

OEHHA Proposes Acrylamide Proposition 65 Regulations

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Food, Drugs, and Devices

On September 17, the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) proposed regulations that would establish tailored safe harbor warning language to be used with products that exceed the No Significant Risk Level (NSRL) for acrylamide. We describe below why acrylamide has taken center stage, the content of the rulemaking, and the potential impact on industry.

Acrylamide and California's Proposition 65

Acrylamide is formed in certain foods during cooking or processing at high temperatures, such as frying, roasting, grilling, and baking. In 1990, the State of California listed acrylamide as a chemical known to cause cancer, and OEHHA currently sets the NSRL for acrylamide at 0.2 micrograms per day.¹ OEHHA has also initiated rulemaking proposing to establish higher safe harbor levels for acrylamide in various specific products, below which no warning would be required.² OEHHA's listing of acrylamide as a carcinogen largely rests on the US Environmental Protection Agency's (EPA) finding that acrylamide is a "probable human carcinogen." Several other health authorities -- primarily relying on animal studies -- have similarly opined that acrylamide is probably, potentially, or likely carcinogenic to humans. That said, human epidemiological studies have thus far yielded inconclusive and inconsistent data regarding the association between acrylamide and cancer in humans.

OEHHA's listing of acrylamide triggered Proposition 65's requirement that any product that could potentially expose consumers to a known carcinogen must contain a clear and reasonable warning of the cancer risk posed by the chemical. Recently, the California Chamber of Commerce sought a preliminary injunction barring new lawsuits against businesses that do not display the warning for acrylamide-containing products, arguing that the warning requirement violates the First Amendment by forcing businesses to make false statements (i.e., the assertion that the State of California "knows" that eating food containing acrylamide causes cancer in humans). Finding that the warning had not yet been shown to be "purely factual and

¹ Cal. Code. Regs. tit. 27, § 25705(c).

² OEHHA, Initial Statement of Reasons, Proposition 65, Title 27, California Code of Regulations, Proposed Adoption of Article 5, Section 25505, Exposures to Listed Chemicals in Cooked or Heat Processed Foods (Aug. 7, 2020), available at <https://oehha.ca.gov/media/downloads/cmr/isor080720.pdf>.

uncontroversial,” the district court granted a preliminary injunction.³ Subsequently, the 9th Circuit stayed the preliminary injunction to the extent it bars private enforcers from bringing Proposition 65 actions.⁴ Accordingly, private enforcers now may initiate such actions, but public prosecutors may not. Against this backdrop, OEHHA has initiated rulemaking to, in its words, provide consumers with “clearer and more factual information for the benefit of the consumers who may be exposed.”⁵

OEHHA’s Proposed Regulations

OEHHA’s rulemaking proposes to establish the following tailored safe harbor warning for food products that exceed the NSRL for acrylamide:

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.

This proposed warning language explains that the consumer must consume the product to be exposed to acrylamide, describes acrylamide as a “probable human carcinogen,” clarifies that the chemical is not intentionally added by the manufacturer, and notes that the frequency and amount of the chemical consumed affect a consumer’s cancer risk. Under this proposed amendment, businesses could provide a safe harbor warning by providing this warning language or by using the more general warning language found in section 25607.2(a).⁶ In OEHHA’s Statement of Reasons for this rulemaking, the Agency states that, as drafted, the proposed regulations aim to “facilitate provision of safe harbor warnings for food in a manner that avoids the First Amendment concerns that have been raised about the more general consumer product warnings.”⁷ We note that OEHHA’s statutory authority to require any warning at all hinges on whether the state can conclude that acrylamide is “known” to cause cancer or reproductive toxicity. This proposed rulemaking raises the substantial question of whether OEHHA can meet that threshold in the first instance.

³ *Cal. Chamber of Commerce v. Becerra*, No. 2:19-CV-02019-KJM-EFB, 2021 WL 1193829, at *13, *18 (E.D. Cal. Mar. 30, 2021).

⁴ *Cal. Chamber of Commerce v. Bonta*, No. 21-15745 (9th Cir. May 27, 2021).

⁵ OEHHA, Initial Statement of Reasons, Title 27, California Code of Regulations, Proposed Amendments to Article 6: Safe Harbor Clear and Reasonable Warnings for Acrylamide Exposures from Food, New Subsection 25607.2(b) (September 24, 2021), at 13, available at <https://oehha.ca.gov/media/downloads/crn/isoracrylamide091721.pdf>.

⁶ Cal. Code. Regs. tit. 27, § 25607.2(a).

⁷ OEHHA, Initial Statement of Reasons, Title 27, California Code of Regulations, Proposed Amendments to Article 6: Safe Harbor Clear and Reasonable Warnings for Acrylamide Exposures from Food, New Subsection 25607.2(b) (September 24, 2021), at 13, available at <https://oehha.ca.gov/media/downloads/crn/isoracrylamide091721.pdf>.

Industry Impact

This proposed regulation signals OEHHA's continued willingness to craft tailored warning statements when there is some uncertainty about the impact of certain chemicals on humans, though we think important to make clear that Proposition 65 only requires a warning for exposures to chemicals "known" to cause cancer or reproductive toxicity. For example, in July, OEHHA proposed a tailored warning for glyphosate, as different regulatory agencies had reached different conclusions about the carcinogenicity of the chemical. Moving forward, where there is uncertainty about the risk associated with exposure to a chemical, OEHHA may attempt to provide for a tailored safe harbor warning.

Comments on OEHHA's proposed regulations are due November 8, 2021. Covington will continue to monitor California's treatment of products containing acrylamide and other Proposition 65 developments.

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