



October 21, 2022

Ms. Monet Vela  
 Office of Environmental Health Hazard Assessment  
 1001 I Street, 23rd Floor  
 Sacramento, CA 95814

(Submitted Online Via Portal at: <http://oehha.ca.gov/comments>)

*Subject: Adoption of Section 25506, Exposures to Acrylamide in Cooked or Heat Processed Foods*

Dear Ms. Vela:

The California Chamber of Commerce (“CalChamber”), the Consumer Brands Association (“Consumer Brands”), and the organizations listed below (collectively, “the Coalition”) thank you for the opportunity to submit comments regarding the Office of Environmental Health Hazard Assessment’s proposed regulation on Exposures to Acrylamide in Cooked or Heat Processed Foods (the “Proposed Regulation” or “Section 25506”). The Coalition also appreciates the opportunity to have participated in OEHHA’s original regulatory proposal as part of a broader coalition of business entities.<sup>1</sup>

The Coalition supports the Proposed Regulation for the same reasons we supported OEHHA’s original regulatory proposal addressing listed chemicals in cooked or heat processed foods. The formation of acrylamide and other listed chemicals formed in cooking or heat processing is simply unavoidable in many foods. While no business can stop these substances from forming in foods, hundreds of businesses have been targeted in enforcement actions alleging that they expose California consumers to acrylamide. Indeed, since 2016, private enforcers have issued more than 1,300 notices of violation regarding acrylamide in foods to food manufacturers and their retailers, resulting in settlement payments of over \$10 million. The multitude of notices of violation has created uncertainty both for businesses trying to comply with Proposition 65 and for California consumers—who have been exposed to inconsistent warnings on a variety of foods they purchase and consume every day.

A workable regulation exempting exposures to listed chemicals arising from cooking or heat processing of foods that have been reduced to the lowest level feasible would curtail this uncertainty by providing businesses with a compliance roadmap and discouraging private enforcers from filing lawsuits aimed more at collecting payments

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<sup>1</sup> The Coalition incorporates by reference the prior comments it submitted as part of this coalition of business entities. This letter may be accessed on OEHHA’s website at [https://oehha.ca.gov/media/dockets/19871/19943-consumer\\_brands\\_association\\_california\\_chamber\\_of\\_commerce\\_et\\_al/coalition\\_comments\\_re\\_adoption\\_of\\_section\\_25505.pdf](https://oehha.ca.gov/media/dockets/19871/19943-consumer_brands_association_california_chamber_of_commerce_et_al/coalition_comments_re_adoption_of_section_25505.pdf)

than at protecting consumers. OEHHA's Proposed Regulation does just that. Although the Coalition is disappointed that OEHHA narrowed the scope of the Proposed Regulation to focus only on acrylamide, we appreciate OEHHA's continued effort to address the most-litigated of all heat formed substances listed under Proposition 65 and believe that the Proposed Regulation could help ameliorate the current situation. Furthermore, because the same feasibility principles that apply for acrylamide will apply for all listed substances formed in cooking or heat processing, we believe that the structure of the Proposed Regulation will work well in the future for more foods and more listed chemicals. Consumer Brands, CalChamber, and the rest of the Coalition would welcome the opportunity to work with OEHHA on initiatives to address those chemicals accordingly.

The Coalition believes that the revisions OEHHA made to the original regulatory proposal address the concerns raised by the Office of Administrative Law. Below, we share for your consideration two suggested revisions to the regulatory text that we believe will clarify the Proposed Regulation, facilitate its implementation, and help achieve OEHHA's important policy goals. We also provide a marked-up version of the Proposed Regulation that shows our proposed changes.

## **I. OEHHA Should Clarify that Subsection (c) Neither Requires Nor Prevents Modification of Pre-Existing Consent Judgments.**

Subsections (a) and (d) of Section 25506 set forth the substance of the Proposed Regulation. Subsection (a) broadly provides that manufacturers who reduce exposures to acrylamide created through cooking or heat processing of food products to the lowest levels currently feasible do not "expose" an individual to acrylamide under Proposition 65.<sup>2</sup> Subsection (d) sets nonmandatory safe harbor "maximum average" and "maximum unit" concentration levels of acrylamide for specific listed categories of foods.<sup>3</sup>

Subsections (b) and (c), meanwhile, are intended to clarify the limited and prospective scope of the Proposed Regulation. Subsection (b) seeks to make clear that the concentration levels established in subsection (d) are "provided as guidance" and that businesses are not precluded from establishing maximum concentrations that differ from these levels.<sup>4</sup> This ensures that businesses are not bound by the safe harbor average and unit concentration levels specified in section (d), consistent with how businesses are not bound by Proposition 65's safe harbor exposure levels for carcinogens and reproductive toxins and can prove that different levels apply as a scientific matter.<sup>5</sup>

For its part, subsection (c) attempts to clarify that "[c]ourt-ordered settlements or final judgments completed prior to the effective date of the proposed regulation are not affected by the adoption of the levels in subsection (d)."<sup>6</sup> Subsection (c) would ensure that subsection (d)'s establishment of new nonmandatory safe harbor levels does not retroactively affect parties to existing settlements or judgments approved or entered by courts.<sup>7</sup> Parties to existing consent judgments, of course, would be free to make modification motions to courts with appropriate jurisdiction.<sup>8</sup>

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<sup>2</sup> OEHHA, Addendum to the Initial Statement of Reasons, Proposed Section 25506 (Oct. 6, 2022) ("ISOR Addendum") at 5.

<sup>3</sup> ISOR Addendum at 8-10.

<sup>4</sup> ISOR Addendum at 6 (observing that modifications to subsection (b) were made for clarity); OEHHA Initial Statement of Reasons, Proposed Section 25505 (Aug. 7, 2020) ("Original ISOR") at 11 (observing that "the concentration levels established in this proposed regulation in subsection (d), are provided as guidance that can be used by businesses to establish that a warning is not required for a given exposure" and that subsection (b) is intended to make clear that businesses may rely on other evidence, methods, and provisions of the existing regulations to establish compliance).

<sup>5</sup> Cal. Health & Safety Code § 25249.10 (exemption for "[a]n exposure for which the person responsible can show" does not cause cancer or reproductive harm per applicable standards); Cal. Code Regs. tit. 27 § 25705 (nonmandatory no significant risk levels); *Id.* § 25805 (nonmandatory no observable effect levels).

<sup>6</sup> ISOR Addendum at 6.

<sup>7</sup> ISOR Addendum at 7 (observing that the Proposed Regulation "is prospective, not retroactive"); *see also* Original ISOR at 11-12 (observing that subsection (c)'s time period limitation "is simply a statement of existing law").

<sup>8</sup> ISOR Addendum at 7.

The Coalition is concerned that subsection (c) does not fully express OEHHA's intent as stated in the ISOR and the ISOR Addendum, specifically that subsection (c) could be read to automatically modify some consent judgments and to preclude a court from modifying its prior consent judgment to conform to the levels set forth in subsection (d). We are also concerned that the reference to pre-existing consent judgments might be read to carry an unintended negative implication with respect to consent judgments that are entered into in the future. We believe OEHHA's intent is to *not* modify prior consent judgments automatically but also to permit such modifications, in light of the Proposed Regulation, in the discretion of the applicable court, and—consistent with subsection (b)—to not constrain the latitude of parties and courts, in future consent judgments, to use different concentration levels. The Coalition endorses that approach, which prevents upsetting the settled expectations of the parties without due process. We therefore propose that subsection (c) be revised to read as follows:

(c) Nothing in this section shall modify the terms of a court-ordered settlement or final judgment to the extent that such settlement or judgment establishes a concentration of acrylamide in a specific product that is covered in the settlement or judgment, but nothing in this section shall preclude a court from modifying its prior order or judgment.

This revision would fulfill OEHHA's stated intent in the Original ISOR and ISOR Addendum and avoid unnecessary disputes about the scope of the Proposed Regulation or need to refer to the ISOR or the ISOR Addendum. We emphasize that this is not a change in the intent of subsection (c) as proposed, but simply a clarification of its language.

## **II. OEHHA Should Revise Subsection (d)(2) To Clarify Its Application to Foods Produced on a Non-Continuous Basis.**

Subsection (d)(2) provides that “[t]he average concentration is determined by adding together the unit concentrations of at least five samples taken over a period of no less than 60 days with no less than 10-day intervals between sampling and then dividing this total by the total number of samples.” This definition seems to assume that all foods are produced continuously on a rolling assembly line over a period of time longer than 60 days.

But many foods are not produced on a regular basis, including foods that are produced in infrequent batches, foods that are seasonal, and foods that are produced during a short period of time based on freshly harvested produce or limited shelf-life. It is not clear how the “no less than 10 day intervals” element or the 60-day duration element of subsection (d)(2) could be applied for these foods. The Coalition therefore recommends that OEHHA revise subsection (d)(2) to account for these foods while maintaining its intent to ensure that there are sufficient samples and that the samples are randomly selected.

The Coalition believes that this can be accomplished by revising subsection (d)(2) to provide:

- In this subsection, ‘average concentration’ refers to the average of unit concentrations measured. The average concentration is determined by adding together the unit concentrations from at least five samples and then dividing this by the total number of samples. The samples will be randomly selected from as many different lots (as that term is defined in 21 Code of Federal Regulations section 101.9(g)(1)) as possible that span production dates of at least 60 days or the entire production period if it is shorter than 60 days.

This proposed revision would replace the time interval element of subsection (d)(2) with a requirement that samples be randomly selected. Further, the introduction of the term “lot” from 21 CFR section 101.9(g)(1) would provide clarity for food manufacturers, who are familiar with this term. That section defines the term “lot” as “[a] collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, or in the absence of any common container code or marking, a day’s production, constitutes a ‘lot.’”

The proposed revision would also require the samples to be taken over a period of at least 60 days for products whose production dates cover a time period that is 60 days or longer, while also providing that the samples span the entire production period if it is shorter than 60 days. And it would require that they be taken from as many lots as possible in order to account for the possibility that the production spans fewer than five lots.

In sum, Consumer Brands, CalChamber, and the other members of the Coalition believe that this proposed revision is a practical way of ensuring clarity in how the Proposed Regulation is to be applied to all foods that may contain acrylamide, whether they are produced continuously or in batches or infrequently. Again, we emphasize that this language is not a change in the intent of subsection (d)(2) as proposed. Instead, it holds true to the intent of OEHHA to ensure that samples are randomly selected and span a sufficient period to account for variability in ingredients and cooking conditions so that the level of acrylamide in the food product is accurately characterized.

### III. Conclusion

For the reasons discussed above and in our prior comment letter, CalChamber, Consumer Brands, and the entire Coalition support the Proposed Regulation. With the minor modifications noted above, we believe that the Proposed Regulation is a significant step towards reducing litigation over acrylamide, assisting businesses in their compliance efforts, and reducing unnecessary warnings that have the potential to confuse and alarm consumers.

We commend OEHHA for taking this step, and we reiterate our view that the Proposed Regulation's framework will prove useful in future efforts to address exposures from other Proposition 65 listed chemicals arising from cooking or heat processing of food. We look forward to continuing to working with OEHHA on efforts to improve the implementation of Proposition 65.

Respectfully,



Adam Regele  
California Chamber of Commerce



John Hewitt  
Consumer Brands Association

On behalf of the following organizations:

Agricultural Council of California  
Almond Alliance  
American Bakers Association  
American Chemistry Council  
American Frozen Food Institute  
Asian Food Trade Association  
California Restaurant Association  
California Manufacturers and Technology Association  
California Attractions and Parks Association  
CA Automatic Vendors Council  
Can Manufacturers Institute  
Frozen Potato Products Institute  
National Confectioners Association  
NAMA  
Peanut and Tree Nut Processors Association  
SNAC International  
The Food Industry Association