October 7, 2021

Ms. Monet Vela
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1001 I Street, 23rd Floor
Sacramento, CA 95812-4010

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

RE: PROPOSED AMENDMENTS TO ARTICLE 6, CLEAR AND REASONABLE WARNING, NEW SECTIONS 25607.48 AND 25607.49, WARNINGS FOR EXPOSURES TO GLYPHOSATE FROM CONSUMER PRODUCTS

Dear Ms. Vela:

The California Chamber of Commerce, the Consumer Brands Association and the below-listed organizations (hereinafter, "Coalition") thank you for the opportunity to submit comments regarding the Office of Environmental Health Hazard Assessment's ("OEHHA") Notice of Proposed Rulemaking: Amendments to Article 6, Clear and Reasonable Warnings, New Sections 25607.48 and 25607.49, Warnings for Exposures to Glyphosate from Consumer Products ("Proposed Rulemaking"). The Coalition consists of California-based and national organizations and businesses of varying sizes that, collectively, represent nearly every major business sector that would be directly impacted by OEHHA's Proposal.

The Coalition opposes the Proposed Rulemaking because it is inconsistent with OEHHA's long-standing approach to safe harbor warnings; it is not based in sound policy but instead is a strategic tactic in litigation; and there is no need or justification based in the reality of sale and use of glyphosate-containing products in California. For the reasons discussed below, the Proposed Rulemaking should be withdrawn.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 communicates 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. Cal. Health & Safety Code § 25249.6. 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."[1] 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."[2] Consistent with these authorities, OEHHA and its predecessor agency have always interpreted the 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. 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.

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,***

[1] 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.").

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

> ***or diminish*** the warning. Supplemental information may not be substituted for the warning required by section 25249.6 of the Act.[3]

The Coalition submitted comments and stated that the proposal "was going in the wrong direction."[4] 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."[5] 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 manufacturers from offering helpful, truthful product information to consumers.[6]

The January 16, 2015 regulatory package was ultimately withdrawn on November 27, 2015 and a new regulatory proceeding was initiated.[7] 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."[8] Again, the Coalition commented stating that the provision is "unconstitutionally vague, and potentially violates the First Amendment commercial free speech rights of affected businesses."[9] 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.[10]

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

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[3] Proposed Repeal and Adoption of New Article 6, Regulations for Clear and Reasonable Warning, dated January 6, 2015 (emphasis added).
[4] California Chamber of Commerce Coalition Comments dated April 8, 2015 at p. 5.
[5] *Id.*
[6] *Id.*
[7] 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.
[8] *See id.* at p. 12 (emphasis added).
[9] California Chamber of Commerce Coalition Comments dated January 25, 2016 at p. 5.
[10] 27 Cal. Code Regs. § 25601(e).

restriction on free speech.[11] 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."[12]

In stark contrast to its position during the safe harbor warning regulatory proceedings in 2015-16, OEHHA now proposes a safe harbor warning for glyphosate that is "engaging in the public discourse regarding listing decisions."[13] The Initial Statement of Reasons acknowledges the debate and explains:

> The warning includes information on why the chemical is considered a carcinogen (in part because it is classified as "probably carcinogenic to humans by IARC), and a statement that the level and duration of exposures affect a person's cancer risk. Each of these statements is based on purely factual information contained in the listing record for glyphosate or the supporting scientific information for the NSRL. ***The statements regarding carcinogenicity also reflect the range of opinion***, described above. USEPA and some governmental bodies found glyphosate is unlikely to be a human carcinogen, while other bodies noted the evidence of effects in epidemiology studies and certain findings from animal studies, but concluded this evidence is insufficient for assigning a cancer category.[14]

As discussed below, OEHHA's change in position is nothing more than a litigation tactic designed to require more litigation of the issue of glyphosate warnings and delay the ultimate judgment that compelled Proposition 65 warnings for this chemical, whose carcinogenicity has not been established, are unconstitutional. It is an expedient reversal of OEHHA's unwavering practice over decades and is not sound policy.

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 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. *See* 11 Cal. Code Regs. § 3202.

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[11] 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.
[12] *Id.* at p. 20.
[13] *Id.*
[14] Initial Statement of Reasons, Title 27, California Code of Regulations, Proposed Amendments to Article 6, Clear and Reasonable Warnings, New Sections 25607.48 and 25607.49, Warnings for Exposures to Glyphosate from Consumer Products dated July 23, 2021("ISOR") at p. 14 (emphasis added).

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.[15]

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."[16] 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 Proposed Rulemaking does not even acknowledge its inconsistency with the Attorney General's regulations, nor does it mention that the Proposed Rulemaking directly contradicts OEHHA's own longstanding interpretation of the warning requirement. Since OEHHA does not mention the reversal of its position and the conflict with the Attorney General's position, it cannot justify that change; similarly, it does not provide any criteria on which OEHHA will in future cases base any 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 exposures to the chemical acrylamide suggests 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.

Far from OEHHA's statement that glyphosate "is an unusual case," 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 more accurately convey the reality of scientific knowledge. For example, the extensive litigation

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[15] 11 Cal. Code Regs. § 3202(b) (emphasis added).

[16] 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). 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.

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 taken the position that an appropriate Proposition 65 warning would use the term "known to the state to cause reproductive toxicity in animals."[17] OEHHA's Regulatory Proposal, particularly when viewed in light of its more recent proposal on dietary acrylamide warnings, provides no policy basis for determining which chemicals are entitled to use language other than "known to the state to cause" or words to that effect.

II. While the Coalition Fully Supports Contextual Proposition 65 Warnings, the Proposed Rulemaking Is Not a Contextual Warning But Only Alerts Consumers to the Existence of a Controversy.

A. The Coalition Fully Supports Contextual Proposition 65 Warnings.

The Coalition has consistently supported "contextual warnings" the practice of providing supplemental, contextual information about potential exposures to listed chemicals, in order to allow consumers to make informed choices concerning those exposures. The Coalition 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:

> 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.

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."[18] The California Supreme Court, over the objection of the Attorney General, ultimately

[17] *Baxter Healthcare Corp. v. Denton*, 120 Cal. App. 4th 333 (2004).
[18] *Dowhal*, 32 Cal. 4th at 935.

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.[19]

Despite the California 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).[20]

B. The Proposed Warning Is Not a Contextual Warning But Simply Alerts Consumers to the Existence of a Controversy.

The Proposed Rulemaking 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. OEHHA itself tacitly acknowledges this issue in the ISOR, stating: "The standard Proposition 65 safe harbor warning language – which includes the phrase 'known to cause cancer' – is not the best fit for the situation."[21]

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 and therefore whether a Proposition 65 warning is necessary or appropriate in the first place. No amount of context can cure the fundamental issue that a Proposition 65 warning is not appropriate in this "unusual case."

OEHHA claims that "[t]he warning is intended to provide ***balanced and understandable information*** to individuals who may be exposed to glyphosate at levels requiring warning."[22] But

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[19] *Id.*
[20] California Chamber of Commerce Coalition Comments dated January 25, 2016 at p. 6.
[21] ISOR at p. 6.
[22] ISOR at p. 4 (emphasis added).

it is unreasonable to expect ordinary consumers to review the science and come to their own conclusion as to whether a chemical is appropriately considered a carcinogen or not. A warning that contains statements about which agencies arrived at one of two conflicting conclusions serves only to confuse the consumer. It asks the consumer, lacking in scientific expertise (as well as time and resources), to choose which agency/authoritative body they choose to believe.[23]

This undermines both the scientific enterprise and the legitimacy of safety warnings and turns the product label into a forum for deciding which agency/authoritative body the consumer believes and which the consumer does not believe, as if the decision were one of credibility, popularity, or politics, rather than science. 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. 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. The Coalition has no objection to OEHHA providing this information to consumers on its own, for example on OEHHA's website, which already houses significant information on glyphosate and links to extensive information on the websites of other agencies and authoritative bodies. But there is no policy or legal justification for California to commandeer the labels of consumer 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 is misleading and confusing and therefore at odds with the statutory mandate for a warning that is "clear and reasonable".[24]

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

It is clear from the context that the pending *Wheat Growers* 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 *Wheat Growers* appeal. The ISOR acknowledges as much stating that "OEHHA is aware of the District Court decision in the National Association of Wheat Growers case in which Plaintiffs challenged a potential Proposition 65 warning for glyphosate"[25] and that "OEHHA has developed the proposed regulation taking into account the concerns expressed in the District court decision in that case."[26]

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[23] *See* 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. 12-13 ("Consumers tend to accept negative health information from trusted sources and find it difficult to wade through competing views.").
[24] *See* Cal. Health & Safety Code § 25249.6.
[25] ISOR at p. 12.
[26] *Id.*

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 Rulemaking comes after the district court rejected three other variations of an alternative warning (like this one) as violating the First Amendment. In rejecting those three alternative warnings, the district court focused on the fact that the alternative warnings would have been considered by OEHHA and the Attorney General to be impermissible absent litigation:

> The court cannot condone the state's approach here, where it continues to argue that the warning requirement poses no First Amendment concerns and then repeatedly proposes iterations of alternative warnings that the state would never allow under normal circumstances, absent this lawsuit. Even assuming the state may continue to propose alternative warnings, as it has in this case, none of them qualify as purely factual and uncontroversial.[27]

OEHHA claims that its Proposed Rulemaking serves "[t]o facilitate glyphosate warnings in a manner that avoids the First Amendment concerns that have been raised about the standard consumer product warnings when used in the context of glyphosate."[28] If OEHHA had a genuine policy interest in creating a tailored warning for glyphosate in light of the safe harbor warning not being the "best fit" with the science, as well as First Amendment issues, OEHHA had at least four years to do so. Instead, OEHHA waited until the *Wheat Growers* appeal was poised for oral argument at the Ninth Circuit to propose a fourth alternative warning that, it is clear, "the state would never allow under normal circumstances."[29]

OEHHA published the notice of listing for glyphosate on March 27, 2017 and listed glyphosate as a carcinogen on July 7, 2017. The National Association of Wheat Growers filed suit challenging the Proposition 65 warning requirement for glyphosate on First Amendment grounds in November of 2017. On June 22, 2020, the district court found that a cancer warning compliant with Proposition 65 "is false and misleading as to glyphosate."[30] The court further found that the warning would be "misleading to the ordinary consumer" and issued a permanent injunction because the Proposition 65 warning requirement as to glyphosate violates the First Amendment.[31]

This Proposed Rulemaking is 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 explained by amici Chamber of Commerce of the United States of America and the California Chamber of Commerce in the *Wheat Growers* appeal:

> But those alternatives are no less offensive to the First Amendment. The alternatives either rephrase the same direct message – that glyphosate is known to California to cause cancer

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[27] *National Association of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247, 1262 (E.D. Cal. 2020).
[28] ISOR at p. 15.
[29] *Wheat Growers,* 468 F. Supp. 3d at 1262.
[30] *Wheat Growers,* 468 F. Supp. 3d at 1259.
[31] *Wheat Growers,* 468 F. Supp. 3d at 1259, 1265.

– or, at best, imply the same conclusion. On the contrary, it can make matters worse. *Cf. Borgner v. Florida Bd. of Dentistry*, 537 U.S. 1080, 1080 (2002) (Thomas and Ginsburg, JJ., dissenting from denial of certiorari) ("If the disclaimer creates confusion, rather than eliminating it, the only possible constitutional justification for this speech regulation is defeated.").[32]

In the ISOR, OEHHA acknowledges the ongoing scientific controversy, stating "[w]hile the lack of consensus in scientific opinions is not unusual in risk evaluation of chemicals, this is an unusual case because several regulatory agencies did not reach a similar conclusion as IARC."[33]
But, as the District court properly found in *Wheat Growers*, a Proposition 65 warning is not appropriate while there is a legitimate scientific controversy about whether a chemical causes cancer in the first place. As long as there is a scientific controversy about the carcinogenicity of glyphosate, OEHHA will not be able to craft a glyphosate safe harbor warning that is consistent with the First Amendment. This fact does not change because the Labor Code listing mechanism makes automatic the listing of chemicals that IARC determines are only "probable" or "possible" human carcinogens. Rather, the infirmities of the Labor Code listing mechanism create the opportunity for the listing of chemicals for which there is a robust scientific debate as to whether they cause cancer, which – together with the warning requirement of Proposition 65 – runs headlong into the First Amendment.

B. OEHHA Has No Basis for Its Belief Regarding How Consumers Will Understand and React to the Proposed Glyphosate Warning.

Without any basis or expertise, OEHHA makes significant unfounded claims of the purported benefits of the Proposed Rulemaking. OEHHA claims:

- "The health and welfare of California residents will likely benefit by increasing the public's ability to understand the warnings they receive for certain consumer products containing glyphosate they may choose to purchase."[34]

- "The proposed regulatory action will benefit worker safety, the state's environment, and the health and welfare of California residents by providing more meaningful information and increasing the public's understanding of the potential risk posed by exposures to glyphosate."[35]

- "OEHHA has determined that a tailored safe harbor warning for significant glyphosate exposures from consumer products can provide clear and factual and (sic) information for the benefit of those who could be exposed."[36]

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[32] Brief for Amicus Curiae Chamber of Commerce of the United States of America and the California Chamber of Commerce in Support of Plaintiffs-Appellees, filed in *National Association of Wheat Growers v. Bonta*, Ninth Circuit Court of Appeals, Case No. 20-16758 at p. 12.
[33] ISOR at p. 6.
[34] *See* https://oehha.ca.gov/proposition-65/crnr/notice-public-hearing-and-extension-comment-period-proposed-rulemaking-warnings
[35] *See* https://oehha.ca.gov/proposition-65/crnr/notice-public-hearing-and-extension-comment-period-proposed-rulemaking-warnings
[36] ISOR at p. 15.

However, despite OEHHA's expertise in numerous fields that are relevant to its mission, 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 offers no basis to determine how consumers will understand its proposed glyphosate warning or modify their behavior, if at all, in response to it. Any claimed benefit for the tailored warning for glyphosate is simply speculation. Thus, contrary to OEHHA's assertions, the agency has no grounds to conclude that the Proposed Rulemaking will increase California's health and welfare.

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."[37] 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 motivating."[38] And this is consistent with Proposition 65's requirement that warnings be "clear and reasonable."

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.[39]

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."[40]

OEHHA has not considered any of these factors in designing this proposed glyphosate warning. Indeed, 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

[37] 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.
[38] Guidance on the Application of Human Factors to Consumer Products, Division of Human Factors, U.S. Consumer Product Safety Commission (February 2020) at p. 16.
[39] 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.
[40] *Id.* at p. 6.

will react to this "nuanced" and confusing glyphosate safe harbor warning, and any potential benefit from the warning cannot be presumed.

IV. There Is No Need For This Tailored Warning.

OEHHA claims that the Proposed Rulemaking is needed because "[g]lyphosate is a registered herbicide used extensively in consumer products."[41] Contrary to OEHHA's contention, there is no need for a tailored safe harbor warning for glyphosate.

First, under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), commercial herbicides such as glyphosate must be registered with the US EPA.[42] A central focus of US EPA's registration and registration review is on the product's label. A product label "is required to bear hazard and precautionary statements for humans and domestic animals."[43] "Pesticide product labels provide critical information about how to safely and legally handle and apply pesticides."[44] A "critical function of the label is to translate the results of the science evaluations into a set of conditions, directions, precautions, and restrictions that define who may use a pesticide, as well as where, how, how much, and how often it may be used."[45]

The US EPA has mandated and specific precautionary statements which "provide the pesticide user with information regarding the toxicity, irritation, and dermal sensitization hazards associated with the use of the pesticide, in addition to medical treatment instructions and information to reduce exposure potential."[46] Although the precautionary statements do not expressly call out cancer risk, and indeed US EPA has determined that glyphosate is not likely to be carcinogenic to humans, the instructions for use that are required on these products provide clear, concise, practical directions to consumers that go far beyond the controversy warning proposed by OEHHA and instruct consumers as to how to reduce exposure to glyphosate. Indeed, pesticide labels have the force of law.[47] U.S. EPA notes that:

> Unlike most other types of product labels, pesticide labels are legally enforceable, and all of them carry the statement: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." In other words, the label is the law.[48]

Furthermore, it is quite uncertain whether the new safe harbor warning proposed by OEHHA could even be provided to consumers on the label of herbicides or otherwise in conjunction with their

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[41] ISOR at p. 5.
[42] 7 U.S.C. § 136a.
[43] 40 C.F.R. § 156.60.
[44] EPA, Office of Pesticide Programs, Label Review Manual at 1-2.
[45] *Id.*
[46] *Id.* at 7-2.
[47] FIFRA section 12(a)(2)(G).
[48] *See* U.S. EPA, Introduction to Pesticide Labels (available at: *https://www.epa.gov/pesticide-labels/introduction-pesticide-labels#:~:text=Unlike%20most%20other%20types%20of,the%20label%20is%20the%20law.&text=pesticide%20users%20read%20and%20follow%20the%20label%20directions.*).

sale. As OEHHA well knows, U.S. EPA has informed all registrants of herbicides containing glyphosate that

> Given EPA's determination that glyphosate is "not likely to be carcinogenic to humans," EPA considers the Proposition 65 warning language based on the chemical glyphosate to constitute a false and misleading statement. As such, pesticide products bearing the Proposition 65 warning statement due to the presence of glyphosate are misbranded pursuant to section 2(q)(1)(A) of FIFRA and as such do not meet the requirements of FIFRA. . . . . Therefore, EPA will no longer approve labeling that includes the Proposition 65 warning statement for glyphosate-containing products. The warning statement must also be removed from all product labels where the only basis for the warning is glyphosate, and from any materials considered labeling under FIFRA for those products.[49]

As a result, to the extent that OEHHA intends its new proposed warning to be used on the label of or in conjunction with the sale of herbicides containing glyphosate, the Regulatory Proposal will be preempted by federal law and will not result in any warnings for these products.

Accordingly, it is simply not the case that this special warning is needed because "[g]lyphosate is a registered herbicide used extensively in consumer products." These products may be the most highly regulated of consumer products in the United States such that an additional warning – even if it were permitted under federal law, and even if it were not confusing or misleading – would not provide any marginal improvement to public health and welfare.

Second, glyphosate is not going to be used "extensively in consumer products" in the United States, including California, for much longer. Consumer residential use of glyphosate will be drastically reduced as Bayer, the maker of the most popular consumer products containing glyphosate (primarily sold under the RoundUp brand name) has announced that it "will replace its glyphosate-based products in the U.S. residential Lawn and Garden market with new formulations that rely on alternative active ingredients beginning in 2023 . . . ."[50]

Finally, as recognized by OEHHA and the Attorney General in its litigation filings, the only exposures to glyphosate that will require a Proposition 65 warning are likely to be occupational exposures because other exposures are likely to be below the No Significant Risk Level ("NSRL"). In the ISOR, OEHHA states that "[c]urrently available information indicates that exposures to glyphosate from the use of many consumer products are likely to be lower than the NSRL and therefore will not require a warning."[51] Similarly, in the *Wheat Growers* case, the Attorney General argued that no warnings would be required on food products because OEHHA established

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[49] U.S. EPA, Letter To Registrants (Aug. 7, 2019) (available at: *https://www.epa.gov/ingredients-used-pesticide-products/letter-glyphosate-registrants-california-proposition-65*).

[50] *See* Bayer Provides Update on Path to Closure of Roundup Litigation (July 29, 2021) (available at https://media.bayer.com/baynews/baynews.nsf/id/Bayer-Provides-Update-on-Path-to-Closure-of-Roundup-Litigation) (noting that the timing is "subject to a timely review by the U.S. Environmental Protection Agency (EPA) and state counterparts").

[51] ISOR at p. 7.

a NSRL for glyphosate of 1,100 micrograms per day.[52] On appeal, the Attorney General has acknowledged "to the extent warnings for glyphosate are required by statute, the evidence in the record reveals that the practical effect of the NSRL is that they are more likely to be required for occupational or other use of glyphosate-based weedkillers, not for food products."[53]

Occupational exposures to glyphosate do not require OEHHA to adopt a tailored warning for glyphosate in consumer products. Once glyphosate is no longer available in the residential market, glyphosate will be used primarily by qualified applicators, who are highly regulated. The Proposition 65 regulations define "occupational exposures" as "an exposure to any employee at his or her place of employment."[54] The federal Hazard Communication Standard ("HCS") preempts the Proposition 65 warning requirement as it applies to workplace exposures except to the extent that Proposition 65 is incorporated in the State Plan approved by the federal Occupational Safety and Health Administration ("OSHA").[55] The California HCS requires an employer to comply with the California HCS as the method to comply with Proposition 65 where the chemical exposure involved is subject to both the California HCS and Proposition 65.[56] Here, the HCS requires the availability of the SDS to workers handling glyphosate, and the SDS provides detailed health protective information for those workers. Glyphosate does not present a situation where the chemical exposure is not otherwise subject to the California HCS. In that situation, the employer can comply with Proposition 65 by providing safe harbor warnings that are consistent with consumer product or environmental exposure warnings by placing warnings on the packaging of products or posting warning signs in the workplace.[57] But that is not the situation with glyphosate and thus, there is no need for a glyphosate consumer product warning to be used for occupational exposures.

The Proposed Rulemaking is therefore addressing a set of products that (1) are already highly regulated under federal law; (2) are prevented by federal law from being sold with a Proposition 65 cancer warning for glyphosate; (3) are being phased out for general consumer use; and (4) are already covered by robust occupational warning programs. OEHHA's proposed controversy warning for glyphosate in consumer products is therefore unnecessary for any legitimate policy reason under Proposition 65. This is hardly the sort of non-issue on which OEHHA should be spending its limited resources.

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[52] *Wheat Growers*, 468 F. Supp. 3d at 1254; Opening Brief of Appellant Xavier Becerra, Attorney General of the State of California, filed in Association *of Wheat Growers v. Bonta*, Ninth Circuit Court of Appeals, Case No. 20-16758 at pp. 27-28.

[53] Opening Brief of Appellant Xavier Becerra, Attorney General of the State of California, filed in *Association of Wheat Growers v. Bonta*, Ninth Circuit Court of Appeals, Case No. 20-16758 at p. 28.

[54] 27 Cal. Code Regs. § 25600.1(k).

[55] *California Labor Federation v. California Occupational Safety & Health Standards Board*, 221 Cal. App. 3d 1547, 1552 (1990).

[56] *See* 8 Cal. Code Regs. § 5194; *see* 27 Cal. Code Regs. § 25606(a).

[57] 27 Cal. Code Regs. § 25606(b).

V. The Proposed Rulemaking Should Be Withdrawn.

In conclusion, the Coalition respectfully requests that OEHHA withdraw the Proposed Rulemaking amending Article 6 to provide for tailored warnings for glyphosate in consumer products.

Respectfully,

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On behalf of the following organizations:

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American Chemistry Council, Tim Shestek, Senior Director, State Affairs
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Carlsbad Chamber of Commerce, Bret Schanzenbach, President & CEO
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