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Via portal at: <https://oehha.ca.gov/comments>

RE: PROPOSED AMENDMENTS TO ARTICLE 6, CLEAR AND REASONABLE WARNING, NEW SUBSECTION 25607.2(B) WARNING CONTENT FOR ACRYLAMIDE EXPOSURE FROM FOOD

The Consumer Brands Association, the California Chamber of Commerce, and the organizations listed below (hereinafter, “Coalition”) thank you for the opportunity to submit comments regarding the Office of Environmental Health Hazard Assessment’s (“OEHHA’s”) Proposed Amendments to Article 6, New Subsection 25607.2 regarding warnings for acrylamide exposure from food (“Proposed Rulemaking”). 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 opposes the Proposed Rulemaking because it is inconsistent with OEHHA's long-standing approach to safe harbor warnings and is not based in sound policy, but instead is a strategic tactic in litigation. The fact is: Proposition 65 warnings for acrylamide in food and beverages are inappropriate because neither the State of California nor any authoritative body knows that dietary acrylamide actually causes cancer in humans.

While acrylamide is known to cause cancer in laboratory animals, the relevance of those findings to humans has not been established. Indeed, because humans have been consuming acrylamide as part of their diet for millennia, there is a robust body of epidemiological data that shows, in the words of the National Cancer Institute, "no consistent evidence that dietary acrylamide exposure is associated with the risk of any type of cancer."¹ The American Cancer Society likewise explains: "So far, reviews of studies done in groups of people (epidemiological studies) suggest that dietary acrylamide isn't likely to be related to risk for most common types of cancer."²

Indeed, despite its awareness of the same studies cited by OEHHA, the U.S. Food & Drug Administration (FDA) has not recommended warnings on foods containing acrylamide and indeed has cautioned that such warnings may confuse consumers and result in harm to their health from alternative dietary choices.³ For example, the FDA has directly opposed warnings for acrylamide in whole grain foods because "[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."⁴ Based on similar reasoning, the FDA also enthusiastically supported OEHHA's proposed regulation, now adopted, exempting coffee from Proposition 65 cancer warnings for acrylamide.⁵

It is telling that the one food group that is a significant source of exposure to acrylamide in the human diet and that has been studied the most extensively -- coffee -- has been determined by esteemed scientific bodies, consistently and emphatically, to **not** cause cancer in humans. OEHHA of course adopted a regulation specifically finding that chemicals in coffee that are created by roasting and brewing -- including acrylamide --

¹ National Cancer Institute, Acrylamide and Cancer Risk (Dec. 5, 2017), <https://www.cancer.gov/about-cancer/causes-prevention/risk/diet/acrylamide-fact-sheet> (concluding that "a large number of epidemiologic studies (both case-control and cohort studies) in humans have found no consistent evidence that dietary acrylamide exposure is associated with the risk of any type of cancer" and noting that "toxicology studies have shown that humans and rodents not only absorb acrylamide at different rates, they metabolize it differently as well").

² See American Cancer Society, *Acrylamide and Cancer Risk* (Feb. 11, 2019), <https://www.cancer.org/cancer/cancercauses/acrylamide.html> (further noting, "It's not yet clear if the levels of acrylamide in foods raise cancer risk . . .").

³ See Letter from Lester M. Crawford, Deputy Commissioner, U.S. Food & Drug Administration, to Joan E. Denton, Director, OEHHA (July 14, 2003, p. 2).

⁴ <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-support-exempting-coffee-californias-cancer>

⁵ *Id.*

do not pose any significant risk of cancer.⁶ It is not clear why, based on the data noted above, acrylamide in other foods and beverages should be treated any differently.

In fact, numerous scientific studies support the conclusion that exposure to acrylamide from food does not increase cancer risk in humans. In a 2012 systematic review published in the *European Journal of Cancer Prevention*, for example, researchers evaluated the association between dietary acrylamide and cancer.⁷ The researchers explained that “[c]onjectured associations between dietary acrylamide intake and cancer have been evaluated in more than 15 epidemiologic studies examining almost every major cancer site.”⁸ After critically reviewing the available studies, the researchers concluded:

After an extensive examination of the published literature, we found no consistent or credible evidence that dietary acrylamide increases the risk of any type of cancer in humans, either overall or among nonsmokers. In particular, the collective evidence suggests that a high level of dietary acrylamide intake is not a risk factor for breast, endometrial, or ovarian cancers. . . . In conclusion, epidemiologic studies of dietary acrylamide intake have failed to demonstrate an increased risk of cancer. In fact, the sporadically and slightly increased and decreased risk ratios reported in more than two dozen papers examined in this review strongly suggest the pattern one would expect to find for a true null association over the course of a series of trials.⁹

Based on the strength of this data and analysis showing that dietary acrylamide does not cause cancer in humans, the United States District Court for the Eastern District of California preliminarily enjoined Proposition 65 cancer warnings for acrylamide in foods and beverages as contravening the First Amendment’s prohibition on government-compelled speech that is false or misleading¹⁰. OEHHA’s proposed warning seeks to evade the science and force businesses who make and sell food products to take one side in the controversy over whether acrylamide in foods and beverages causes cancer in humans. The warning set forth in the Proposed Rulemaking will also fail to comply with the First Amendment’s requirements.

Furthermore, OEHHA’s proposal will open the door for similarly misleading warnings that point to the existence of a controversy rather than warn of exposure to a truly known carcinogen. Warnings such as those embodied in the Proposed Rulemaking will make Proposition 65 warnings even more likely, without regard to any actual risk posed by consumer products. The burden on businesses to overcome the presumption that a

⁶ [Cal. Env’tl Protection Agency, Office of Env’tl Health Hazard Assessment, Final Statement of Reasons on Adoption of New Section 25704.](#)

⁷ See L. Lipworth, et al., Review of Epidemiologic Studies of Dietary Acrylamide Intake and the Risk of Cancer, *European Journal of Cancer Prevention*, Vol. 21:375-386 (2012).

⁸ *Id.*

⁹ *Id.*

¹⁰ *California Chamber of Commerce v. Xavier Becerra*, No. 2:19-cv-02019-KJM-JDP, Doc. 114 (E.D.C.A. 30 Mar. 2021)

listed chemical, present in merely detectable quantities in a food or beverage, requires a warning is almost unsurmountable, forcing the rational decision to provide a warning when none is actually needed based on the science and the law. This will be, and in many instances already is, the inevitable result of OEHHA's effort to evade the strictures of the First Amendment and encourage warnings for chemicals that are not actually known to the state to cause cancer.

As discussed below, OEHHA's change in position is nothing more than a litigation tactic designed to require more litigation of the issue of acrylamide warnings and delay the ultimate judgment that compelled Proposition 65 warnings for this chemical, whose carcinogenicity via dietary consumption has not been established, are unconstitutional. It is an expedient reversal of OEHHA's unwavering practice over decades, is necessary only for OEHHA's litigation goals, and is not sound policy. The Proposed Rulemaking should be withdrawn.

I. The Proposed Rulemaking Is Inconsistent with OEHHA's Longstanding Approach To Safe Harbor Warnings.

From the beginning of Proposition 65's implementation 35 years ago, OEHHA and the California Attorney General have insisted that a Proposition 65 warning does not satisfy the statutory mandate of a "clear and reasonable" warning unless it unequivocally states that the chemical is "known to the state to cause" cancer and/or birth defects or other reproductive harm. The Proposed Rulemaking violates this longstanding standard and does so without so much as an acknowledgment of OEHHA's dramatic change in policy and reversal of its prior legal position.

A. Until Now, OEHHA Has Consistently Required Safe Harbor Warnings To Clearly Communicate That The Chemical Is Known To The State To Cause Cancer Or Reproductive Harm.

The Proposition 65 statute requires that California consumers receive a "clear and reasonable" warning prior to exposure to a listed chemical.¹¹ Until their reorganization in 2018, the Proposition 65 regulations explicitly required that for a warning to be "clear," "[t]he message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm."¹² And the California Supreme Court has held that the warning must communicate that the chemical is "known to the state of California cause [cancer]", or words to that effect."¹³ Consistent with these authorities, OEHHA and its predecessor agency have always interpreted the

¹¹ 27 Cal. Health & Safety Code § 25249.6.

¹² 27 Cal. Code Regs. § 25601 (repealed in 2018); *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910, 918 (2004) (quoting the regulation); *Environmental Law Foundation v. Wykle Research, Inc.*, 134 Cal. App. 4th 60, 66 n.6 (2005) ("[T]he method of transmission relates to the reasonableness of the warning, whereas the content of the message relates to its clarity.").

¹³ *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910, 918 (2004).

Proposition 65 warning requirement as binary: either a simple, unequivocal warning or no warning at all.

Although the overhaul of the warning regulations in 2018 left out the regulatory language of section 25601 that “the message must clearly communicate that the chemical in question is known to the state to cause cancer,” during those regulatory proceedings OEHHA held fast to its position that safe harbor warnings must clearly communicate that the chemical causes cancer or reproductive harm without any equivocation. Indeed, all of OEHHA’s safe harbor warnings -- 19 of them -- use this longstanding formulation of “known to the state to cause” cancer and/or reproductive harm and the short form warnings permitted in some circumstances abbreviate it with a simple reference to “cancer” or “reproductive harm” and a link to the OEHHA Proposition 65 website that refers to “chemicals that cause cancer, birth defects or other reproductive harm” (again, without equivocation).

Moreover, OEHHA reinforced this longstanding position with respect to the proposal in the warning regulations to restrict language that was supplemental to the warning language. On January 16, 2015, OEHHA issued a regulatory package for proposed repeal of the old warning regulations and adoption of new warning regulations. This 2015 warning proposal included a draft section 25600(d) that provided as follows:

A person may provide information to the exposed individual that is supplemental to the warning required by Section 25249.6 of the Act, such as further information about the form or nature of the exposure and ways to avoid the exposure. In order to comply with this Article, supplemental information may not **contradict, dilute, or diminish** the warning. Supplemental information may not be substituted for the warning required by Section 25249.6 of the Act.¹⁴

The Coalition submitted comments and stated that the proposal “was going in the wrong direction.”¹⁵ The Coalition emphasized that “[c]onsumers need and deserve accurate and truthful, contextual information about the safety of consumer products they use and consume every day.”¹⁶ The Coalition explained the need for contextual warnings as follows:

OEHHA should either remove this provision outright or replace it with clarification that truthful, accurate supplemental information from the manufacturer (or other regulated entity) is always permitted, and supplemental information that puts risk into context and communicates the product benefits is encouraged. And policy aside, it is likely a First Amendment violation for OEHHA to circumscribe or prohibit

¹⁴ Proposed Repeal and Adoption of New Article 6, Regulations for Clear and Reasonable Warning, dated January 6, 2015 (emphasis added).

¹⁵ California Chamber of Commerce Coalition Comments dated April 8, 2015 at p. 5.

¹⁶ *Id.*

manufacturers from offering helpful, truthful product information to consumers.¹⁷

The January 16, 2015 regulatory package was ultimately withdrawn on November 27, 2015, and a new regulatory proceeding was initiated.¹⁸ In that proposal, OEHHA deleted the words “dilute or diminish,” but retained “contradict.” The November 27, 2015 language for proposed section 25600(d) stated that “[a] person may provide information to the exposed individual that is supplemental to the warning” but that “[i]n order to comply with this article the supplemental information may not **contradict** the warning.”¹⁹ Again, the Coalition commented stating that the provision is “unconstitutionally vague, and potentially violates the First Amendment commercial free speech rights of affected businesses.”²⁰ In the final version of the regulations, OEHHA revised this provision so that it only applied to safe harbor warnings. Section 25601(e), as adopted, now reads as follows:

The warning content may contain information that is supplemental to the content required by this subarticle only to the extent that it identifies the source of the exposure or provides information on how to avoid or reduce exposure to the identified chemical or chemicals. Such supplemental information is not a substitute for the warning content required by this subarticle.²¹

In the Final Statement of Reasons, OEHHA explained that it only deleted that objectionable language from the final regulation after considering industry comments that it was an improper restriction on free speech.²² OEHHA further explained that “Subsection (e) does not prevent a business from engaging in public discourse regarding listing decisions and methodology; however, providing this information in the warning would be inconsistent with the safe harbor warning methods and content and a business that chooses to do so would not be afforded safe harbor protection under Article 6.”²³

B. The Attorney General’s Office Has Also Required That Safe Harbor Warnings Unequivocally State That The Chemical Causes Cancer Or Reproductive Harm.

Similar to OEHHA and its predecessor agency, the Attorney General’s Office also has had a longstanding requirement that Proposition 65 safe harbor warnings clearly

¹⁷ *Id.*

¹⁸ Initial Statement of Reasons, Title 27, California Code of Regulations, Proposed Repeal of Article 6 and Adoption of New Article 6, Regulations for Clear and Reasonable Warnings dated November 27, 2015 at p. 10.

¹⁹ See *id.* at p. 12 (emphasis added).

²⁰ California Chamber of Commerce Coalition Comments dated January 25, 2016 at p. 5.

²¹ 27 Cal. Code Regs. § 25601(e).

²² Final Statement of Reasons, Title 27, California Code of Regulations, Proposed Repeal of Article 6 and Adoption of New Article 6, Regulations for Clear and Reasonable Warnings, at pp. 18-19.

²³ *Id.* at p. 20.

communicate that the chemical is known to cause cancer or reproductive harm. This position was formalized almost two decades ago in the Attorney General's 2003 Proposition 65 regulations setting forth the Attorney General's guidelines regarding clear and reasonable warnings in Proposition 65 settlements by private enforcers.²⁴

Section 3202(b) of the Attorney General's regulations reads as follows:

(b) Warning language. Where the settling parties agree to language other than the "safe harbor" language set forth in the governing regulations (22 CCR § 12601(b)) the warning language should be analyzed to determine whether it is clear and reasonable. Certain phrases or statements in warnings are not clear and reasonable, such as (1) ***use of the adverb "may" to modify whether the chemical causes cancer or reproductive toxicity*** (as distinguished from use of "may" to modify whether the product itself causes cancer or reproductive toxicity); (2) additional words or phrases that contradict or obfuscate otherwise acceptable warning language. Certain other deviations from the safe-harbor warnings are generally clear and reasonable, such as (1) using the language "Using this product will expose you to a chemical..." in lieu of "This product contains a chemical...;" or (2) deleting the reference to "the state of California" from the safe-harbor language.²⁵

For the last 18 years, and to this day, the Attorney General's own regulation has declared that it is not "clear and reasonable" to say the chemical "may" cause cancer, *i.e.*, to cast doubt on whether the chemical is, indeed, "known to the state to cause cancer."²⁶ Notably, the Attorney General's regulations underwent a significant revision in 2016, but section 3202 was not revised in that overhaul and remains the official guidance from the California Attorney General's Office on clear and reasonable warnings.

Again, OEHHA's Regulatory Proposal does not so much as acknowledge its potential inconsistency with the Attorney General's regulations or the unwavering and longstanding legal interpretation of both OEHHA and the Attorney General. Nor does it provide any criteria on which OEHHA will base a decision to alter its longstanding formulation of the "known to the state to cause cancer" wording that has been deemed "clear and reasonable" and indeed required, without variation, for decades. In fact, OEHHA's September 17, 2021 proposal to create a new safe harbor warning for dietary

²⁴ See 11 Cal. Code Regs. § 3202 (b)

²⁵ *Id.*

²⁶ The Attorney General has permitted variations on the term "known," as it did in settlements over alleged exposures to acrylamide in potato chips where the warning required by the consent judgment referred to acrylamide as "a substance identified as causing cancer under California's Proposition 65." See, e.g., Consent Judgment as to Frito-Lay at 10, *People v. Frito-Lay, Inc.*, No. BC 338956 (Los Angeles Superior Court) (filed Aug. 1, 2008). The State also permitted manufacturers to explain that foods other than potato chips contain heat-formed acrylamide that is not added to foods but formed as part of the cooking process. But the Attorney General has never permitted a warning in a Proposition 65 settlement that expresses doubt about whether the chemical actually causes cancer and/or reproductive toxicity.

exposures to acrylamide -- together with its July 20, 2021 proposal to create a similar new safe harbor warning for glyphosate -- shows that the common criterion applied by OEHHA is that a federal court ruling must first cast doubt on the State's ability to compel the warning because of uncertainty about whether the chemical at issue is actually "known" to cause cancer in humans.

Additionally, there are many chemicals on the Proposition 65 list about which there is substantial controversy as to whether they cause the relevant endpoint (cancer or reproductive toxicity) in humans. But OEHHA has never before so much as suggested that the "known to the state to cause" warning language can be modified to convey the reality of scientific knowledge more accurately. For example, the extensive litigation over the chemical di(2-ethylhexyl)phthalate (DEHP) -- which was determined after trial not to cause cancer in humans -- may well have been unnecessary had OEHHA not taken the position that an appropriate Proposition 65 warning would use the term "known to the state to cause reproductive toxicity in animals."²⁷ OEHHA's Regulatory Proposal provides no policy basis for determining which chemicals are entitled to use language other than "known to the state" or words to that effect.

II. The Coalition Fully Supports Contextual Proposition 65 Warnings, Preferably Delivered Using Modern Digital Technology.

The Coalition has consistently supported contextual warnings -- whether crafted by OEHHA as safe harbors or by businesses to supplement the required language -- and it continues to do so. Contextual warnings serve to put the risks of chemical exposure in context and help inform consumers of substantiated hazards as well as ways that the risks of exposure to those hazards can be reduced or avoided. Many federal and state warning schemes administered by health and safety agencies under other statutes permit and indeed encourage contextual warnings that provide this helpful information to consumers.

The Coalition continues to believe that truthful, accurate supplemental information from the manufacturer (or other regulated entity) should always be permitted, and supplemental information that puts risk into context and communicates the product benefits is fully consistent with Proposition 65 and its purposes and, if anything, should be encouraged by the State. But, as noted above, OEHHA and the Attorney General have been consistently hostile to such warnings, even when federal agencies with deep expertise in hazard identification, risk assessment, and risk communication disagree with the rigid warning format that they have, until now, stated is required.

A good example is nicotine replacement therapy (NRT) products such as patches and chewing gum, where the U.S. Food & Drug Administration required the following warning:

²⁷ *Baxter Healthcare Corp. v. Denton*, 120 Cal.App.4th 333, 353-359 (2004).

If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.²⁸

This warning “serves a nuanced goal -- to inform pregnant women of the risks of NRT products, but in a way that will not lead some women, overly concerned about those risks, to continue smoking.”²⁹ The California Supreme Court, over the objection of the Attorney General, ultimately ruled that the standard Proposition 65 warning -- which reflected “the state’s more single-minded goal of informing consumers of the risks” was preempted due to conflict with federal law.³⁰

Despite the Supreme Court’s recognition that there are other policy goals, including the goal of fully informing consumers, that can conflict with the standard Proposition 65 warning, practitioners report numerous instances where the Attorney General’s Office -- since 2003 relying on its codified settlement guidance -- has objected to the wording of warnings in settlements that would more fully inform consumers. Indeed, there are instances in which the Attorney General’s Office has contacted businesses to object to warnings being provided in the marketplace that provide this information, not on the grounds that it is factually inaccurate but on the grounds that it dilutes the Proposition 65 warning message and is therefore not a “clear and reasonable” warning as required by Proposition 65.

The efforts of OEHHA and the Attorney General’s Office to restrict such information are contrary to good policy and to the First Amendment. The Coalition raised this issue during the 2016 Proposition 65 warning regulatory proceedings and stated:

Indeed, the U.S. Supreme Court has made clear in commercial speech cases that the First Amendment “embraces at the least the liberty to discuss publicly and truthfully all matters of public concern.” *Consolidated Edison Co. of N.Y. v. Public Serv. Comm’n of N.Y.*, 447 U.S. 530, 534 (1980); *accord*, *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n of N.Y.*, 447 U.S. 557, 562-63 n.5 (1980). It has also held that speech on matters of public concern (and Proposition 65 certainly qualifies) needs “breathing space” – incorporating subjective or controversial speech and possibly even false or misleading speech – in order to survive. *New York Times Co. v. Sullivan*, 376 U.S. 254, 271-72 (1964).³¹

Rather than continuing its efforts to prescribe the wording of misleading warnings that fail to communicate the complete context of a potential exposure, and particularly for

²⁸ *Dowhal*, 32 Cal 4th at 919

²⁹ *Id.* at 935.

³⁰ *Id.*

³¹ California Chamber of Commerce Coalition Comments dated January 25, 2016 at p. 6.

chemical exposures like acrylamide whose relevance to humans is at best uncertain, OEHHA should embrace digital disclosure options to inform consumers more completely of chemicals that are actually “known to the State to cause cancer and birth defects or other reproductive harm.” The adoption of on-pack triggers (such as QR codes and digital watermarks) and digital disclosure platforms like SmartLabel® allow consumers to obtain detailed product information in a consistent, organized format when and where they want it. These programs have been embraced by legislators in California and regulators in New York to convey important safety and health information in an agile, effective way. Modern, digital solutions are a more effective means of providing transparency and information to consumers, giving them greater ease of access and increased confidence in the accuracy of information and the safety of consumer products, in line with OEHHA’s mission. For food and other consumer packaged goods, digital disclosure would enable businesses to provide more information to consumers, including reliable research and science-based advice on how to reduce potential exposures.

OEHHA’s own data shows substantial web traffic for food and chemicals found in food, further bolstering the viability of digital disclosure for contextual warnings for chemicals found in food. For example, the OEHHA website’s search function encompassed 11.8 million of page views spanning September 2020 until mid-September 2021, yielding nearly 1 million views a month of its website. OEHHA’s own data concerning the top 10 most searched categories showcases immense interest and viability for digital disclosure on products relevant to the Coalition. For instance, “food” was the most searched category on the website (with 90,000 views or 8.58% of all searches). Digital methods of providing contextual information are clearly quite effective and of great interest to consumers.

But the Coalition’s support for contextual warnings, and particularly warnings and related information delivered through modern, digital technology, should not be misconstrued as support for warnings of any sort for chemicals that are not known to the State to cause cancer or birth defects or other reproductive harm. Proposition 65 only requires warnings for such chemicals, and warnings for chemicals that are only suspected, or even considered to be possible or probable carcinogens, are inappropriate because they mislead consumers.

III. The Proposed Warning Is Not A Contextual Warning But Simply Alerts Consumers To The Existence Of A Controversy.

The Regulatory Proposal is not a contextual warning but instead a “controversy warning.” It does not place the risk of a known hazard in context. Instead, it informs the consumer that a controversy exists about *whether* the chemical at issue poses a risk (even as it places a heavy thumb on the scale in favor of one side of that controversy). This controversy warning informs consumers that there is uncertainty about whether the chemical has been appropriately identified as “known to the state” to cause cancer.

The Coalition opposes this form of warning, which at best does no more than alert the consumer that it is **unknown** whether the chemical can indeed pose any risk. This is the polar opposite of what Proposition 65 authorizes. OEHHA does not have authority under the Act to mandate or invite warnings describing unknown harms. No amount of context can cure the fundamental issue that a Proposition 65 warning is not appropriate in this instance.

OEHHA has no legitimate policy interest in posing this conundrum to consumers, and particularly in attempting to require it to be presented in the small space available on the package of a consumer product. Proposition 65 warnings for dietary acrylamide are misleading because they convey a message to consumers that foods will increase cancer risk when in truth there is insufficient scientific basis for any such warning, a prospect that is categorically antithetical to the spirit and functionality of the statute. Scientific controversy cannot be summarized so succinctly without misleading the lay reader and calling on them to rely on their own prejudices and biases in arriving at their own decision about the product. If OEHHA, aside from its authority to implement Proposition 65, wishes to state its views on the controversy of whether dietary acrylamide causes cancer in humans, it certainly may do so. But there is no policy or legal justification for California to commandeer the labels of food and beverage products to describe, in necessarily misleading terms, a controversy about which well-qualified scientists (and those empowered by their governments to decide such issues) cannot agree.

In sum, while the Coalition supports contextual warnings and believes OEHHA needs to provide much more latitude for businesses to fully inform consumers, the Proposed Rulemaking's acrylamide warning is not a contextual warning. It is misleading and confusing and therefore at odds with the statutory mandate for a warning that is "clear and reasonable."³²

IV. The Proposed Rulemaking Is Litigation Strategy, Not Sound Policy.

It is clear from the context that the pending *CalChamber* litigation is the reason for OEHHA's break with its historical position that warnings contain an unequivocal statement that the chemical is "known" to cause cancer and/or reproductive toxicity. OEHHA's proposal is not a well-considered policy change, but a strategic litigation move made in the prospect of a loss in the *CalChamber* litigation. The ISOR acknowledges as much stating that "OEHHA is also aware of the federal District Court decision in the California Chamber of Commerce v. Bonta (*CalChamber*) case in which the California Chamber of Commerce challenged the existing safe harbor Proposition 65 warning as applied to acrylamide in food, arguing that such warnings are false and misleading and therefore, a violation of the First Amendment rights of its members"³³ and that "OEHHA has considered the concerns expressed in the District Court's

³² See Cal. Health & Safety Code § 25249.6.

³³ See <https://oehha.ca.gov/media/downloads/cmr/isoracrylamide091721.pdf> ISOR at p. 8.

preliminary injunction order in developing the proposed regulation. The purpose of the proposed regulation is to provide an additional optional safe harbor warning for businesses that addresses the District Court’s concerns as well as public health concerns.”³⁴

A. The Proposed Rulemaking Is Inconsistent With OEHHA’s Past Practice And Interpretations of Proposition 65.

As discussed above, the Proposed Rulemaking is inconsistent with past practice and interpretations of Proposition 65 by OEHHA and the Attorney General’s Office outside of defensive litigation. The Proposed Ruling comes as a direct result of litigation dynamics -- after the district granted a preliminary injunction in *CalChamber*, barring the filing of new Proposition 65 lawsuits regarding acrylamide upon finding that the Attorney General’s office failed to show that cancer warnings for acrylamide were purely factual and uncontroversial.³⁵ The district court observed the unsound scientific grounding in the State’s arguments around acrylamide.³⁶ While acknowledging that many governmental authorities have concluded that acrylamide probably or may be likely to cause cancer, this is legally and factually distinct from “known” to cause cancer. What is more, no authorities have cautioned consumers to avoid foods that may contain acrylamide and at most, authorities may identify and acknowledge concerns about acrylamide while concomitantly acknowledging its omnipresence in so many foods and beverages.³⁷

In contravention of the research record and litigation surrounding acrylamide, the Proposed Regulation erroneously declares that there is “no serious scientific debate about the carcinogenicity of acrylamide, or its potential for carcinogenicity in humans” when the district court in *CalChamber* expressly ruled the contrary.³⁸ This Proposed Rulemaking is simply an effort to design a warning that OEHHA (and presumably its lawyers in the Attorney General’s Office), think might pass muster with the courts. But it will not.

As the district court properly found in *CalChamber*, a Proposition 65 warning is not appropriate while there is a legitimate scientific controversy about whether a chemical causes cancer in the first place.³⁹ In short, as long as there is a scientific controversy about the carcinogenicity of acrylamide, OEHHA will not be able to craft an acrylamide safe harbor warning that is consistent with the First Amendment.

³⁴ *Id.*

³⁵ *California Chamber of Commerce v. Xavier Becerra*, No. 2:19-cv-02019-KJM-JDP, Doc. 114 (E.D.C.A. 30 Mar. 2021)

³⁶ *Id.*

³⁷ U.S. Food & Drug Admin., “Guidance for Industry: Acrylamide in Foods” (Mar. 2016)

³⁸ See *California Chamber of Commerce v. Xavier Becerra*, *Order at 23*

³⁹ *Id.* at 25

B. OEHHA Has No Basis For Its Belief Regarding How Consumers Will Understand And React To The Proposed Acrylamide Warning.

Without any basis or expertise, OEHHA makes significant unfounded claims of the purported benefits of the Proposed Rulemaking. OEHHA recites the policies of a number of food regulatory bodies to encourage the reduction of acrylamide in food products as support for “the importance of providing Proposition 65 warnings prior to significant exposures to acrylamide in food . . .”⁴⁰ OEHHA also states that “[t]hese public health concerns . . . indicate a need for a more specific and informative Proposition 65 warning for these exposures.”⁴¹

But OEHHA omits that none of these public health and food regulatory bodies has called for consumer warnings for acrylamide, despite the broad authority that many of them have to require such warnings. Indeed, as noted above, the U.S. FDA has specifically opposed warnings for acrylamide in food because of their potentially harmful consequences for consumers’ health and dietary choices.⁴²

That public health agencies, faced with the widespread presence in food of a chemical that is at best suspected of causing cancer, would take prudent action to encourage means of reducing levels of exposure in no way supports the entirely different, even extreme, policy choice proposed by OEHHA: to warn consumers about this unknown and uncertain risk without regard for other consequences to public health.

OEHHA has many areas of expertise, with well-qualified scientists in numerous fields that are relevant to its mission. But a key area in which OEHHA lacks expertise is risk communication -- an entire field of academic study devoted to the formulation and transmission of health and safety data to consumers. OEHHA therefore has no basis to determine current consumer perceptions around acrylamide, how it may confuse consumers on food choices, or how consumers will understand its proposed acrylamide warning or modify their behavior, if at all, in response to it. Any claimed benefit for this supposed tailored warning for acrylamide is simply speculation.

Fundamentally, “[b]ecause warnings are an important tool to inform and remind consumers about potentially harmful consequences of product use, any warning must be worded to avoid creating confusion.”⁴³ This is well-known by other agencies who formulate and prescribe consumer warnings. For example, the U.S. Consumer Products Safety Commission provides the following guidance for drafting product warnings: “Warnings should be conspicuous, legible, durable, clear, concise, and

⁴⁰ ISOR, at 10.

⁴¹ *Id.*

⁴² See [Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's support for exempting coffee from California's cancer warning law](#) (August 29, 2018)

⁴³ Amicus Curiae Brief of Risk Mitigation Scholars in Support of Appellees and Affirmance, filed in *National Association of Wheat Growers v. Bonta*, Ninth Circuit Court of Appeals, Case No. 20-16758 at p. 19.

motivating.”⁴⁴ And this is consistent with Proposition 65’s requirement that warnings be “clear and reasonable.”

Poorly drafted, misleading, and unnecessary warnings can have unintended consequences. In the *Wheat Growers* appeal, the amicus brief of the risk mitigation experts discusses the research on consumer reaction to warnings as follows:

There is a growing body of research that shows that consumers react to warnings in complex and sometimes counterintuitive ways. Indeed, the research shows that ubiquitous warnings can actually decrease public safety, particularly when those warnings are based on unproven hypotheses that ultimately turn out to be false alarms.⁴⁵

The amicus brief also describes how the research has shown that consumers’ reactions to warnings can be detrimental:

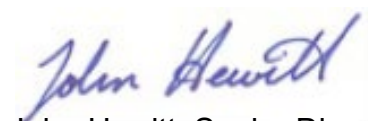
Warnings “often cause consumers to react in ways that are not optimal, such as by discounting the extent of the potential risk, overreacting to the risk, ignoring the message altogether, or engaging in the precise behavior that the warning is designed to prevent. Each of these factors must be considered when determining whether a warning will promote increased public safety and well-being.”⁴⁶

OEHHA’s primary consideration appears to be to design a warning that OEHHA thinks has a better chance -- compared with the prior alternatives proposed to the federal court -- of surviving review under the First Amendment. In short, OEHHA does not know how consumers will react to this “nuanced” and confusing acrylamide safe harbor

V. The Proposed Rulemaking Should Be Withdrawn.

In conclusion, for the foregoing reasons, the Coalition respectfully requests that OEHHA withdraw the Proposed Rulemaking amending Article 6 to provide for tailored warnings for acrylamide in foods and beverages.

Respectfully,



John Hewitt, Senior Director
Consumer Brands Association



Adam Regele, Senior Policy Advocate
California Chamber of Commerce

⁴⁴ Guidance on the Application of Human Factors to Consumer Products, Division of Human Factors, U.S. Consumer Product Safety Commission (February 2020) at p. 17.

⁴⁵ Amicus Curiae Brief of Risk Mitigation Scholars in Support of Appellees and Affirmance, filed in *National Association of Wheat Growers v. Bonta*, Ninth Circuit Court of Appeals, Case No. 20-16758 at pp. 3-4.

⁴⁶ *Id.* at p. 6.

On behalf of the following organizations:

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American Beverage Association, Rick Ravis

American Chemistry Council, Tim Shestek

American Frozen Food Institute, Lory O. Reveil, Ph.D

California Attractions and Parks Association, Sabrina Demayo Lockhart

California Farm Bureau Federation, Taylor Roschen

California Food Producers, Trudi Hughes

Chemical Fabrics and Film Association, Jenny Oblock

California Retailers Association, Steve McCarthy

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Del Monte Foods, Inc., William Sawyers

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National Confectioners Association, Paige Smoyer

Peanut and Tree Nut Processors Association, Jeannie Shaughnessy

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