

MEMORANDUM

From: Martin J. Hahn
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Re: Proposed Regulation would Significantly Change the Warning Requirements for Acrylamide and Other Chemicals Formed During the Cooking of Foods under California's Proposition 65

On August 4, 2020, the Office of Environmental Health Hazard Assessment (OEHHA), the lead agency that implements California's Proposition 65 ("Prop 65"), proposed to adopt a new regulation that would significantly change the warning requirements for listed chemicals formed by the cooking or heat processing of foods. ^{1/} The proposed regulation would provide that intake of such chemicals does not represent an exposure for the purposes of Prop 65 if the concentrations are reduced to the lowest level currently feasible using appropriate quality control measures. The proposal would establish maximum concentration levels for acrylamide in specific foods that are deemed by OEHHA to be the lowest levels currently feasible. Concentrations of the chemical at or below the level identified for the specified products would not require a warning.

It is noteworthy the proposed regulation is published at a time when a new wave of Prop 65 challenges are targeting acrylamide in food. In the past three months alone, private litigants have filed close to one hundred 60-day notices indicating their intent to sue food companies for acrylamide. This translates to about one Prop 65 notice filed every day in California for acrylamide in food. In its Initial Statement of Reasons, OEHHA stated the proposal is intended to (1) reduce exposures to listed chemicals present in food due to the human activities of cooking or heat processing, (2) provide warnings for avoidable exposures to acrylamide, and (3) safeguard the effectiveness of those warnings. ^{2/}

The public can request a hearing on the proposed changes and the request must be received no later than September 21, 2020. Written comments to the proposed regulation are due on October 6, 2020.

^{1/} OEHHA, "Notice Of Proposed Rulemaking Adoption to Section 25505 Exposures to Listed Chemicals in Cooked or Heat Processed Foods," (Aug 4, 2020), *available at*: https://oehha.ca.gov/proposition-65/cnr/notice-proposed-rulemaking-adoption-section-25505-exposures-listed-chemicals?utm_source=Cooking+Chemical&utm_campaign=Proposition+65+-+Proposed+Maximum+Allowable+Dose+Levels+for+Chlorpyrifos&utm_medium=email (accessed on Aug 5, 2020).

^{2/} OEHHA, "Initial Statement of Reasons - Proposed Adoption Section 25505: Exposures to Listed Chemicals in Cooked or Heat Processed Foods," (Aug 7, 2020), *available at*: <https://oehha.ca.gov/media/downloads/cnr/isor080720.pdf> (accessed on Aug 5, 2020).

Background on Acrylamide Prop 65 Litigations

For brief background, Prop 65 requires the Governor of California to publish, at least annually, a list of chemicals known to the state to cause cancer or reproductive toxicity. ^{3/} Businesses are required to provide a “clear and reasonable” warning before knowingly and intentionally exposing anyone in California to a listed chemical. Acrylamide has been a listed Prop 65 carcinogen since 1990. ^{4/} The California Attorney General and plaintiff’s lawyers have filed numerous lawsuits in California seeking to impose Prop 65 warning requirements on food products for acrylamide.

Prop 65 permits private litigants or “bounty hunters” to bring private lawsuits to enforce the warning requirements. ^{5/} A “bounty hunter” seeking to sue for failure to warn as required by Prop 65 must notify the potential defendant and state prosecutors of the alleged violation and its intent to sue 60 days before a suit may be filed. ^{6/} These 60-day notices are publicly posted on the State’s Office of the Attorney General’s website. ^{7/} Over the past ten years, there have been multiple consent decrees for various foods that have set the level of acrylamide that does not require a Prop 65 warning. Food companies who are parties to these settlements and produce products within the negotiated levels do not have to provide the Prop 65 warning. The settlement also will identify the dollar damages the company must pay. Based on the most recent data available (i.e., 2018), the average settlement payment is around USD 42,424. ^{8/}

Acrylamide in certain foods are already “exempt” from warning requirements. For example, on June 7, 2019, OEHHA adopted a regulation clarifying that exposures to Prop 65 substances in coffee do not pose a significant cancer risk. ^{9/} In essence, the regulation exempts coffee products from Prop 65 carcinogen warning requirements for chemicals such as acrylamide, to the extent that these carcinogens are created by and inherent in the process of roasting coffee beans or brewing coffee.

The Proposed Rulemaking

OEHHA is proposing to amend Title 27 of the California Code of Regulations, by adopting a new Section 25505, to address listed chemicals formed by cooking or heat processing foods. OEHHA noted that some degree of formation of listed chemicals in many foods (such as acrylamide) is unavoidable when the foods are cooked or otherwise processed with heat. As such, OEHHA reasoned, exposures to these chemicals in food are not necessarily the type of “knowing and intentional” exposures that require a warning under Prop 65. The proposed regulation provides that a person otherwise responsible for an exposure to a listed chemical in a food does not “expose” an individual to the extent the chemical was created by cooking or other heat processing, if the quality control measures that reduce the chemical to the lowest level currently feasible are utilized.

^{3/} Cal. Health & Safety Code § 25249.8(a).

^{4/} Acrylamide is also currently listed under Prop 65 as causing reproductive toxicity.

^{5/} Cal. Health & Safety Code § 25249.7(d).

^{6/} *Id* § 25249.7(d)(1).

^{7/} Office of the Attorney Gen., Cal. Dep’t of Justice, 60-Day Notice Search, *available at* <https://oag.ca.gov/prop65/60-day-notice-search> (last accessed July 23, 2020).

^{8/} See Proposition 65 Settlement Executive Summary 2018, *available at* <https://oag.ca.gov/sites/all/files/agweb/pdfs/prop65/2018-summary-settlements.pdf> (last accessed July 23, 2020).

^{9/} See “Notice of Adoption – Section 25704 Exposures to Listed Chemicals in Coffee Posing No Significant Risk,” *available at* <https://oehha.ca.gov/proposition-65/cnr/notice-adoption-section-25704-exposures-listed-chemicals-coffee-posing-no> (last accessed on July 23, 2020).

Regarding acrylamide in particular, OEHHA has discussed examples of quality control measures to feasibly reduce acrylamide. Subsection (d) of the proposed rulemaking also sets forth the maximum concentration levels for acrylamide in certain foods that are considered currently feasible by OEHHA. If a person does not reduce the level of the chemical in a food to the lowest level currently feasible, the resulting exposure must be calculated without regard to the levels set out in subsection (d). OEHHA noted that in the event a business is unable to, or chooses not to, reduce the levels of acrylamide in a product to the level adopted in the regulation for that product, a warning would be required if the exposure exceeds the safe harbor levels for that chemical, unless another defense is available. The proposed levels are listed below:

Foods/Food groups	Maximum average concentration level (ppb)	Maximum unit concentration level (ppb)
Almonds, roasted, roasted almond butter, and chocolate-covered almonds	225	---
Bread, non-wheat-based products including loaves, rolls, buns, baguettes	100	---
Bread, wheat-based products including loaves, rolls, buns, baguettes	50	---
Cookies, animal and animal crackers (sweet)	75	100
Cookies, thin and crispy	281	300
Cookies, sandwich wafers	115	---
Crackers, savory, including crispbread	350	490
Potato products, French fried potatoes	280	400
Potato or sweet potato products, not otherwise specified, such as hash browns and potato puffs	350	490
Potato or sweet potato products, sliced chips	281	350
Prune juice, 100% (not from concentrate)	---	250
Prune juice, made with concentrate	---	150
Waffles	280	---

With two exceptions (wheat-based and non-wheat based bread categories), these levels are based on recent court-approved settlements. OEHHA takes the position the approval of a settlement by a court means that compliance by the defendant with the levels established in that settlement will not require a warning under the statute. Further, where a food industry defendant has agreed to a given concentration level in a court-approved settlement, OEHHA is presuming that the level is currently feasible. Interestingly, for bread, OEHHA is proposing the acrylamide levels published by the European Union (EU) as the lowest feasible level in accordance with the EU regulation. OEHHA noted it did not find a settlement under Prop 65 that was below the EU benchmark levels.

Subsection (d) adopts the approach in many acrylamide settlements whereby one or two concentration levels are established: The Maximum Average Concentration and/or the Maximum Unit Concentration. The term “Average Concentration” refers to the average level measured in multiple items or individual packaging units of a specific food product. The term “Maximum Unit Concentration” refers to the maximum concentration measured in a single item/individual packaging unit. The requirement to comply with both “Average Concentration” and “Maximum Unit Concentration” of acrylamide levels could pose challenges in those foods where there is significant variability in acrylamide levels even when following the best practices currently feasible.

Also importantly, OEHHA noted the levels provided in the above table should be viewed as guidance levels and businesses may instead choose to rely on other provisions of the existing Prop 65 regulations such as the safe harbor levels or the alternative risk level for establishing compliance. OEHHA could add other foods or chemicals in future rulemaking. We believe one potential candidate of such chemicals is furfuryl alcohol, which like acrylamide can also be formed during cooking or heat processing of food. Also, the regulation would not apply to parties to an existing court-ordered settlement or final judgment establishing a concentration of acrylamide in a specific product covered in that settlement or judgment.

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The proposed rule, if finalized, has the potential to significantly impact the warning requirements for acrylamide and other listed chemicals formed during the cooking of food. We will continue to monitor all regulatory actions related to Prop 65. Please contact us if you have any questions.