Proposition 65 Initial 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

> > April 5, 2024



California Environmental Protection Agency Office of Environmental Health Hazard Assessment

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### I. Summary

Proposition 65<sup>1</sup> requires businesses to provide a clear and reasonable warning before they knowingly and intentionally cause an exposure to a chemical listed as a carcinogen or reproductive toxicant under the Act.<sup>2</sup> The Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency that implements Proposition 65 and has the authority to promulgate and amend regulations to implement and further the purposes of the Act.

This proposed rulemaking would amend subsection 25607.2(b) of Title 27, California Code of Regulations, to provide an additional safe harbor warning option for businesses 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 existing law.<sup>3</sup> The warning content and methods provided in the safe harbor regulations are deemed "clear and reasonable" by OEHHA for purposes of the Act. (27 CCR § 25601(a).)

### II. Statement of Purpose and Problem to be Addressed

## a. Background

Acrylamide is a chemical that is formed in certain plant-based foods during cooking or processing at high temperatures, such as frying, roasting, grilling, and baking. Acrylamide was originally added to the Proposition 65 list of chemicals in 1990 based on findings by the International Agency for Research on Cancer (IARC) and the US Environmental Protection Agency (US EPA).

Several prominent authorities have described the potential for acrylamide to be a human carcinogen:

- The International Agency for Research on Cancer (IARC):
  - probably carcinogenic to humans<sup>4</sup>

<sup>&</sup>lt;sup>1</sup> Health & Safety Code § 25249.5 et seq., The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as "Proposition 65, hereafter referred to as "Proposition 65" or "the Act."

<sup>&</sup>lt;sup>2</sup> Health & Safety Code § 25249.6.

<sup>&</sup>lt;sup>3</sup> All references are to sections of Title 27, California Code of Regulations, unless otherwise indicated.

<sup>&</sup>lt;sup>4</sup> 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 <u>https://publications.iarc.fr/78</u>.

- US Environmental Protection Agency (US EPA):
  - likely to be carcinogenic to humans<sup>5</sup>
- The National Toxicology Program (NTP):
  - reasonably anticipated to be a human carcinogen<sup>6</sup>
- National Institute of Occupational Safety and Health (NIOSH):
  - potential occupational carcinogen<sup>7</sup>

Due to concerns over the potential carcinogenic risks to humans from consuming foods with high levels of acrylamide, several governmental agencies and international organizations 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."<sup>8</sup>
- The European Union:
  - A regulation, in 2017, establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food.<sup>9</sup>

<sup>&</sup>lt;sup>5</sup> U.S. Environmental Protection Agency, *Toxicological Review of Acrylamide in Support of Summary Information on the Integrated Risk Information System (IRIS),* (2010), available at <u>https://cfpub.epa.gov/ncea/iris/iris\_documents/documents/toxreviews/0286tr.pdf</u>.

<sup>&</sup>lt;sup>6</sup> National Toxicology Program, Dept. of Health and Human Services, Report on Carcinogens, 15th Ed. (2021), listing for acrylamide CAS No. 79-06-1 available at <a href="https://ntp.niehs.nih.gov/ntp/roc/content/profiles/acrylamide.pdf">https://ntp.niehs.nih.gov/ntp/roc/content/profiles/acrylamide.pdf</a>.

<sup>&</sup>lt;sup>7</sup> Dept. of Health & Human Services, National Institute of Occupational Safety & Health, NIOSH Pocket Guide to Chemical Hazards (3rd ed. 2007), publication no. 2005-149, listing for acrylamide available at: <u>https://www.cdc.gov/niosh/npg/npgd0012.html</u>.

<sup>&</sup>lt;sup>8</sup> Food and Drug Administration, Center for Food Safety and Applied Nutrition, *Guidance for Industry: Acrylamide in Foods* (2016), available at: <u>https://www.fda.gov/media/87150/download</u>; see also: Food and Drug Administration, FDA Issues Final Guidance for Industry on How to Reduce Acrylamide in Foods (March 10, 2016), available at <u>https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-finalguidance-industry-how-reduce-acrylamide-certain-foods</u>.

<sup>&</sup>lt;sup>9</sup> Official Journal of the European Union, Commission Regulation (EU) 2017/2158. In addition, the European Food Safety Authority states on its website "... 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." European Food Safety Authority, Acrylamide (site rev. 2024), FAQ section available at: <a href="https://www.efsa.europa.eu/en/topics/topic/acrylamide#faq">https://www.efsa.europa.eu/en/topics/topic/acrylamide#faq</a>.

- The United Nation's 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."<sup>10</sup>
- The United Nation's 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." <sup>11</sup>

In addition to the US and international agencies noted above, other public health agencies have provided guidance to reduce acrylamide levels in foods. These include: Food Standards Australia New Zealand,<sup>12</sup> Heath Canada,<sup>13</sup> the French Agency for

<sup>&</sup>lt;sup>10</sup> FAO/WHO Codex Almentarius, Code of Safe Practices for the Reduction of Acrylamide in Foods, (2009) CAC/RCP 67-2009. The Codex Alimentarius is a collection of standards, guidelines, and practices adopted by the Codex Alimentarius Commission, which was established by the Food and Agriculture Organization of the United Nations and the World Health Organization to protect consumer health and promote fair practices in food trade.

<sup>&</sup>lt;sup>11</sup> Joint FAO/WHO Expert Committee on Food Additives, Evaluation of Certain Contaminants in Food (2011) WHO Technical Report Series No. 959, page 9.

<sup>&</sup>lt;sup>12</sup> Food Standards Australia New Zealand, Acrylamide in Food (rev. Dec. 6, 2023), available at <u>https://www.foodstandards.gov.au/consumer/chemicals/acrylamide</u>. Food Standards Australia New Zealand is an independent statutory agency established by the Food Standards Australia New Zealand Act of 1991 (the FSANZ Act).

<sup>&</sup>lt;sup>13</sup> Health Canada, Acrylamide in Food (rev. Aug. 13, 2021), available at <a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/chemical-contaminants/food-processing-induced-chemicals/acrylamide.html#a3">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/chemical-contaminants/food-processing-induced-chemicals/acrylamide.html#a3</a>

Food, Environmental and Occupational Health and Safety,<sup>14</sup> the German Federal Institute for Risk Assessment,<sup>15</sup> and the United Kingdom Food Standards Agency.<sup>16</sup>

## b. Proposition 65 and Acrylamide

Under Proposition 65, when a product exposes a consumer to a cancer-causing chemical, a business must first provide a "clear and reasonable" warning (Health & Safety Code § 25249.6), unless it can establish that the level of exposure does not pose a significant risk. To reduce the burden on businesses, those that must provide a warning may rely upon the safe harbor warnings set forth in sections 25602 (methods) and 25603 (content), *et seq.* Such warnings are presumptively clear and reasonable. However, the safe harbor warnings are not required by law, and businesses may develop their own "clear and reasonable" warnings. While safe harbor language is not mandated by regulation or statute, many businesses use the safe harbor warnings to avoid the risk of litigation over whether a given warning is "clear and reasonable" under the Act.

Section 25607.2(a) provides the safe harbor warning language for exposures from food for any listed chemical. There is also a safe harbor warning specifically for acrylamide in food in the existing section 25607.2(b):

**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.

Companies may use the above warning, or the more general food warning found in section 25607.2(a), and still receive the benefits of the safe harbor. (Section 25607.2(b).) This will still be true after the enactment of this proposal, which is intended to provide an additional safe harbor warning option for businesses, rather than replace existing ones.

Many cooked or processed food products containing acrylamide are exempt from the requirement to provide a Proposition 65 warning. This is because, under a regulation effective on April 1, 2023, "[a] person otherwise responsible for an exposure to

<sup>&</sup>lt;sup>14</sup> Agence Nationale de Sécurité Sanitaire de l'Alimentation, Acrylamide in Foods (Jan. 17, 2013), available at <u>https://www.anses.fr/en/content/acrylamide-foods</u>.

<sup>&</sup>lt;sup>15</sup> "...at present the ALARA principle (As Low As Reasonably Achievable) applies to acrylamide intake, which basically means that levels should be kept as low as possible." German Federal Institute for Risk Assessment, Questions and Answers about Acrylamide [FAQ] (rev. Aug. 24, 2011), available at <a href="https://www.bfr.bund.de/en/questions\_and\_answers\_about\_acrylamide-128397.html">https://www.bfr.bund.de/en/questions\_and\_answers\_about\_acrylamide-128397.html</a>

<sup>&</sup>lt;sup>16</sup> Food Standards Agency, Acrylamide (rev. April 26, 2022), available at <u>https://www.food.gov.uk/safety-hygiene/acrylamide</u>.

acrylamide in a food does not 'expose' an individual within the meaning of Section 25249.6 of the Act, to the extent the chemical was created by cooking or other heat processing, if the manufacturer of the food has reduced the levels of acrylamide to the lowest level currently feasible by utilizing applicable practices recommended in Codex Alimentarius Code of Practice for the Reduction of Acrylamide in Foods CAC/RCP 67-2009 (2009)...." (Section 25506(a).) This incentivizes businesses to reduce acrylamide in food products.

Furthermore, even if a manufacturer cannot establish that it has reduced acrylamide to the lowest currently feasible level, OEHHA has set concentrations for acrylamide deemed to comply with Section 25506(a) in a variety of foods for which acrylamide is commonly present: roasted almonds; bread; potato and sweet potato products (such as French fries); waffles; and certain kinds of cookies and crackers. (Section 25506(d).) Those food products do not require a warning, as long as the average and maximum concentrations of acrylamide are at or below the given thresholds. (*Ibid.*) In addition, exposures to listed chemicals in coffee that are caused by the roasting or brewing process, including acrylamide, are excluded from the warning requirements in section 25704.<sup>17</sup>

Despite the exemptions above, businesses may determine that a Proposition 65 warning is still required for acrylamide in some food products. The proposed language offers another option to businesses. It also respects those businesses' First Amendment rights, as does the existing safe harbor warning, while also allowing businesses to provide additional information to consumers, which in turn promotes consumer knowledge in furtherance of the Act.

#### c. Related Legal Matters

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

<sup>&</sup>lt;sup>17</sup> This regulation was adopted based in part on findings of a rich mix of cancer-preventative agents in brewed coffee, decreasing risk with increasing coffee consumption for human cancers of the liver and uterine endometrium, and the overall evidence from animal studies of reduced incidence or reduced multiplicity of cancers with coffee intake. See the Final Statement of Reasons for section 25704, available at: <u>https://oehha.ca.gov/media/downloads/crnr/fsorcoffee060719.pdf.</u>

On November 7, 2023, the Ninth Circuit provided additional guidance regarding Proposition 65 and compelled commercial speech under the First Amendment in *National Association of Wheat Growers v. Bonta* (9th Cir. 2023) 85 F.4th 1263. Although OEHHA believes that the existing safe harbor warning for acrylamide in food complies with the First Amendment, OEHHA has determined that providing an additional safe harbor warning will further the right-to-know provisions of the Act while ensuring that the warning remains "(1) purely factual, (2) noncontroversial, and (3) not unjustified or unduly burdensome."<sup>18</sup> The proposal also provides businesses with increased flexibility.

## III. Proposed Amendments

### Amendment to 25607.2(b):

The first sentence of subsection (b) is amended to state that companies availing themselves of the acrylamide-specific safe harbor warning may comply with either subpart (1) or subpart (2). This is necessary to establish that two options are available, so that companies currently relying upon the existing warning language need not change their product warnings to benefit from safe harbor protections.

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 (c). If that rulemaking is finalized before this proposal, that non-substantive change will affect the numbering of this proposal.

**Amendment to 25607.2(b)(1):** The existing acrylamide-specific safe harbor language is amended to allow the signal words "CA Warning" or "Warning" in addition to "California Warning." This is necessary for consistency with other proposed revisions to consumer product safe harbor warnings. Proposed changes to those sections are included in a rulemaking package that was noticed on October 27, 2023 (Clear and Reasonable Warnings, Safe Harbor Methods and Content).<sup>19</sup> This subsection has also been amended to make the existing warning part of a single subsection, for ease of comparison with the new warning option in proposed subsection (b)(2). Non-substantive amendments to allow the existing safe harbor warning for acrylamide in food to be described in (b)(1) and the proposed warning in (b)(2).

**New subsection 25607.2(b)(2):** This proposed addition creates a new, additional safe harbor warning for acrylamide in food. As with the existing safe harbor warning for acrylamide in food, the proposed additional safe harbor warning only refers to cancer, not reproductive harm. This is because exposures through food that are high enough to

<sup>&</sup>lt;sup>18</sup> American Beverage Assoc. v. City and County of San Francisco (9th Cir. 2023) 916 F.3d 749, 756.

<sup>&</sup>lt;sup>19</sup> Information about this rulemaking can be found at: <u>https://oehha.ca.gov/proposition-65/crnr/proposed-amendments-regulations-clear-and-reasonable-warnings-safe-harbor</u>.

trigger the warning requirement for reproductive harm are expected to be very rare in comparison to the cancer endpoint.

The new safe harbor warning in proposed subsection 25607.2(b)(2) must begin with the words "WARNING:" or "CA WARNING" or "CALIFORNIA WARNING:" in all capital letters and bold print. Use of these signal words is necessary in order to be consistent with proposed amendments to the consumer products warning, as described above.

This subsection also states that the proposed addition must include the mandatory language described in subsections (b)(2)(A) and (B) and may include the optional language in (C). This is necessary to indicate the required content of the new safe harbor warning and to distinguish it from language that is purely optional. This subsection also states that "United States" can be abbreviated as "US" and Environmental Protection Agency as "EPA" to allow businesses to have shorter warnings for commonly understood acronyms.

**New subsection 25607.2(b)(2)(A):** This states that the new safe harbor warning must contain one of the following two sentences:

"Consuming this product can expose you to acrylamide," or

"Consuming this product can expose you to acrylamide, a chemical formed in some foods during cooking or processing at high temperatures."

As in the existing acrylamide-specific safe harbor warning, these sentences explain that the person must actually consume the product in order to be exposed to acrylamide. This is needed to provide consumers with information about how exposure occurs. These two options allow businesses to provide factual and noncontroversial context about acrylamide while deciding whether to prioritize brevity or to include additional context.

The second option is provided for any businesses that wish to clarify that acrylamide is not added to the product; rather, the chemical is a result of cooking/processing at high temperatures. This language is consistent with the existing acrylamide in food safe harbor warning.

**New subsection 25607.2(b)(2)(B):** This states that the new safe harbor warning must contain "[a]t least one of the following sentences," which are listed in parts (b)(2)(B)(i) through (iii) as follows:

(i) "The International Agency for Research on Cancer has found that acrylamide is probably carcinogenic to humans." (ii) "The United States Environmental Protection Agency has found that acrylamide is likely to be carcinogenic to humans." <sup>20</sup>

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

This is intended to fulfill the right-to-know purposes of the Act while allowing businesses the flexibility to choose between several factual statements.

Each of these statements is accurate and consistent with the findings of the authoritative entities that have evaluated the carcinogenicity of acrylamide, as described above.<sup>21</sup> There are a number of different but substantively equal narrative statements used by authoritative entities to describe the potential for acrylamide exposure to cause human cancer. Acrylamide "is probably carcinogenic to humans" (IARC); "is likely to be carcinogenic to humans" (US EPA); and "is reasonably anticipated to be a human carcinogen" (US NTP). These findings are consistent with those of other entities which use similar language, such as the European Food Safety Authority (EFSA), which states that acrylamide "potentially increases the risk of developing cancer for consumers in all age groups."<sup>22</sup>

These phrases effectively represent the same levels of confidence in the chemical's carcinogenicity, i.e., that it probably causes cancer in humans. However, the proposed amendment allows businesses to select from the narratives used by different authoritative agencies to describe acrylamide's potential to cause cancer.

**New subsection 25607.2(b)(2)(C):** This subsection provides optional sentences that can be added to the warning. The requirements of the safe harbor warning are met whether or not one or more of the optional sentences in (b)(2)(C)(i) through (iii) are included in the warning:

<sup>&</sup>lt;sup>20</sup> In 1990, when acrylamide was added to the Proposition 65 list the US EPA had used the terminology "probable human carcinogen" with respect to acrylamide. In 2010, when US EPA re-evaluated acrylamide, it used the new term adopted in its 2005 Carcinogen Risk Assessment Guidelines, "likely to be carcinogenic to humans."

<sup>&</sup>lt;sup>21</sup> Although the organizations in (b)(2)(B) are not the only ones that have stated that acrylamide is probably carcinogenic (or made an equivalent finding), the proposed warning uses statements by the entities that existing law deems "authoritative bodies" with expertise in the identification of chemicals as causing cancer. (27 CCR § 25306).

<sup>&</sup>lt;sup>22</sup> "... 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." European Food Safety Authority, Acrylamide (site rev. 2024) FAQ section, available at: <u>https://www.efsa.europa.eu/en/topics/topic/acrylamide#faq</u>.

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

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

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

OEHHA is providing this optional language in order to give businesses the opportunity to provide additional context for the warning, while still taking advantage of the protection offered by the use of a safe harbor warning. Some businesses may prioritize brevity, and thus may decide not to include this additional language.

Subsection (b)(2)(C)(i) notes the basis of the findings stated in subsection (b)(2)(B). That subsection reflects the fact that studies of experimental animals were the basis of the NTP determination and the primary basis of the determinations by IARC and EPA. All three entities found sufficient evidence of carcinogenicity in animals. This does not imply that animal studies are the only evidence of potential carcinogenicity in humans.<sup>23</sup> Nor does it mean that the agencies listed in (b)(2)(B) were unaware of supporting evidence from mechanistic studies at the time of their hazard determinations.<sup>24</sup> Rather, those agencies, at the time of their evaluations, would not have made the determinations listed in (b)(2)(C)(i) through (iii) absent the animal evidence.

Subsections (b)(2)(C)(ii) and (iii) note that consumers' risk is related to their levels of consumption, and that consumers can find information about how to reduce their risk on the OEHHA website. This indicates that people who choose to consume the product may still evaluate their overall exposure and take reasonable steps to protect themselves. This language also informs consumers that they can find additional information about acrylamide at OEHHA's website.

<sup>&</sup>lt;sup>23</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: <a href="https://www.efsa.europa.eu/en/efsajournal/pub/7293">https://www.efsa.europa.eu/en/efsajournal/pub/7293</a>; 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 <a href="https://www.efsa.europa.eu/en/efsajournal/pub/4104">https://www.efsa.europa.eu/en/efsajournal/pub/7293</a>; See: European Food Safety Authority, Assessment of the Genotoxicity of Acrylamide in Food (June 4, 2025 [adopted April 30, 2015]) EFSA Journal vol. 13, issue 6, available at <a href="https://www.efsa.europa.eu/en/efsajournal/pub/4104">https://www.efsa.europa.eu/en/efsajournal/pub/7293</a>; See: European Food Safety Authority, Assessment vol. 13, issue 6, available at <a href="https://www.efsa.europa.eu/en/efsajournal/pub/4104">https://www.efsa.europa.eu/en/efsajournal/pub/4104</a>.

<sup>&</sup>lt;sup>24</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 <a href="https://publications.iarc.fr/78">https://publications.iarc.fr/78</a>.

### IV. Economic Impact Assessment Required by Gov. Code section 11346.3(b)

In compliance with Government Code section 11346.3, OEHHA has assessed all the elements pursuant to sections 11346.3(b)(1)(A) through (D).

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

#### Creation or elimination of jobs within the State of California

This regulatory action will not impact the creation or elimination of jobs within the State of California. The proposed regulation will help businesses comply with the requirements of Proposition 65 by providing an additional, non-mandatory safe harbor warning for acrylamide in food. As stated above, businesses are not required to take any action based on this rulemaking.

# Creation of new businesses or elimination of existing businesses within the State of California

This regulatory action will not impact the creation of new businesses or the elimination of existing businesses within the State of California. Businesses are not required to take any action as a result of this proposal.

#### Expansion of businesses currently doing business within the State of California

This regulatory action will not impact the expansion of businesses within the State of California. Businesses are not required to take any action as a result of this proposal.

## V. Statement of Benefits

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

# VI. Technical, Theoretical, and/or Empirical Study, Reports, or Documents Relied Upon

Citations to documents relied on for this proposal are provided in this document.

Additionally, the rulemaking for the existing acrylamide-specific safe harbor warning, effective Jan. 1, 2023, included an appendix with extensive information relevant to the carcinogenicity of acrylamide ("Appendix 1), which is also relied upon for the current proposal.<sup>25</sup>

Copies of these documents will be included in the regulatory file for this action and are available from OEHHA upon request.

# VII. Reasonable Alternatives to the Regulation and the Agency's Reasons for Rejecting Those Alternatives

Alternative 1: OEHHA considered drafting a new safe harbor warning, specific to acrylamide in food, which would replace the existing warning rather than supplementing it. This alternative was rejected because businesses that prefer to continue using the existing safe harbor language are still providing adequate information to consumers and should therefore be allowed to continue.

Alternative 2: OEHHA also considered whether the new safe harbor warning should simply state the full text, without providing a variety of options for businesses to select. OEHHA rejected this alternative because it determined that it was appropriate to give businesses multiple options, so they can select the safe harbor language that best suits their needs.

### VIII. Reasonable Alternatives to the Proposed Regulatory Action that Would Lessen Any Adverse Impact on Small Business and the Agency's Reasons for Rejecting Those Alternatives

As stated in the Notice, OEHHA has initially determined that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the proposed action, or would be as effective and less burdensome to small business, or would be more cost-effective and equally effective in implementing the statutory policy or other provision of law to small

<sup>&</sup>lt;sup>25</sup> This appendix was referred to as "Appendix A" in the Initial Statement of Reasons associated with that rulemaking but was actually titled Appendix 1.

business. Some small businesses—those with fewer than ten employees—are not subject to the Act.<sup>26</sup>

No reasonable alternatives would less any adverse impact on small business. Alternative 1, described above, would deny small businesses safe harbor protection if they continued to use the existing acrylamide-specific warning language. Alternative 2 would give small businesses less flexibility.

The current proposal furthers the purposes of Proposition 65 by providing additional non-mandatory safe harbor language for businesses regarding exposures to acrylamide in food. Small businesses are not required to use the proposed warning content. Small businesses would benefit from this proposal, because it provides them with an additional safe harbor warning option for acrylamide in food.

# IX. Use of Specific Technologies or Equipment

This proposal does not mandate the use of any specific technology or equipment.

# X. Evidence Supporting Finding of No Significant Adverse Economic Impact on Business

OEHHA does not anticipate that the regulation will have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. Businesses are not required to take any action in response to this rulemaking, because it only provides an additional option for safe harbor warnings.

## XI. Efforts to Avoid Unnecessary Duplication or Conflicts with Federal Regulations Contained in the Code of Federal Regulations Addressing the Same Issues

Proposition 65 is a California law that has no federal counterpart. OEHHA has determined that the regulation does not duplicate and will not conflict with federal regulations.

<sup>&</sup>lt;sup>26</sup> Health & Safety Code § 25249.11(b).