



**AMERICAN
BAKERS
ASSOCIATION**

By Electronic Submission

November 8, 2021

Ms. Monet Vela
Office of Environmental Health Hazard Assessment
1001 I Street, 23rd Floor
P. O. Box 4010
Sacramento, California 95812-4010

**Re: Notice of Proposed Rulemaking – Adoption of
Subsection 25607.2(b): Warning Content for Acrylamide
Exposure from Food**

Dear Ms. Vela:

The American Bakers Association (ABA) is pleased to submit these comments in response to the Office of Environmental Health Hazard Assessment's (OEHHA's) notice of proposed rulemaking to adopt Subsection 25607.2(b), regarding the warning content for acrylamide exposure from food, by amending Title 27, California Code of Regulations. ABA endorses and incorporates by reference the comments being submitted to OEHHA by the Coalition headed by the California Chamber of Commerce and the Consumer Brands Association. ABA's individual comments focus on issues related to baked goods.

ABA is the voice of the baking industry. Serving Members from global wholesale baking companies and suppliers to baking industry entrepreneurs, ABA is the only bakery-specific national and state trade association, delivering results on priorities affecting the companies that feed the world. Since 1897, ABA has worked to increase protection from costly government actions, build the talent pool of skilled workers with specialized training programs, and forge industry alignment by establishing a more receptive environment to grow the baking industry. ABA's Membership has grown to represent more than 300 companies with a combined 1000+ facilities.

The Members of ABA support and commend OEHHA's efforts to protect consumers, and appreciate OEHHA's attempt to refine the Proposition 65 warning requirements associated with acrylamide. However, ABA believes that not even OEHHA's modified warning should be required for food products containing acrylamide. Dietary acrylamide has not been shown to cause cancer in humans, and even as modified, OEHHA's proposed warning suggests to consumers that products containing acrylamide cause cancer. In fact, many baked goods (which may contain acrylamide) are endorsed by federal nutrition policy and may reduce the likelihood of cancer. As a result, OEHHA's proposed warning requirement would violate the First Amendment by compelling speech that is false or misleading. Additionally, ABA continues to believe that OEHHA does not have the authority to enforce a warning requirement for acrylamide food products when acrylamide has not been shown to cause cancer in humans.

I. A Proposition 65 warning (even with OEHHA’s proposed modified language) is not warranted for food products that contain acrylamide.

Under OEHHA’s proposed rule, food products containing acrylamide could satisfy Proposition 65 warning requirements by including a statement that acrylamide is “a probable human carcinogen” and that “[m]any factors affect your cancer risk, including the frequency and amount of the chemical consumed.”¹ While more narrowly tailored than the general Proposition 65 warning language, this proposed warning is still inaccurate and unwarranted for several reasons.

First, acrylamide should not be characterized as a probable human carcinogen. California’s listing of acrylamide was based primarily upon evidence of carcinogenicity in studies of animals. Such studies do not prove that acrylamide is carcinogenic to humans. Animal studies may involve acrylamide exposure that does not accurately represent real-world levels of acrylamide exposure for consumers, and acrylamide may affect animals differently than it does humans. Indeed, studies conducted in humans have not demonstrated that acrylamide causes cancer. Along those lines, the district court in the ongoing acrylamide Proposition 65 litigation 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.”²

Second, a warning requirement is especially inappropriate for baked goods given the wealth of scientific literature showing that many grain foods such as bread and other grain-based baked goods actually *lower* the risk of cancer and other diseases, given their overall nutritional profile.³

Third, while the U.S. Food and Drug Administration (FDA) has published guidance and various other resources addressing acrylamide in food, the agency recommends that consumers do not stop eating foods that are fried, roasted, or baked (*i.e.*, foods that contain acrylamide).⁴ Moreover, the 2020-2025 edition of the Dietary Guidelines for Americans, published by the U.S. Departments of Agriculture (USDA) and Health and Human Services (HHS), explains that “[h]ealthy dietary patterns include whole grains” and recommends increased consumption of

¹ OEHHA, Proposed § 25607.2. Food Exposure Warnings - Content, *available at* <https://oehha.ca.gov/media/downloads/crn/acrylamidedraftregtext091721.pdf>.

² *Cal. Chamber of Commerce v. Becerra*, No. 2:19-CV-02019-KJM-EFB, 2021 WL 1193829, at *13 (E.D. Cal. Mar. 30, 2021).

³ *See, e.g.*, Glen A. Gaesser, *Whole Grains, Refined Grains, and Cancer Risk: A Systematic Review of Meta-Analyses of Observational Studies*, 12 *Nutrients* 3756 (2020), *available at* <https://www.mdpi.com/2072-6643/12/12/3756>.

⁴ FDA, Acrylamide Questions and Answers, *available at* <https://www.fda.gov/food/chemical-contaminants-food/acrylamide-questions-and-answers>.

dietary fiber, which can be found in whole grain foods.⁵ Certain foods that contain acrylamide, many of which are whole grain foods and/or foods that are high in dietary fiber, thus advance this health policy. FDA has expressed concern that Proposition 65 warnings may discourage consumers from eating such healthful foods, for example, in a 2018 statement by then-Commissioner Gottlieb that “[l]abeling whole grain foods with a cancer warning may cause American consumers to avoid foods that would have a benefit to their health, including avoiding foods that may reduce cancer risks.”⁶ Unfortunately, because of the Proposition 65 acrylamide warning requirements, many bakeries have been targeted with meritless lawsuits despite offering for sale foods that are consistent with federal nutrition recommendations.

Finally, OEHHA’s 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).⁷ 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. Accordingly, the proposed warning about the carcinogenicity of acrylamide would not be consistent with the First Amendment.

II. OEHHA does not have the authority to require a Proposition 65 warning for acrylamide where it is not known that the chemical causes cancer.

Proposition 65 warnings are required where chemicals are “known to the state [of California] to cause cancer or reproductive toxicity.”⁸ (Emphasis added.) A chemical is “known” to cause cancer or reproductive toxicity if “in the opinion of the state’s qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity, or if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity, or if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity.”⁹

⁵ USDA and HHS, Dietary Guidelines for Americans, 2020-2025, at 32, 36, *available at* https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf.

⁶ Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA’s support for exempting coffee from California’s cancer warning law (August 29, 2018), *available at* <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-support-exempting-coffee-californias-cancer>.

⁷ See *Nat’l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361, 2372 (2018) (quoting *Zauderer v. Off. of Disciplinary Couns. of Supreme Ct. of Ohio*, 471 U.S. 626, 651 (1985)) (explaining that required disclosure must be “limited to ‘purely factual and uncontroversial information’”).

⁸ Cal. Health & Safety Code § 25249.6.

⁹ Cal. Health & Safety Code § 25249.8(b).

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OEHHA's proposed warning would allow the Proposition 65 warning requirement to be satisfied with a statement referring to acrylamide as a "probable human carcinogen." On its face, this does not align with the statutory authority granted to OEHHA, which requires warnings only where a chemical is known to cause cancer (*i.e.*, not just a "probable carcinogen").

III. Conclusion

In conclusion, ABA believes that a Proposition 65 warning should not be required for food products containing acrylamide, and that OEHHA does not have the authority to require such a warning.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Rasma Zvaners", with a long horizontal flourish extending to the right.

Rasma Zvaners
Vice President, Regulatory and Technical Services