October 21, 2020

Ms. Monet Vela
Office of Environmental Health Hazard Assessment
1001 I Street, 23rd Floor
Sacramento, CA 95812-4010
(Submitted Online Via Portal at: https://oehha.ca.gov/comments)

Re: Adoption of Section 25505, Exposures to Listed Chemicals in Cooked or Heat Processed Foods

Dear Ms. Vela:

The Consumer Brands Association, the California Chamber of Commerce, and the organizations listed (hereinafter, "the Coalition") thank you for the opportunity to submit

comments regarding the Office of Environmental Health Hazard Assessment's ("OEHHA's") proposed regulation on Exposures to Listed Chemicals in Cooked or Heat Processed Foods (Proposed Section 25505). We appreciate your extension of the deadline for these comments as well.

The membership of the Coalition consists of thousands of California-based and national businesses that produce, process, and prepare foods consumed by virtually all Californians. The Coalition strongly supports OEHHA in its efforts to develop a regulatory framework for listed chemicals in cooked and heat-processed foods.

OEHHA and the courts have long recognized that Proposition 65 chemicals are ubiquitous in foods, and that applying the statute to food creates unique issues of fact and law that require special treatment in order to avoid unintended and detrimental consequences. Consistent with OEHHA's regulatory authority under the statute, the proposed regulation ("Proposed Regulation") creates a regulatory framework that has the potential to provide meaningful guidance to food companies and potential enforcers of the statute. The Coalition appreciates OEHHA's willingness to embrace a pragmatic and thoughtful solution for the complex and important issue of listed chemicals in cooked and heat-processed foods. This proposed regulatory framework furthers the purposes of Proposition 65, will help food companies comply with its requirements, and will reduce unnecessary litigation. The Coalition therefore endorses the concept of this Proposed Regulation and the State's recognition that listed chemicals that are unintentionally formed or increased by cooking and heat processing should not be subject to Proposition 65 if they are reduced to the lowest level currently feasible.

I. BACKGROUND

a. OEHHA and the Courts Have Long Recognized that Foods Require Special Regulatory Treatment.

From the early days of Proposition 65's implementation, the lead agency recognized that listed chemicals that are unavoidably created by cooking or heat processing require special treatment under the regulations. Unlike other consumer products subject to Proposition 65, the purchase and consumption of food is universally necessary for human health and both attempts to eliminate or to warn consumers about listed chemicals in cooked and heat-processed foods may have unintended and detrimental public health consequences. For these and other reasons, long-standing regulatory and judicial precedent exists for treating foods differently from other regulated products.

i. The Naturally-Occurring Regulation

The previously-adopted and judicially upheld naturally-occurring section of Proposition 65's regulations exempts chemicals that are "naturally-occurring" in foods and reduced to the "lowest level currently feasible" from the definition of "exposure" under the statute. *See* 27 Cal. Code Regs. § 25501. When OEHHA's predecessor, the California Health and Welfare Agency, adopted the naturally-occurring regulation, it recognized that food is different

because "[f]ood is a basic necessity of life on par with the water that we drink and the air we breathe." Final Statement of Reasons, 27 California Code of Regulations Section 25501 ("25501 FSOR") at p. 5.[1] The exemption was adopted, in part, out of the concern that "warnings could appear on a large number of food products, and consequently, diminish the overall significance of food warnings." 25501 FSOR at p. 3. In addition, the exemption was adopted to facilitate compliance with Proposition 65. *Id.*

The California Court of Appeal upheld the regulation in *Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652, 660-61 (1991). The Court recognized that the naturally-occurring regulation furthers the purposes of Proposition 65, stating:

> Since one of the principal purposes of the statutes in question is to provide "clear and reasonable warning" of exposure to carcinogens and reproductive toxins, such warnings would be diluted to the point of meaninglessness if they were to be found on most or all food products.

Nicolle-Wagner, 230 Cal. App. 3d at 660-61. The Court held that the exemption "reasonably promotes the statutory purposes of Proposition 65," and was within the lead agency's authority. *Id.* at 661-62.

Indeed, this ruling is consistent with the findings of numerous courts in numerous contexts that over-warning is against the public interest. *See, e.g., Johnson v. Am. Standard, Inc.*, 43 Cal. 4th 56, 70 (2008) (over-warning "invite[s] mass consumer disregard and ultimate contempt for the warning process"); *Thompson v. Cty. of Alameda*, 27 Cal. 3d 741,754-55 (1980) (recognizing that excessive warnings "produce a cacophony . . . that by reason of their sheer volume would add little to the effective protection of the public"); *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 392 (7th Cir. 2010) (concluding that over-warning "can dilute the effectiveness of valid warnings"). And in the more recent context of revamping the safe-harbor warning regulations under Proposition 65, OEHHA itself has reiterated its policy: "OEHHA does not encourage the practice of 'over-warning' and discourages businesses from providing prophylactic warnings when no warning may actually be required." Final Statement of Reasons, Title 27, California Code or Regulations, Proposed Repeal of Article 6 and Adoption of New Article 6, Regulations for Clear and Reasonable Warnings at p. 197. In short, OEHHA's policy against over-warning is longstanding and consistent and has been upheld by the courts.

ii. The Cooking Provision

The cooking provision of Proposition 65's regulations allows for an alternative risk level for carcinogens "where chemicals in foods are produced by cooking necessary to render food palatable or to avoid microbiological contamination . . . ." 27 Cal. Code Regs. § 25703(b). In this manner, the cooking provision defines the meaning of "significant risk" as used in the statute. *See id.*

[1] The regulation was originally number as 22 Cal. Code Regs. § 12501. For simplicity, this letter refers to the regulation's current citation.

Just like the naturally occurring regulation, the cooking provision was adopted, in part, to avoid over-warning. Final Statement of Reasons, Section 25703[2] ("25703 FSOR") at p. 4 ("It would be ironic and counterproductive if, as the result of warnings, the public avoided practices which protect public health."). The Final Statement of Reasons explains:

> Businesses may have considerable difficulty determining in any particular case whether cooking has resulted in the concentrations of listed chemicals which meet the 10^{-5} standard. Thus, businesses may feel compelled to provide a warning to protect them from liability in the event the level of risk does exceed 10^{-5}.

Id. at p. 5. "The confusion which would result if all purveyors of cooked or heat-processed foods provide a warning with their product, to avoid any potential liability, could be enormous." *Id.*

The cooking provision was supposed to provide the regulated community with "flexibility" for compliance with respect to cooked and heat-processed foods. *See* 25703 FSOR at p. 6. However, as discussed below, the recent acceleration in the number of Proposition 65 notices of violation and lawsuits on acrylamide in foods make clear that it has not served its intended purposes. The limited utility of the cooking provision is one of the reasons that the Proposed Regulation is needed.

b. There is an Urgent Need for the Proposed Regulation.

Meanwhile, enforcement activity on listed chemicals that are unavoidably created by cooking or heat processing has increased dramatically since the first pre-litigation notices on acrylamide in food in 2002. As stated in the Initial Statement of Reasons for the Proposed Regulation:

> Over the past several years there has been an increase in enforcement activity related to chemicals such as acrylamide that can be formed in a multitude of foods during heat processing and cooking. In the absence of regulatory action, the proliferation of enforcement actions related to listed chemicals formed in food could result in businesses putting warnings on foods that do not require them, which is contrary to the statutory purpose of enabling consumers to make informed choices.

Initial Statement of Reasons ("ISOR") at p. 6. Indeed, since 2016, private enforcers have issued more than 875 notices of violation regarding acrylamide in foods to food companies and their retailers, and the total settlement payments on these acrylamide notices have been over $10.3 million. In addition to acrylamide notices, in the last eight years there have been 54 notices of violation alleging exposure to other listed heat-formed chemicals. These notices

[2] The regulation was originally number as 22 Cal. Code Regs. § 12703. For simplicity, this letter refers to the regulation's current citation.

of violation for all of these chemicals formed in cooking and heat processing apply to a wide variety of food products, including almonds, peanut butter, baked beans, vegetable-based baby foods, olives, cereal, cookies, crackers, confections, molasses, and grilled chicken.

This multitude of notices of violation creates uncertainty for businesses and the potential for a proliferation of Proposition 65 warnings for unavoidable chemicals formed by cooking and heat processing. Each such case, whether resolved through settlement or by judgment after trial, increases the likelihood that inconsistent warnings will appear on thousands of food products sold throughout California.

The Coalition agrees with OEHHA that "the public would benefit from the proposed regulatory action because sound considerations of public health support the establishment of feasible concentration levels for chemicals unavoidably formed in foods by cooking or heat processing." August 7, 2020 Notice of Proposed Rulemaking at p. 5. The regulated community would also benefit because the Proposed Regulation will assist companies in their Proposition 65 compliance efforts. The Coalition believes that the Proposed Regulation would discourage frivolous litigation against food companies when the average acrylamide level in the food is the lowest feasible level or otherwise below an applicable safe harbor concentration level set in the Proposed Regulation.

c. OEHHA Has the Authority to Adopt Special Regulations for Foods.

California Health & Safety Code section 25249.12 authorizes OEHHA to adopt regulations as necessary to conform with and implement Proposition 65 and to further its purposes. Cal. Health & Safety Code § 25249.12. The Proposed Regulation is consistent with the purpose and past implementation of Proposition 65 and is well within OEHHA's authority. As discussed above, OEHHA and its predecessor agency have adopted several provisions addressing the unique issues related to foods. These provisions, as recognized by the California Court of Appeal, fall well within OEHHA's authority to promulgate regulations to further the purposes of Proposition 65.

In *Nicolle-Wagner*, the Court of Appeal recognized OEHHA's ability to define the term "expose" by enacting regulations. *Nicolle-Wagner*, 230 Cal. App. 3d at 660, n. 3. The Proposed Regulation fits within this judicially-approved regulatory approach because, like the naturally-occurring regulation, the Proposed Regulation defines the term "expose" based on a feasibility standard.

II. THE PROPOSED REGULATION

a. The Coalition Endorses the Proposed Regulation's Adoption of a Feasibility Standard.

The Coalition recognizes that the Proposed Regulation is a significant first step for resolving a complex issue. In particular, the Coalition agrees with OEHHA that it is important to base compliance on feasibility because, as recognized in the Initial Statement of Reasons,

unavoidable chemicals formed or increased by cooking and heat-processing should be exempt from the warning requirement. ISOR at p. 5. Significantly, feasibility is well-known and understood in the law both in the context of Proposition 65 and more broadly. For example, the naturally-occurring regulation incorporates the concept of feasibility with reference to federal law. 27 Cal. Code Regs. § 25501(a)(4) ("The producer, manufacturer, distributor, or holder of the food shall at all times utilize quality control measures that reduce natural chemical contaminants to the 'lowest level currently feasible,' as this term is used in Title 21, Code of Federal Regulations, Section 110.110, subdivision (c) (2001)."). As discussed above, the naturally-occurring regulation and its use of the lowest level currently feasible as a criterion were upheld by the appellate court. *See Nicolle-Wagner*, 230 Cal. App. 3d at 661-62.

In addition, this principle of feasibility is rooted in many Proposition 65 consent judgments.[3] These time-tested feasibility definitions and concepts that have been incorporated into multiple consent judgments, including many entered into with the California Attorney General as designated lead enforcer of the statute, can provide the regulated community and the courts with additional guidance for implementing the Proposed Regulation on a case-by-case basis based on such factors as the nature of the product, availability of technologies and materials, and the size and role of the business involved.

b. The Coalition Understands that Subsection (d) of the Proposed Regulation Is a First Step.

The Coalition notes that subsection (d) of the Proposed Regulation addresses only one listed chemical -- acrylamide -- of the many listed chemicals that can be created or increased in cooking and heat processing. Subsection (d) also identifies only a handful of the many types of foods that contain acrylamide. The Coalition understands that the Proposed Regulation is a first step in adopting a framework and that OEHHA will be receptive to future proposals or petitions to include in subsection (d) additional foods containing acrylamide as well as the already identified foods or additional foods containing other listed chemicals that are created or increased in cooking and heat processing. ISOR at p. 4, 30.

The Coalition also appreciates that, although OEHHA has looked to existing consent judgments in formulating the initial list of foods and levels in subsection (d), this framework does not require that future safe harbor concentration levels be set using standards from consent judgments. Under this framework, OEHHA could set additional safe harbor concentration levels that evaluate feasibility based on the relevant data regarding the listed chemical concentration in the particular food or food category. And OEHHA could revise these levels based on new information.

The Coalition believes the Proposed Regulation is a workable framework and that subsection (d) addresses the most pressing issues while the agency and its proposed framework remain

[3] *See, e.g., People v. Warner Lambert, et al.* (San Francisco Superior Court, Case No. 984503) (paragraph 2.9); *People v. 21st Century Healthcare, Inc. et al.* (Alameda Superior Court, Case No. RG08426937) (Paragraph 2.5(c)).

flexible for addressing other issues related to chemicals associated with heat processed and cooked foods in the future.

c. The Coalition Believes Certain Refinements Would Improve the Proposed Regulation and Ensure that it Achieves its Goals.

The Coalition believes that certain refinements of the regulatory text will facilitate implementation of the Proposed Regulation and result in a more workable regulation that achieves OEHHA's important policy goals. The Coalition makes the following general comments on the regulatory framework:

- **Feasibility of Safe Harbor Concentration Levels**. The Coalition supports the Proposed Regulation establishing safe harbors in the form of acrylamide concentration levels in certain foods and food categories. These proposed acrylamide safe harbor concentration levels set forth in subsection (d) of the Proposed Regulation are generally based on Proposition 65 consent judgments. But, as OEHHA recognizes, the fact that a consent judgment sets a level for acrylamide does not necessarily mean that the level is achievable and represents the "lowest level currently feasible." *See* ISOR at pp. 6-7 ("Absent evidence to the contrary, OEHHA presumes that a company's agreement to such a level indicates that it is currently feasible to achieve the level."); ISOR at p. 12 ("[W]here 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. This may not always be the case, but absent evidence demonstrating otherwise, OEHHA is treating the levels established in selected court-approved settlements as identifying the lowest levels currently feasible.").

  The prior consent judgments utilized by OEHHA to set the safe harbor concentration levels give an incomplete picture as to whether the acrylamide concentration level identified is actually feasible and achievable for the product category or the entire range of products that may fall within the category. For some product categories, this may be a good first step, but flexibility is needed to determine that the level is achievable for any given product, any given business, and across the entire product category. As suggested by OEHHA, some consent judgments may have unachievable acrylamide concentration levels for the product. For example, this can occur when the settling company has withdrawn the product from the California market and no longer produces the product and thus, the company is not producing the product with the acrylamide level set in the consent judgment and is not concerned with whether it is even possible to do so. It can also occur where a business has a proprietary technology or a supply of raw materials not available to others or where it tailors its food products to a subset of consumer preferences that is not representative of the entire product category (e.g., consumers who will accept higher prices or who prefer a certain flavor profile).

  The Coalition also notes that for some of the foods and food categories, the Proposed Regulation has set a level that is lower than some of the prior consent judgments for

those products. In order to have a level playing field, the concentration levels in the Proposed Regulation must ensure fairness and be careful not to give a competitive advantage to companies that have consent judgments that incorporate more lenient concentration levels. *See* ISOR at pp. 34-35 (recognizing that manufacturers of competing products should not be held to different acrylamide standards).

- **Increased Concentration Levels.** The Coalition notes that cooking and other heat processing of foods not only creates listed chemicals; it can also increase the concentration levels of listed chemicals that are present in the raw materials (e.g., through dehydration). The Coalition therefore believes the intent of the Proposed Regulation will be furthered by adding in subsection (a) the words "or its concentration increased by" after the words "created by" so that the first sentence of subsection (a) reads:

  > A person otherwise responsible for an exposure to a listed chemical 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, or its concentration increased by, cooking or other heat processing if the producer, manufacturer, distributor, or holder of the food has utilized quality control measures that reduce the chemical to the lowest level currently feasible.

  A conforming change would also need to be made in subsection (b).

- **Average Concentration Level.** The Coalition supports using the average concentration of acrylamide in food products to determine whether there is an exposure under the Proposed Regulation. The Coalition believes that the "average concentration" definition in subsection (d) of the Proposed Regulation provides the flexibility needed to address a wide array of production conditions and circumstances, as well as differences based on a company's role in the supply chain (manufacturer, producer, or distributor). The Coalition also agrees that the "average concentration" in a finished food product must be measured based on test results on the food "in the form the product is sold to California consumers."

  By contrast, the Coalition believes that the concept of "unit concentration" in subsection (d) of the Proposed Regulation has no basis in science and has the potential to create an impracticable standard. The Coalition understands that this "unit concentration" level is derived from provisions in various consent judgments that were negotiated between private enforcers and defendant businesses. But those consent judgments have other requirements that make the application of that unit concentration standard more workable in practice, such as a meet and confer requirement prior to further enforcement by plaintiff for a violation of the maximum unit concentration level.

More importantly, this limitation on the concentration of acrylamide in every single unit of a product fails to account for the significant variability in acrylamide concentrations in any given food type. *See* https://www.fda.gov/food/chemicals/survey-data-acrylamide-food (recognizing "unit-to-unit and lot-to-lot variation in acrylamide levels within food products"). This variability can be more than 3x from lowest to highest, reflecting the natural variability of the raw materials and the cooking process that contributes to appetizing organoleptic qualities. *See id.* (2015 FDA acrylamide data spreadsheet). The Coalition therefore believes that the Proposed Regulation should be adopted without the concept of "unit concentration" in subsection (d), at least as to acrylamide, the only listed chemical for which there are specific levels proposed.

- **The Safe Harbor Approach in Subsection(d)**. The Coalition supports OEHHA's use of a safe harbor approach in subsection (d) of the Proposed Regulation because it is a consistent approach in the Proposition 65 regulations. *See* 27 Cal. Code Regs. § 25600(a) ("Subarticle 2 provides 'safe harbor' content and methods for providing a warning that have been determine 'clear and reasonable' by the lead agency."); *see* Proposition 65 Safe Harbor Levels at https://oehha.ca.gov/media/downloads/proposition-65//safeharborlist032519.pdf ("Below is a list of NSRLs and MADLs that provide 'safe harbor' for businesses subject to the requirements of Proposition 65. These NSRLs and MADLs are established in regulation in Title 27, Cal. Code of Regulations, Sections 25705, 25709 and 25805. These safe harbor levels do not preclude the use of alternative levels that can be demonstrated by their users as being scientifically valid."). The Coalition recommends that the Proposed Regulation make clearer that the levels set forth in subsection (d) are truly ***safe harbor*** concentration levels. The Coalition recommends adding the following sentence to the end of subsection (d):

  > The concentration levels for foods in this subsection do not preclude the use of alternative levels that comply with the requirements of subsection (a).

  This clarification is consistent with the safe harbor approach and makes clear that a company can rely on the safe harbor concentration levels set forth in subsection (d) or establish compliance with subsection (a)'s requirements for the lowest level currently feasible. This approach should also reduce frivolous litigation that is based on disputes regarding the categories identified in subsection (d) and whether a particular food is covered by that category.

- **How to Apply Subsection(d)**. The Coalition believes that the second sentence of subsection (a) is confusing because it is attempting to explain how to apply subsection (d), not subsection (a). The sentence in the Proposed Regulation reads as follows: "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)." The ISOR explains that "if a business sells products

with acrylamide levels that exceed the applicable levels set forth in subsection (d), the level established in subsection (d) for a given product may not be subtracted from the total concentration before making this calculation." ISOR at p. 11.

The Coalition understands and endorses that concept but believes that the regulatory text should make it more clear without the need to refer to the ISOR. The Coalition proposes deleting the second sentence in subsection (a) of the Proposed Regulation as unnecessary and inserting a new subsection (e): [4]

> If the concentration level in a product type identified in subsection (d) exceeds the applicable level in subsection (d), then the applicable level in subsection (d) shall not be subtracted from the concentration level for purposes of determining the "level in question" as defined in Sections 25721(a) and 25821(a).

- **Safe Harbor Concentration Levels.** The Coalition understands that individual companies and trade associations will be addressing the specific safe harbor concentration levels set forth in subsection (d). We encourage OEHHA to consider these specific comments in light of the general considerations outlined above and the need for the Proposed Regulation to accomplish its goals of providing practical guidance to the regulated community and not creating unintended consequences in the foods enjoyed by Californians.

III. CONCLUSION

In conclusion, for the reasons discussed above, the Coalition supports the Proposed Regulation and believes that, with the minor modifications noted above and in other comments, it can provide an important framework to assist foods companies and their compliance with Proposition 65. We look forward to working with OEHHA to refine the wording of the Proposed Regulation in order to accomplish its intended purpose.

Respectfully,

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Consumer Brands Association

Adam J. Regele, Policy Advocate
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[4] In addition, deleting the second sentence in subsection (a) would clarify the cross-reference in subsection (d) which reads: "The concentration levels for chemicals in foods in this subsection are deemed to comply with subsection (a)."

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