The proposed warning is consistent with the consensus of the scientific findings of the agencies noted above in that it states that acrylamide is a “probable human carcinogen,” that acrylamide is “formed in some foods during cooking or processing at high temperatures,” that various factors can affect an individual’s cancer risk (including amount and frequency of exposure), and that additional information may be found on the linked website.

None of these statements is false, misleading, or difficult for a consumer to understand. Instead, the proposed warning provides consumers with truthful, accurate information they can use to make informed decisions about their exposures to a probable human carcinogen.

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

Acrylamide is a “Probable Human Carcinogen”

Comment 6 (CEH): CEH agrees with OEHHA that there is no scientific debate about the carcinogenicity of acrylamide or its potential for carcinogenicity in humans. Extensive evidence of carcinogenicity of acrylamide in animals, and the identification of the same genotoxic mechanism in both animals and humans, make it clear that the findings of acrylamide’s carcinogenicity in animals is also applicable to humans.

Response: OEHHA acknowledges the comment and agrees with the commenter concerning the carcinogenicity of acrylamide and the applicability of animal studies to human exposures. The scientific findings of several respected organizations are set out

³⁴ <https://www.cancer.gov/about-cancer/causes-prevention/risk/substances>.

³⁵ <https://www.cancer.gov/about-cancer/causes-prevention/risk/diet/acrylamide-fact-sheet>.

in the ISOR for this rulemaking beginning on page 4. See also Response to Comment 5.

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

Comment 7 (Coalition): The Coalition argues that OEHHA erroneously declares that there is “no serious scientific debate about the carcinogenicity of acrylamide, or its potential for carcinogenicity in humans.” The Coalition states the District Court found in *CalChamber* that a Proposition 65 warning is not appropriate while there is a legitimate scientific controversy about whether a chemical causes cancer in the first place. It states that where there is a scientific controversy about the carcinogenicity of acrylamide, OEHHA will not be able to craft an acrylamide safe harbor warning that is consistent with the First Amendment.

Response: As noted above, warnings are required for exposures to acrylamide in foods that businesses cannot demonstrate pose no significant risk of causing cancer. The District Court’s opinion in *CalChamber* does not accurately reflect the state of the science concerning the carcinogenicity of acrylamide; neither does the Ninth Circuit opinion affirming the District Court’s decision. Consuming a given food product containing acrylamide can, depending on dose and frequency of exposure, increase a person’s risk of developing cancer.³⁶ See also discussion of the science in Response to Comment 5, and the discussion of the *CalChamber* case in Response to Comment 16.

OEHHA has determined that providing this tailored safe harbor warning for acrylamide exposures from foods is a reasonable means of addressing the District Court’s concerns with the general consumer product warning as applied to acrylamide exposures from foods while addressing related public health concerns. As set forth in the ISOR:

Because of concerns over the potential carcinogenic risks to humans from consuming foods with acrylamide, several governmental organizations have called for or are recommending ways to reduce formation of acrylamide in food and human exposures to it through consumption of food.³⁷

³⁶ Acrylamide is ubiquitous in the diet. It is estimated that more than one-third of the calories consumed in the US comes from food that contains acrylamide. This makes study of dietary acrylamide exposures and cancer especially challenging with respect to the exposure misclassification issue. For additional discussion of the scientific evidence of acrylamide’s carcinogenicity, see pages 12-18 of ISOR.

³⁷ See pages 6-7 of the ISOR.

These organizations include the US Food and Drug Administration, the European Union, and the United Nation’s Joint FAO/WHO Expert Committee on Food Additives³⁸. Their recommendations are based on the existing body of scientific evidence. California consumers have a right under Proposition 65 to know about their exposures to acrylamide in foods so they can decide for themselves if they want to reduce or eliminate their exposures to this chemical. The proposed warning would accomplish the right-to-know purposes of Proposition 65 in a manner that addresses the District Court’s concerns.

No changes were made to the proposed regulation based on this comment. **Comment 8 (ABA):** ABA states that the proposed warning would allow the Proposition 65 warning requirement to be satisfied with a statement referring to acrylamide as a “probable human carcinogen”. This commenter asserts that this does not align with the statutory authority granted to OEHHA, which requires warnings only where a chemical is “known to cause cancer,” not just a “probable carcinogen”.

Response: Nothing in the statute requires the lead agency to use the particular phrase “known to the State of California to cause . . .” in a safe harbor warning.

Separate rules govern the listing of a chemical and the content of warnings for chemical exposures. Chemicals known to cause cancer in animals must be listed under Proposition 65³⁹. Chemicals need not be known to cause *human* cancer to be listed or require a warning. This conclusion is based on the clear language in the statute⁴⁰ and the scientific assumption that a chemical that causes an effect in animals will cause a similar effect in humans, absent compelling evidence to the contrary⁴¹.

Acrylamide is a known animal carcinogen and a probable human carcinogen; this means it is “known to the state to cause cancer” within the meaning of the statute, which is why acrylamide was placed on the Proposition 65 list.⁴²

As explained in the ISOR beginning on page 5:

There is no serious scientific debate about the carcinogenicity of acrylamide, or its potential for carcinogenicity in humans. There is extensive evidence of

³⁸ Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO).

³⁹ Health and Safety Code section 25249.6 requires warnings for chemicals that are known to cause cancer or reproductive toxicity. *AFL-CIO v. Deukmejian*, *supra*, 212 Cal.App.3d 425, requires the Governor to list both animal and human carcinogens under Proposition 65.

⁴⁰ *Ibid.*

⁴¹ See *supra* note 23.

⁴² See *AFL-CIO v. Deukmejian*, *supra*, 212 Cal.App.3d at p. 441.

carcinogenicity from studies in animals and detailed mechanistic studies of humans and animals. Acrylamide is unequivocally a carcinogen in animals that causes tumors in multiple sites in rats and mice of both sexes.

See also discussion of the science in Response to Comment 5.

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

Comment 9 (Coalition, ABA, PRC): The commenters state acrylamide should not be characterized as a probable human carcinogen. They state that the listing of acrylamide was based primarily on evidence of carcinogenicity in animal studies and such studies do not prove that acrylamide is carcinogenic to humans. They further claim that animal studies may involve exposure that does not accurately represent real-world levels of acrylamide exposure for consumers, and acrylamide may affect animals differently than it does humans. They claim the District Court in *CalChamber* observed that “dozens of epidemiological studies have failed to tie human cancer to a diet of food containing acrylamide” and described the Proposition 65 safe harbor warning as controversial “because it elevates one side of a legitimately unresolved scientific debate about whether eating foods and drinks containing acrylamide increases the risk of cancer.”

PRC states that the International Agency for Research on Cancer (IARC) defines acrylamide as a Class 2A carcinogen because a definite carcinogenic effect on animals was found in animal experiments, but there is insufficient evidence of carcinogenicity in humans, so it can only be considered a potential human carcinogen. They assert that although the term “a probable human carcinogen” is used in the proposed regulatory provisions, the carcinogenic potential of acrylamide is specifically mentioned in the warning, which still shows insufficient scientific basis and is misleading to some extent.

Response: There is no debate about the fact that acrylamide is an animal carcinogen. Nor do the available epidemiological studies in any way undermine the conclusion of these and other regulatory and health agencies that acrylamide is either a probable or a likely human carcinogen. Thus, warnings are required for exposures to acrylamide that are above the statutory threshold⁴³. These issues are discussed in more detail in Responses to Comments 5, 7, and 8.

OEHHA disagrees with the commenter’s opinion that acrylamide is not a probable human carcinogen. IARC determined that acrylamide is “probably carcinogenic to humans”, based on the extensive findings of animal carcinogenicity and damage to

⁴³ Health and Safety Code section 25249.10.

chromosome, mutations and other effects on DNA in animal studies, and US EPA similarly determined that the chemicals is “likely to be carcinogenic to humans”.

Regarding the District Court’s conclusion in the *CalChamber* case about cancer risks from dietary acrylamide, in addition to IARC’s and US EPA’s findings, it is also notable that based on their independent evaluations the European Union, the United Nation’s Joint FAO/WHO Expert Committee on Food Additives, and other organizations have developed guidance or regulations to reduce the risk of cancer by reducing human exposures to acrylamide in food. See Response to Comment 7, above. Moreover, in proposing this safe harbor language specific to acrylamide, OEHHA has incorporated several of the suggestions the District Court made that it believed would make the warning pass muster under the First Amendment. The proposed warning is purely factual and not misleading. For this reason, OEHHA also disagrees with the commenters’ opinion that the proposed warning will be misleading to consumers.

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

Other Elements of the Proposed Warning Language

Comment 10 (DSteinman): The commenter states that the proposed regulation benefits some of the world’s biggest corporations and violators of Proposition 65, like Coca Cola, Hormel, and General Mills, whose products egregiously violate Proposition 65 due to irresponsible manufacturing by overprocessing foods targeted to children and young mothers. The proposed regulation also rewards large corporations through unfair competition achieved by using cheaper processing methods to yield bigger margins while sacrificing people’s health.

Response: The comment is largely outside the scope of the present rulemaking, with the exception of its contention about the benefits of the proposed warning. The proposed regulation provides optional safe harbor warning language that OEHHA believes will address the District Court’s concerns in the *CalChamber* case (see Response to Comment 16) and that a business can use for acrylamide exposures from foods.

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

Comment 11 (PNewman, DSteinman, and HLF): The commenters allege that OEHHA’s proposal is based on reacting to biased science and is opening the door for further erosion of the integrity of the scientific agencies that have declared acrylamide a “known” carcinogen. They claim is the first carve out for a chemical related warning for

food. But it is the third instance where OEHHA is regulating a chemical known to cause cancer.

Response: The proposed warning does not exempt any acrylamide exposures from the Proposition 65 warning requirement. The warning provides consumers with factually accurate information they can use to decide if they want to be exposed to acrylamide, a probable human carcinogen. As noted in Response to Comment 5 above, it accurately reflects findings made by several regulatory and health agencies regarding acrylamide's potential for carcinogenicity in humans.

The reference to other rulemakings is outside the scope of this rulemaking and require no response.

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

Comment 12 (ABA): ABA states that the warning is inappropriate for baked goods given the scientific literature showing that many grain-based foods such as bread and baked goods lower the risk of cancer and other diseases. To support this statement the commenter cites a review by Glen A. Gaesser on whole grains and refined grains and cancer risk⁴⁴. The commenter states that the FDA recommends that consumers should not stop eating foods that contain acrylamide. The 2020-2025 edition of the Dietary Guidelines for Americans, published by the US Departments of Agriculture (USDA) and Health and Human Services (HHS), explains that “[h]ealthy dietary patterns include whole grains” and recommends increased consumption of dietary fiber, which can be found in whole grain foods. FDA has expressed concern that Proposition 65 warnings may discourage consumers from eating such healthful foods. They allege that because of the Proposition 65 acrylamide warning requirements, many bakeries have been targeted with meritless lawsuits despite offering foods for sale that are consistent with federal nutrition recommendations.

Response: Proposition 65 is a right-to-know law intended to provide consumers with information they can use to make their own choices about exposures to chemicals listed as carcinogens or reproductive toxins. Given this, OEHHA's proposed warning takes no position on the relative nutritional benefits of baked, roasted, or fried foods. It provides consumers with information they requested when they passed Proposition 65 with nearly a 2/3 majority.

⁴⁴ Gaesser GA (2020), *Whole Grains, Refined Grains, and Cancer Risk: A Systematic Review of Meta-Analyses of Observational Studies*, 12 *Nutrients* 3756. Available at <https://www.mdpi.com/2072-6643/12/12/3756>.

The purported dietary benefits of certain foods containing acrylamide are thus outside the scope of this rulemaking. Nonetheless, OEHHA notes that information about the benefits of eating a balanced, high-fiber diet are readily available, OEHHA also notes that not all grain-based foods contain whole grains, which is the focus of the language commenter quotes from USDA and HHS. Further, numerous whole grain foods will not contain acrylamide at levels that require a warning.

Additionally, the commenter cites two documents – a meta-analysis and a review paper – that do not necessarily support the commenter’s contentions. The commenter provides no indication of the cooking or food preparation techniques for the foods underpinning the meta-analysis and review paper. The paper reports that whole grains were associated with reductions in cancer risk. However, although the paper’s author concluded that the data on refined grains was inconclusive, cancer risks for all studies tabulated were elevated, including one meta-analysis of 19 studies showing a 63% increase in gastric cancer risk in the top exposure group.

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

Comment 13 (APoulsen): APoulsen states that the phrase "formed in some foods during cooking or processing at high temperatures" is hardly an accurate representation of acrylamide formation and exposes the California Attorney General and private enforcers to more litigation, specifically over this language due to its inaccuracies.

Response: The statement that acrylamide is "formed in some foods during cooking or processing at high temperatures" is accurate. It is well established in the scientific literature that acrylamide is created during the cooking or heat processing of certain plant-based foods at high temperature.⁴⁵ Accordingly, OEHHA does not think the commenter’s allegation about future litigation has merit.

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

Comment 14 (APoulsen): The commenter argues that the warning language includes words that do not convey a "clear and reasonable" warning, such as "some foods," "cooking or processing" (where "processing" is inclusive of "cooking"), "many factors," "including frequency and amount," without explaining in the warning what frequency or amount could cause cancer.

Response: OEHHA disagrees that the language of the proposed warning is vague and does not convey a clear and reasonable warning. The plain language is clear on its face. Further, the ISOR explains on page 4, "Acrylamide is a chemical that is formed in

⁴⁵ See ISOR pages 4-6, and discussion in documents cited on these pages.

certain plant-based foods during cooking or processing at high temperatures, such as frying, roasting, grilling, and baking.” The proposed warning conveys this information in a succinct way.

The proposed warning also includes a link to a website where consumers can find more detailed information about the scientific basis for the listing of acrylamide, acrylamide’s effects, how acrylamide is formed in foods, and how to reduce an individual’s exposure. The level of detail the commenter suggests should be included in the warning would be too unwieldy, especially given the multitude of products that may need a warning for exposures to this chemical. Further, providing individualized advice on the frequency or amount of exposure that may cause an effect is beyond the scope of this rulemaking and is not required by Proposition 65.

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

First Amendment and the *CalChamber v. Bonta* decision

Comment 15 (CEH): CEH states that it supports the proposed alternative acrylamide warning language to protect Proposition 65 from First Amendment challenges like the pending *CalChamber* case. While CEH supports OEHHA in providing more nuanced warning language for acrylamide exposure from food in this case, it does not necessarily support using the same approach for other chemicals or in other future instances.

Response: OEHHA acknowledges the CEH comment, and its support for this specific proposal.

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

Comment 16 (ABA): The commenter states that the proposed warning would violate the First Amendment, which prohibits the government from requiring companies to make false or misleading statements (i.e., statements that are not purely factual and uncontroversial). They claim that given the ongoing scientific controversy about the carcinogenicity of acrylamide, the proposed warning does just that, by requiring companies to take a side in this controversy. Thus, they claim the proposed warning about the carcinogenicity of acrylamide would not be consistent with the First Amendment.

Response: OEHHA disagrees with the commenter’s statements that the proposed warning would violate the First Amendment. In the context of a preliminary injunction against enforcement, the District Court and Ninth Circuit in *CalChamber* found that the general consumer product safe harbor “known to the state to cause . . .” warning would

be false and misleading as applied to acrylamide in foods, and therefore requiring such a warning would violate the First Amendment rights of CalChamber's members.⁴⁶

However, the proposed warning differs materially from the warning that was before the District Court and Ninth Circuit in the *CalChamber* case. In particular, the Ninth Circuit found the general consumer product safe harbor warning to be misleading as applied to acrylamide in foods because of its use of the phrase "known to the state of California to cause cancer".⁴⁷ The warning proposed in this regulation does not use that phrase. It provides consumers with factually accurate information they can use to decide if they want to be exposed to acrylamide, a probable human carcinogen. This furthers the purposes of the statute.

Notably, the District Court laid out in its opinion some of the ways the general warning could be modified to comport with the First Amendment.

The State could allow businesses to explain that acrylamide forms naturally when some foods are prepared. It could permit businesses to say that California has listed acrylamide as a chemical that "probably" causes cancer or is a "likely" carcinogen or that the chemical causes cancer in laboratory animals. It could permit businesses to say that acrylamide is commonly found in many foods and that neither the federal government nor California has advised people to cut acrylamide from their diets.⁴⁸

The proposed warning includes several of these components. OEHHA explained the reasoning for the proposed warning language in the ISOR (page 4) for this regulatory action:

OEHHA has considered the concerns expressed in the District Court's preliminary injunction order in developing the proposed regulation. The purpose of the proposed regulation is to provide an additional optional safe harbor warning for businesses that addresses the District Court's concerns as well as public health concerns.

⁴⁶ *California Chamber of Commerce v. Becerra* (E.D. Cal. 2021) 529 F.Supp.3d 1099, 1117-1118; *California Chamber of Commerce v. Council for Education and Research on Toxics* (9th Cir. 2022) 29 F.4th 468, 479.

⁴⁷ *California Chamber of Commerce v. Council for Education and Research on Toxics*, *supra*, 29 F.4th at p. 479; see also *California Chamber of Commerce v. Becerra*, *supra*, 529 F.Supp.3d at p. 1117-1118.

⁴⁸ *California Chamber of Commerce v. Becerra*, *supra*, 529 F.Supp.3d at p. 1118.

Moreover, the commenter states, and the District Court and Ninth Circuit also concluded, that there is a scientific controversy about the carcinogenicity in acrylamide. This is incorrect for the reasons explained in response to Comment 5 above.

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

Comment 17 (PNewman, HLF, and DSteinman): Commenters state that, based on the preliminary injunction in the *CalChamber* case, OEHHA proposes to create an exemption allowing an alternate warning message for acrylamide, one of 838 chemicals in the group of “probable” human carcinogens on the Proposition 65 list. They claim this proposal sets a precedent that could be leveraged by industry lobbyists.

Commenters further state that the finding by the court that the general safe harbor food warning language is “not purely factual” and is “controversial” would effectively repeal Proposition 65’s warning requirements as applied to the carcinogenicity of any chemical toxin that is listed based on animal data.

PNewman states that the court’s order has enormous potential health consequences including:

- (1) the removal from the Proposition 65 list of carcinogens of up to 93% of chemicals (those in the same group of “probable” carcinogens);
- (2) changing the allowable levels of acrylamide in drinking water from 0.2 mcg/day as a carcinogen, to 140 mcg/day as a reproductive toxin only;
- (3) the increasing use of acrylamide polymers in chemical treatment of drinking water, plastics, paints, grout, allowances in oil and gas fracking waste discharge; and
- (4) application of similar relief to unlimited categories, types and number of chemicals and products.

Response: The comment is largely outside the scope of the present rulemaking. The District Court’s ruling did not remove acrylamide or any other chemical from the Proposition 65 list or modify any of the safe harbor levels adopted by OEHHA. OEHHA declines to speculate on whether or how the ruling may be applied to warnings for other chemical exposures or use of acrylamide in products or processes other than those related to food exposures.

OEHHA’s warning proposal does not exempt acrylamide exposures from the Proposition 65 warning requirement. Instead, it provides optional safe harbor warning language that can be used for acrylamide exposures from foods. OEHHA believes the

language addresses the concerns of the District Court and Ninth Circuit in the *CalChamber* case. See Response to Comment 16. OEHHA notes the ruling in the *CalChamber* case was a ruling on a motion for preliminary injunction that only addressed whether *CalChamber* was likely to prevail on its First Amendment challenge to the general safe harbor warning as applied to acrylamide in foods. If the current rulemaking is completed, the courts will have an opportunity to evaluate the more specific warning proposed for acrylamide in foods.

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

Comment 18 (APoulsen): APoulsen states that “[n]aturally occurring’ is a major affirmative defense for Proposition 65’s exposure to toxins.” “If acrylamide was naturally occurring, foods with high amounts of acrylamide would not have been subject to the warning in the first place. Therefore, implementing the judge’s language would have nullified Proposition 65 as it relates to acrylamide.”

Response: The commenter is discussing statements the District Court made in its opinion concerning ways the general warning could be modified to comport with the First Amendment.

The State could allow businesses to explain that acrylamide forms naturally when some foods are prepared. It could permit businesses to say that California has listed acrylamide as a chemical that “probably” causes cancer or is a “likely” carcinogen or that the chemical causes cancer in laboratory animals. It could permit businesses to say that acrylamide is commonly found in many foods and that neither the federal government nor California has advised people to cut acrylamide from their diets.⁴⁹

The proposed warning includes several, but not all, of these components. OEHHA explained the reasoning for the proposed warning language in the ISOR (page 4) for this regulatory action:

OEHHA has considered the concerns expressed in the District Court’s preliminary injunction order in developing the proposed regulation. The purpose of the proposed regulation is to provide an additional optional safe harbor warning for businesses that addresses the District Court’s concerns as well as public health concerns.

Acrylamide does not meet the regulatory definition of “naturally occurring” in subsection 25501(a)(1) because it is not a natural constituent of a food or present solely as a result

⁴⁹ *California Chamber of Commerce v. Becerra*, *supra*, 529 F.Supp.3d at p. 1118.

of absorption or accumulation from the environment in which is grown and obtained. Further, subsection 25501(a)(3) states that a chemical is naturally occurring **only to the extent that the chemical did not result from any known human activity**. Acrylamide is formed through the human activity of cooking or heat processing foods. Because it is human activity that causes the chemical to form in the food, it does not meet the regulatory definition of “naturally occurring”. Including the suggested phrase would thus be misleading in the context of prepared foods under Proposition 65.

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

Comment 19 (APoulsen): APoulsen states that the District Court’s statement that “acrylamide is commonly found in many foods” is misleading, as acrylamide is found only in processed foods, when prepared by certain methods.

Response: The statement that acrylamide is commonly found in many foods is correct, but, as the commenter notes, its presence results from certain processing methods. The warning language in the proposed regulation more accurately states that acrylamide is formed in “some foods during cooking or processing at high temperatures.”⁵⁰ Thus, the proposed warning is more accurate in the context of Proposition 65 than the language suggested by the commenter or the District Court.

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

Outside the Scope of the Proposed Rulemaking

Comment 20 (HLF, APoulsen): Commenters make several statements about the *CalChamber* case for OEHHA to consider before adopting the proposed regulation. These include the commenters’ views on the presiding judge, expert testimony offered by Cal Chamber’s expert, Dr. Lipworth, and other information the commenters believe should have been considered by the court.

Response: These are the commenters’ views on the court proceedings in the *CalChamber* case. They are irrelevant to the current rulemaking and therefore require no response.

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

Comment 21 (Coalition): The Coalition states that OEHHA should embrace digital disclosure options to inform consumers more completely of chemicals that are “known to the State to cause cancer and birth defects or other reproductive harm”. They assert

⁵⁰ Section 25607.2(b)(2).

that the adoption of on-package triggers (such as QR codes and digital watermarks) and digital disclosure platforms like SmartLabel® allow consumers to obtain detailed product information in a consistent, organized format when and where they want it. They further assert that modern, digital solutions are a more effective means of providing transparency and information to consumers, giving them greater ease of access and increased confidence in the accuracy of information and the safety of consumer products. For food and other consumer packaged goods, they claim digital disclosure would enable businesses to provide more information to consumers, including reliable research and science-based advice on how to reduce potential exposures.

The Coalition states that the OEHHA website's search function received 11.8 million page views between September 2020 and mid-September 2021, yielding nearly 1 million views a month of its website. OEHHA's own data concerning the top 10 most searched categories indicates immense interest and viability for digital disclosure on products relevant to the Coalition. "Food" was the most searched category on the website (with 90,000 views or 8.58% of all searches). They assert digital methods of providing contextual information are clearly quite effective and of great interest to consumers.

Response: This comment is outside the scope of the current rulemaking, which proposes specific warning language for exposures to acrylamide from food products but does not address methods of transmission of the warning. OEHHA nonetheless notes that the proposed warning includes a URL for a Proposition 65 website maintained by OEHHA; there, consumers may obtain additional information about relevant chemicals. Businesses could, however, use QR Codes or other technology in addition to OEHHA's URL. OEHHA further notes that, pursuant to section 25601(e)⁵¹, businesses currently are allowed to provide contextual information in this manner, as part of a safe harbor warning, to the extent the contextual information addresses the source of exposure and ways to reduce or avoid exposure.

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

Comment 22 (PRC): The commenter states it does not object to providing a warning, but requests that OEHHA clarify the detection method for measuring acrylamide levels in food, along with a limit value to assist businesses in complying with Proposition 65.

⁵¹ 25601(e) states, "The warning content may contain information that is supplemental to the content required by this subarticle only to the extent that it identifies the source of the exposure or provides information on how to avoid or reduce exposure to the identified chemical or chemicals. Such supplemental information is not a substitute for the warning content required by this subarticle."

Response: This comment is beyond the scope of the proposed rulemaking. OEHHA notes, however, that existing regulatory provisions may assist the commenter in determining when a warning would be required for a given product. See, for example, Sections 25701 et seq. and 25705.

OEHHA staff are available to assist the commenters in applying OEHHA's regulations to a given set of facts.

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

Comment 23 (NAFEM): The commenter states that customers of its member food preparation equipment manufacturers, such as restaurants, could use its members' products and create acrylamide in food products that are subsequently served or packaged for later sale to customers. NAFEM's members, they state, have no control over the "ingredients, cooking method, length of cooking, temperature at which foods were processed, storage of food, micronutrient composition of the raw food, and other factors" that a customer, such as a restaurant, might use to make its food products. NAFEM "encourages OEHHA to clarify the scope of necessary Proposition 65 warnings to those entities that are cooking, preparing, or otherwise creating food products, and not the entities that manufacture the commercial equipment used in the creation of such products".

Response: This comment is outside the scope of the proposed safe harbor warning regulation. The proposed regulation provides non-mandatory warning language and only applies where a business has determined a warning is required and has decided to follow the OEHHA regulations to receive safe harbor protection. OEHHA notes however, that Proposition 65 only requires businesses to provide a warning for "knowing and intentional exposures" to listed chemicals.⁵²

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

Comment 24 (Anon): The commenter states that labels need to be required on all food products sold in stores or restaurants that could expose someone to a chemical that causes cancer.

Response: The comment is outside the scope of the proposal. The proposed regulation provides safe harbor warning language for acrylamide but does not address when a warning for acrylamide should be given.

⁵² Health and Safety Code section 25249.6.

OEHHA notes that requiring warnings on all food products sold in stores or restaurants that could expose someone to a chemical that causes cancer is beyond OEHHA's authority and the statutory requirement. Proposition 65 requires businesses to provide warnings to Californians about "knowing and intentional" exposures to listed chemicals above certain levels.⁵³ It does not require warnings for all exposures to listed chemicals regardless of the level of exposure.

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

Comment 25 (DSteinman and HLF): Commenters state that studies show everyday foods like almond butter and snack mixes are contaminated with exorbitant levels of acrylamide and consumers have a right to know when a chemical like acrylamide is found in foods at harmful levels. They assert OEHHA has an obligation to protect citizens and the integrity of science on which that protection depends.

Response: The comment is outside the scope of the proposal. The proposed regulation provides safe harbor warning language for acrylamide but does not address when warnings related to acrylamide exposure are required. See also Response to Comment 17.

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

Comment 26 (Coalition): The Coalition discusses an earlier rulemaking that was completed in 2016 and became effective in 2018 that, among other things, adopted new safe harbor warning content for a variety of exposures to listed chemicals, including those from consumer products. The commenters cite comments they made during that rulemaking. The Coalition commented then that "[c]onsumers need and deserve accurate and truthful, contextual information about the safety of consumer products they use and consume every day," and that the provision in the proposed regulation that would prohibit addition of language in the warning that would "dilute, diminish or contradict" it was "unconstitutionally vague, and potentially violated the First Amendment commercial free speech rights of affected businesses". OEHHA later revised the provision so that it only applied to safe harbor warnings and explained that "Subsection (e) does not prevent a business from engaging in public discourse regarding listing decisions and methodology; however, providing this information in the warning would be inconsistent with the safe harbor warning methods and content and a business that chooses to do so would not be afforded safe harbor protection under Article 6".

⁵³ Health and Safety Code section 25249.10(c).

The Coalition states that truthful, accurate supplemental information from the manufacturer or other regulated entity should be permitted, and supplemental information that puts risk into context and communicates the product benefits is fully consistent with Proposition 65 and its purposes and should be encouraged by the State. The commenters allege that OEHHA and the AG have consistently opposed such warnings, even when federal agencies with expertise in hazard identification, risk assessment, and risk communication disagree with the rigid Proposition 65 warning format.

The Coalition also states that there are numerous instances where the Attorney General's Office has objected to the wording of warnings in settlements that would more fully inform consumers. There are instances in which the Attorney General's Office contacted businesses to object to warnings being provided in the marketplace, not on the grounds that the warning is factually inaccurate, but on the grounds that it dilutes the Proposition 65 warning message and is therefore not a "clear and reasonable" warning as required by Proposition 65. The efforts of OEHHA and the Attorney General's Office to restrict contextual information are contrary to good policy and to the First Amendment.

Response: The comment is outside the scope of this rulemaking, which proposes to adopt an additional, non-mandatory safe harbor warning that is specific to acrylamide in foods. The quoted regulatory provision, which is not the subject of this rulemaking, is intended to limit the amount of information a business may add to a safe harbor warning so that the message remains clear and reasonable as required by the statute. As was explained in the FSOR for that rulemaking:

Subsection [25600](e) sets forth specific information that can be included with the safe harbor warning content. Specifically the information may only identify the source of the exposure or provide information on how to avoid or reduce exposure to the identified chemical or chemicals.

This restriction only applies where a business chooses to provide a safe harbor warning. Businesses are free to provide other information separate from the warning or provide a non-safe harbor warning so long as the warning is clear and reasonable. The regulation does not apply to OEHHA as the lead agency with the authority to adopt regulations that interpret and further the purposes of the statute.

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 and will not 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.

Alternatives Determination

In accordance with Government Code section 11346.9(a)(7), OEHHA has considered available alternatives, including those suggested by public commenters,⁵⁴ to determine whether any alternative would be more effective in carrying out the purpose of the regulations. OEHHA has determined that no alternative it considered or that was otherwise identified and brought to its attention would be more effective in carrying out the purpose of the proposed regulation, would be as effective and less burdensome to affected private persons than the proposed regulation, nor would be both more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. OEHHA considered taking no action but finds that taking no action is inconsistent with the intent of the Act and its implementing regulations.

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 amendments do not affect small businesses as defined in Government Code Section 11342.610. Proposition 65, by its terms, does not apply to small businesses with fewer than 10 employees. Further, this regulatory action does not require any business to use the proposed warning. Instead, the proposed regulation provides non-mandatory, safe harbor methods and content for consumer product warnings for exposures to acrylamide.

Non-duplication Statement

⁵⁴ Specific responses to proposed alternatives are provided in the summary/response section of this FSOR.

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.