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Ms. Monet Vela
Office of Environmental Health Hazard Assessment
P.O. Box 4010
Sacramento, CA 95812-4010

Electronic filing via: P65Public.Comments@oehha.ca.gov

Re: Comments of the American Chemistry Council on OEHHA's Clear and Reasonable Warning Regulations Proposed Repeal of Article 6 and Adoption of New Article 6

Dear Ms. Vela:

The American Chemistry Council (ACC)¹ appreciates the opportunity to submit comments² regarding the Office of Environmental Health Hazard Assessment's (OEHHA) Proposed Adoption of New Article 6 Proposition 65 Clear and Reasonable Warnings regulation (referred to as "Proposal"). ACC also joins the separate coalition comments submitted by the California Chamber of Commerce.³

In previous related rulemakings, ACC has submitted several sets of comments, including joining other coalition-filed comments. Our earlier comments, and those to which we have been a signatory, are incorporated by reference here for purposes of the administrative record.⁴

¹ The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care[®], common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is an \$801 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for fourteen percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

² OEHHA extended the comment period to January 25, 2016. See extension of Public Comment Period, Proposed Repeal of Article 6 and Adoption of New Article 6, Proposition 65 Clear and Reasonable Warnings.

³ ACC incorporates the Chamber's Coalition comments fully herein, except to the extent that if any comments may be deemed inconsistent or contradictory, ACC's comments herein shall control.

⁴ See, e.g., June 13, 2014, Comments of the American Chemistry Council on OEHHA's Pre-regulatory Proposition 65 Warning Regulation Proposal, <http://oehha.ca.gov/prop65/warnings/pdf/commentsJune2014/AmericanChemistryCouncil.pdf>; April 8, 2015, Comments of the American Chemistry Council on OEHHA's Proposed Clear and Reasonable Warning Regulation and Website Regulation, http://oehha.ca.gov/prop65/CRNR_notices/WarningWeb/pdf/comments/ACCcomsLAweb.pdf; June 12, 2014 Comments of the California Chamber of Commerce and Coalition on Prop 65 Warning Regulation, <http://oehha.ca.gov/prop65/warnings/pdf/commentsJune2014/CalChamber.pdf>; April 8, 2015, Comments of the California Chamber of Commerce and Coalition on Prop 65 Warning Regulation, http://www1.oehha.ca.gov/prop65/CRNR_notices/WarningWeb/pdf/comments/CalChamberCoalition.pdf; April 8, 2015, Coalition Comments on OEHHA's Proposed Clear and Reasonable Warning Regulation and Website Regulation, http://www1.oehha.ca.gov/prop65/CRNR_notices/WarningWeb/pdf/comments/CoalitionPropACCforothers.pdf

In our view, OEHHA has improved a number of aspects of the previous proposal to reform the warning regulations, and we appreciate the Agency’s consideration of our prior comments. However, a number of issues remain unresolved. We are deeply concerned that OEHHA’s Proposal will not meet the Agency’s goal of improving the clarity or effectiveness of statutory “warnings.” We recommend a number of fundamental changes before OEHHA proceeds further with this rulemaking. In addition to the issues raised by the Chamber’s Coalition comments, we have four continuing and unaddressed concerns: (1) the proposed regulatory requirement to include any particular chemical in a safe harbor warning; (2) the proposed limitations on a manufacturer’s right to include information, outside the actual safe harbor warning, that adds properly substantiated, truthful, and accurate information, including contextual product benefit and risk information that helps inform consumers with product selections; (3) the proposed requirement to include an inappropriate “danger/warning/caution” style pictogram in a safe harbor warning; and (4) continued inappropriate designation of specified chemicals for inclusion in particular safe harbor warnings.

In addition, ACC commissioned a critical review by Evolving Studies, LLC, experts in delivering effective messaging, of the methodology of a UC Davis study related to OEHHA’s warning proposal.⁵ The review concludes that the study methodology employed by OEHHA is irreparably flawed and therefore cannot be relied upon to support any conclusion about the function, meaning, or efficacy of either the current Proposition 65 safe harbor warnings or proposed changes to the safe harbor warning.

In short, we see no benefit to the Proposal to modify the existing safe harbor warning language; rather, the Proposal would likely introduce more consumer confusion, more uncertainty for business, and more private enforcement actions.

I. The Chemical Specification Requirement (Single Chemical Requirement) Should be Removed.

ACC has previously commented at length about the problems and disadvantages with requiring safe harbor warnings to include the names of designated chemicals. We recognize that some have argued that including the names of listed chemicals on warnings provides useful information to consumers. However, as discussion has unfolded in the regulatory development process, it has become eminently clear that there is a serious and substantial tension between the poles of two approaches: a “no chemical name approach” embodied in the current safe harbor language, versus a “list every chemical” approach.

Many in the business community have argued powerfully (and early) that listing every Prop 65 chemical on a label is unworkable; would make labels too long and unwieldy; and would increase the risk of litigation for a variety of reasons. With that in mind, OEHHA has not proposed that every listed chemical to which a consumer might be exposed needs to be included in a warning. Nevertheless, apparently wedded to the notion that the presence of chemical names in a warning would somehow improve what the consumer understands the warning to mean,⁶ OEHHA twice has sought to “split the baby” in its recent regulatory proposals: first with a “list of 12” proposal (that was subsequently withdrawn), and now with a “single chemical” proposal. Specifically, Proposed Section 25601(c) states:

⁵ Alexander J. Oliver, MA, Adam B. Schaeffer, PhD, Evolving Studies LLC, *An Assessment of “Proposition 65 Clear and Reasonable Warning Regulations Study*, January 14, 2016, attached and incorporated into these comments by reference.

⁶ OEHHA’s mere assertion or belief that inclusion of a chemical in a warning will improve the content of a warning, or better inform consumer choice, or improve public health, does not constitute substantial evidence or for that matter evidence at all.

Except as provided in Section 25603(c), a warning meets the requirements of this article if the name of one or more of the listed chemicals for which the warning is being provided is included in the text of the warning, to the extent that an exposure to that chemical or chemicals is at a level that requires a warning.

This provision has the virtue of avoiding an unwieldy list of chemicals on the warning. And, to the extent that this “single chemical” Proposal allows the manufacturer discretion to select the chemical to be added to a warning label, we believe this aspect of the Proposal to be an improvement over the “list of 12” proposal. Nonetheless, the “single chemical” Proposal is problematic for several reasons discussed below and we urge OEHHA to return to the existing “no chemical name” approach for safe harbor warnings in the current regulation.

A. The Single Chemical Proposal is an Illegal Burden Shift.

Under Section 25603 of the Proposal, OEHHA would require consumer product safe harbor warnings⁷ to include the name of one or more chemicals: “all warnings must include the name of one or more of the listed chemicals for which a warning is being provided.” This Section appears to mean that, for a product containing several Proposition 65 listed chemicals, a business may choose which chemical(s) it references in the warning, with no restriction on how that selection is made.⁸ However, proposed Section 25601(c) goes on to say that “. . . a warning meets the requirements of this article if the name of one or more of the listed chemicals for which a warning is being provided is included in the text of the warning, to the extent that an exposure to that chemical or chemicals is at a level that requires a warning.” [Emphasis added]. In other words, this clause suggests that there must be actual exposure to the chemical selected for the warning, and that exposure must be at a level not exempt from the warning under Section 25249.10.

The Initial Statement of Reasons (ISOR) does not reconcile these two provisions. Although the ISOR tracks the language of Section 25603 and says “all warnings must include the name of one or more of the listed chemicals for which a warning is being provided” it sheds no light on what “to the extent that an exposure to the chemical or chemicals is at a level that requires a warning” as described in 25601(c) is intended to mean, with respect to the regulated party’s obligations.⁹

This Proposal undermines the core compliance mandate of the statute – and illegally shifts burdens to defendant businesses – in two ways. First, OEHHA would apparently shift the burden to businesses to pre-determine whether there will be an exposure to a particular listed chemical at a level requiring warning from a consumer product (or in a facility) in order to avail themselves of the safe harbor warning. This is inappropriate and inconsistent with the statute. The statutory scheme is designed to encourage warnings. Delivery of a statutorily compliant warning, or elimination of a listed chemical from a consumer product, are the avenues of greatest certainty for businesses wishing to assure compliance with the statute and wishing to avoid enforcement. The statute does not impose a burden on a business to pre-determine that there will be an exposure to a listed substance before offering an exposure warning. The single chemical Proposal undermines the operation of the statute’s fundamental mandate (to offer a warning prior to exposure to a carcinogen/reproductive toxicant) and fundamental compliance mechanism (to have offered a warning prior to exposure to a carcinogen/reproductive toxicant).

⁷ Unless the “short form” warning is used. The UC Davis study, as we note separately, likewise fails.

⁸ OEHHA’s staff presentation from the January 13, 2016 public hearing says “[b]usiness has discretion to select which chemicals to include in warning.” More ambiguously, it then says “[n]amed chemical(s) must be one(s) for which warning is being provided.” http://oehha.ca.gov/prop65/CRNR_notices/WarningWeb/pdf/Jan132016/WarningWebPresentation

⁹ ISOR at 23.

For that matter, the single chemical Proposal operates as an illegal burden shift in enforcement actions. In an enforcement action, the enforcer bears the burden of demonstrating that there is exposure to a listed chemical. The burden then shifts to the defendant business, which could either attempt to rebut the enforcer's proof (e.g., by demonstrating that the test method used to establish exposure was improper or yielded a false positive), or the defendant business could assert as an affirmative defense the statutory exception under 25249.10 that a warning was not required based on the level of exposure presenting no significant risk. In short, the initial burden of demonstrating that there is an exposure belongs to the enforcer, not the business. A business does not need to determine that exposure to a Proposition 65 chemical present in a product or at a facility exceeds the exemption level of 25249.10(c) in order to make a statutorily compliant warning.

Second, the language in 21605(c) – “to the extent that an exposure to that chemical or chemicals is at a level that requires a warning” serves to create an illegal burden shift to businesses to pre-determine not just that an exposure will occur, but what the level (amount) of exposure will be AND that the level of exposure is above the statutory significant risk level. This is plainly inconsistent with the statute. There is no prima facie obligation for a business to demonstrate level of exposure and risk in order to be able to make a statutorily compliant safe harbor warning. There is no mandate at all that a business do this. The right to show the amount of exposure and whether that exposure presents a risk is reserved to a defendant business as an exemption to the warning requirement, which in an enforcement action is asserted as an affirmative defense. In other words, if a business chooses to offer the Section 25249.6 warning, it does not need to determine or communicate the amount of exposure or whether that exposure presents a risk.

If OEHHA wants to discourage the default use of safe harbor warnings where there is no significant risk, it has the power to aid its own cause. OEHHA could much more aggressively set 25249.10 safe harbor levels – No Significant Risk Levels and Maximum Allowable Dose Levels – as well as expediently act on and issue Safe Use Determinations – as quickly as possible after a chemical listing and certainly well before (e.g., at least six months before) enforcement actions may begin.¹⁰ While such actions by the agency do not and cannot solve the fundamental statutory problems that lead to warning where there is no significant health risk – including but not limited to a non-risk based platform, inappropriate burdens of proof and abusive private enforcement – they would help businesses that want to make exposure and risk determinations and assert the 25249.10 exemption.

B. The Single Chemical Proposal is Not Clear with Respect to How a Single Chemical is Selected and by Whom.

While we strongly disagree with the single chemical Proposal and encourage OEHHA to withdraw it in full and maintain the language in the current safe harbor warning, we note that to the extent any particular chemical name is required in a warning label it is essential that OEHHA be as clear as possible about

¹⁰ A check of OEHHA's Proposition 65 list reveals that less than half of the listed chemicals have regulatory safe harbors – whether NSRLs or MADLs – in place. Proposition 65 Clearinghouse notes: “Of the over 800 substances that are on the list of chemicals known to cause cancer, birth defects or other reproductive harm, OEHHA has developed threshold levels for about 300 of the chemicals to guide businesses in determining whether a warning is necessary or whether discharges of a chemical into drinking water source are prohibited.” <http://www.prop65clearinghouse.com/prop-65-plain-english.html> The agency has issued only a handful of safe use determinations, despite the observation from a legal practitioner that “[n]evertheless, for those handful of products having received SUDs, virtually no enforcement actions have been threatened.” <http://grimaldilawoffices.com/flurry-proposition-65-activity-dinp/>

what is required and who in the supply chain has primary responsibility for making the chemical selection. First, the regulations should be clear that the product manufacturer has primary responsibility – and full discretion – to select any chemical contained in the product for a product label. It would make little sense for others in the supply chain to then modify the warning with different chemicals, or to add chemicals; this would merely invite confusion and frivolous enforcement actions. Likewise, it must be clear that the manufacturer has full discretion to make the chemical choice, and this choice cannot be challenged by private enforcers because they would have preferred a different chemical be named. It should be clear that it is adequate to use the same chemical name on the Proposition 65 list itself; in other words, if the name “matches” the name on the list, that is adequate.¹¹ Where a category is listed, such as “anabolic steroids,” the regulation should make clear that it is adequate to note the name on the Proposition 65 list (e.g., “anabolic steroids”) or the specific chemical name at issue (e.g., a specific steroidal compound by chemical name). Equivalencies should also be deemed acceptable (e.g., steroids (anabolic)). We suggest that examples and illustrations would be helpful here.

OEHHA should also caution about the inappropriate use of “chemical groupings” that introduces inaccuracies. Where the name of a listed substance is, for example, is ethyl-methyl-oxylate,¹² for example, that should be required; common abbreviations, family names, and acronyms should be disallowed. This is extremely important for accuracy and to avoid confusing similarly named substances. It is often the case that one chemical in a chemical family is listed on Proposition 65, but others are not.

This problem is illustrated by the safe harbor warnings proposed in Sections 25607.17 and 25607.19, which provide that operating, servicing and maintaining a covered vehicle “can expose you to chemicals such as, engine exhaust, carbon monoxide, phthalates and lead, that are known to the State of California to cause cancer and birth defects or other reproductive harm.” OEHHA inappropriately and arbitrarily proposes to group phthalate esters into one catch-all category called “phthalates.” There are at least eighteen commercial phthalate esters, only six of which are included on the Proposition 65 list. These substances are 1,2-benzenedicarboxylic acids, with side chain esters ranging in carbon chain length from C1 to C13.

Phthalate esters can be further described by three subcategories based on their physicochemical and toxicological properties: low molecular weight phthalates, transitional phthalates, and high molecular weight phthalates. On the Proposition 65 list, some phthalate esters are listed for carcinogenicity, some for reproductive toxicity, others for both health endpoints.

Even more important, the majority of phthalate esters are not on the Proposition 65 list. This means that a generic reference to “phthalates” on a Proposition 65 label delivers fundamentally incorrect information about the consumer product affected but also confuses consumers about the class of chemistry. To use another example, it would not be appropriate to allow manufacturers to claim that a particular product contained “solvents” or in lieu of naming specific chemicals – the functional description “solvents” sweeps across many categories of chemistry and even includes water.

We recognize that court settlements, in the past, may have resulted in inappropriate chemical “groupings” being deemed acceptable for safe harbor warnings. We further recognize that many stakeholders have requested “grandfathering” of settlement-based safe harbor language. That said, if OEHHA must reference such language derived from a settlement in the regulations, we urge OEHHA to include an

¹¹ For that matter, any state-run website purporting to offer additional information about a Proposition 65 chemical would also need to reference the listed chemical by name specifically.

¹² This is a hypothetical chemical used for illustrative purposes only.

explanation why such approaches are inappropriate, offer an example, and caution that OEHHA will not consider such approaches acceptable.

C. Inclusion of a Single Chemical is Not Supported by the UC Davis Study.

As an initial note, many conclusions cannot be drawn from the UC Davis study because the researchers were not charged to, and did not, ask these and other questions that relate to how consumers actually perceived the information being offered. The study did not ask the participants the kinds of questions that would typically be asked in evaluating product warnings, information, and instructions, such as:

- What do you interpret this information to mean about this product?
- What are you being warned of?
- Do you interpret this to be a warning about something to be avoided, or important information, or useful information, or something else?
- What does this information say about whether this product is safe to use?
- What information is conveyed about safe use or handling instructions?
- What information is being conveyed about whether this product meets or exceeds safety standards or regulations?
- This information is being conveyed to you before you purchase a product or enter a facility. Do you have enough information to be able to make an informed choice about whether to purchase or use the product, consume the food, or enter the facility?
- You responded that the chemical specific information made the sign more “helpful.” What do you understand your risk to be of getting cancer/birth defects if you use/consume the product/enter the facility?
- You responded that the chemical specific information helps you to “make an informed choice.” How does it help you make an informed choice? Based on the information provided, what would your choice be?
- Would that decision change if the manufacturer offered additional information to confirm that the product meets all federal and state safety standards?
- How serious is this “warning?” What is the nature of the harm warned of? What is the risk that the harm will happen if the product is used or consumed? How imminent is the harm warned of (could it occur now, a decade, 5 decades from now)?

In short, the study did not ask, and thus cannot answer, what information the study participants understood was being communicated to them (e.g., what were they being warned of). It essentially limited itself to asking a generic question of which warning was more “helpful” without probing the content of what was being communicated in the first place. It failed to ask questions about what the subjects would do with the information and how they would act on it (e.g., would they use the product or consume the food). And it failed to test the warning language in actual uses – on products, foods, and facility entrances – severely if not entirely limiting the utility of study findings.¹³

This initial critique of the UC Davis study is based on the parameters of the study design itself – most notably, substantive flaws in the charge questions and questions asked of the participants. ACC separately commissioned an expert review of the UC Davis study also to examine the procedural, methodological, design, and execution elements of the study so we could better understand and discuss study conclusions. Key results of the study are noted separately in Section IV below.

¹³ See Attachment A at 8-11.

II. The Supplemental Information Section Should Allow Manufacturers to Communicate Legally Accurate, Supplemental Information.

OEHHA’s proposed section 25600(d), which notes that “supplemental information may not contradict the warning,” illegally restricts manufacturers from communicating truthful, accurate information about their products and, at the same time, seeks to step improperly in their shoes and offer this information generically on its own agency website.

Aside from presenting serious First Amendment¹⁴ questions, it is counterproductive to public health and undermines a consumer’s ability to make informed decisions by restricting his or her access to complete, contextual information.¹⁵ The statute itself never contemplated nor purported to restrict a manufacturer’s right to communicate accurate information about safety, risk, relative risk, risk of alternative products, product benefits, health and safety information about the complete product formulation, safe use information, warnings, and so forth. Certainly nothing in the plain language of the statute suggests that the state may, or will, restrict manufacturers from offering useful, accurate, truthful information about the content and safety of their own products.

The example of coffee illustrates this problem. Coffee contains chemicals listed on Proposition 65, including acrylamide, and is a significant target of bounty hunter suits. The complex mixture that is coffee has documented health benefits and health risks. Under proposed section 25600(d), companies arguably could not inform consumers that a Federal government scientific advisory committee concluded in February 2015 that “consistent evidence indicates that coffee consumption is associated with reduced risk of type 2 diabetes and cardiovascular disease in adults” and “moderate evidence shows a protective

¹⁴ The same First Amendment questions that have been raised before remain. There is a serious compelled speech question whether manufacturers of safe products can be compelled to offer an inaccurate and scientifically unfounded cancer or reproductive toxicity warning. On the flip side, there is a serious question whether a state agency can place a gag order on legitimate, truthful, accurate commercial speech by prohibiting manufacturers from offering supplemental information. We also note that with respect to pure political speech, the state most assuredly has no authority to preclude manufacturers from criticizing Proposition 65, expressing their sentiment that they disagree with the law, or asking their customers to exercise their First Amendment rights to criticize the law. The example OEHHA offers at footnote 16 of the ISOR is illustrative: it contains additional technical information, risk information, and the manufacturer’s perspective on the law, all of which should be permitted under First Amendment commercial and political speech doctrines. We note further that the systematic and sustained lack of notice to the regulated community with respect to what is an adequate safe harbor warning is a mounting due process problem. It cannot be the case that the regulated community has no certainty regarding how to issue a warning that will comply with the statute such that it must be subjected to private enforcement to answer compliance questions. It would be a clear substantive due process problem for speed limits to be designated by statute as simply “reasonable” limits - with what constitutes “reasonable” to be determined by private enforcement action. Here, unless there is a very clear, very consistent, ambiguity-removed safe harbor provision, compliance and enforcement is so uncertain – and left in the hands of private enforcers to pursue – that due process is called into serious question.

¹⁵ The statute is based on outdated assumptions about the safety of consumer products and the information consumers need and want to make informed choices. It is also based on the now dated notion that the choice to be made by a consumer is whether to use a product or not use it; whether to enter a facility or not -- we now understand that consumer choice does not work that way: consumers choose between alternatives. To choose between alternative products, consumers must have information that is contextual and comparative. They must also have information that allows them to understand the benefits, risks, and uses of a product and its alternatives. A consumer deciding between coffee, tea, orange juice, soy milk, calcium enhanced milk, tap water, and bottled water at breakfast is not helped in making this choice by being offered limited information about the mere presence of listed chemicals; each of the options has chemical compositions that offer “pros” and “cons.” Each may contain a chemical or offer a health benefit a consumer specifically wants and is actively seeking. If anything, the simple act of providing a Proposition 65 warning may confuse or discourage a consumer from making the “healthiest” choice or the best choice for that particular consumer. But without question, compounding the problem by subsequently restricting a manufacturer from offering this very relevant and important supplemental information undermines the objectives of public health and informed consumer choice.

association between caffeine intake and risk of Parkinson’s disease.”¹⁶ This information is truthful and substantiated and could allow consumers to make better informed decisions.

We suggest that a compliant safe harbor warning should be deemed complete – and discharged – when the elements that OEHHA set out, e.g., font size, specific text – are met. If the presentation of the warning label itself (the warning “box,” in other words) meets these elements; if the warning meets the requirements for method of delivery and content, it should be clear that enforcers cannot challenge the clarity or reasonableness of the warning by pointing to accurate supplemental information they claim dilutes the warning.

As a practical matter, there is no real need for this restriction; laws already exist to discourage consumer product manufacturers from downplaying real health risks that their products may present (or inflating health benefits, or making improperly substantiated health benefit claims). Advertising and marketing claims and communications about consumer products already must comply with California’s Business and Professions Code Sections 17200-17210, as well as Federal Trade Commission Act Section 5 – marketing claims about health and safety must be properly substantiated and truthful, and deceptive claims are prohibited.¹⁷ Furthermore, a strong tort and warranty system in the U.S. creates a significant firewall as well; there is potential legal accountability for manufacturers that make unfounded safety claims about their products or fail to appropriately warn about a substantial health risk.

We encourage OEHHA to clarify that as long as the requirements are met for the Proposition 65 warning itself – i.e., the safe harbor information presented in the warning label or “box” -- a manufacturer is not precluded from adding any other accurate and substantiated information it chooses, consistent with existing laws. We recommend including this clarification; outright removal of the discussion may lead some private enforcers to seek to litigate the legitimacy of the safe harbor warning where supplemental information has been offered, so we believe a clear statement from OEHHA that such supplemental information does not invalidate an otherwise compliant safe harbor warning is in order.

III. The Pictogram Proposal Should Be Removed.

Proposed Section 25603(a)(1) would now require Proposition 65 warnings to include an American National Standards Institute (ANSI) symbol consisting of a black exclamation point in a yellow equilateral triangle with a bold black outline. There is no need for this addition to the safe harbor warning. We believe that the inclusion of this symbol, which magnifies the problem of “warning” where no warning at all may be justified, triples down on the First Amendment compelled speech problem: it makes manufacturers offer a warning with the word “warning,” which then has to be offered in all caps, which then has to be highlighted further with a visual warning pictogram. If a warning was not needed in the first place, we now have unnecessary warning happening in triplicate. OEHHA’s UC Davis study supports this conclusion: over 50% of the study group interpreted the pictogram as meaning “warning” and a shocking 30% thought it meant “danger.”¹⁸ For that reason alone, we urge OEHHA to consider that

¹⁶ Scientific Report of the 2015 Dietary Guidelines Advisory Committee, Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture (Feb. 2015). Available at <http://health.gov/dietaryguidelines/2015-scientific-report/>.

¹⁷ “The basic consumer protection statute enforced by the Commission is Section 5(a) of the FTC Act, which provides that “unfair or deceptive acts or practices in or affecting commerce...are...declared unlawful.” (15 U.S.C. Sec. 45(a)(1)),” www.ftc.gov/about-ftc/what-we-do/enforcement-authority

¹⁸ UC Davis Extension, Proposition 65 Clear and Reasonable Warning Regulations Study, Survey Results Assessing the Effectiveness of Existing and Proposed Proposition 65 Warnings, October 27, 2015. We note, however, that the UC Davis study is seriously flawed, and should not be relied upon as reliable or quality evidence to support any conclusion. If it were to be relied upon, this finding alone would suggest the inappropriateness of using this pictogram. Experts note that standards have

providing consumer notice in accordance with the statute does not require either the use of the word “warning” or any accompanying warning pictogram.

Importantly, OEHHA’s commissioned study through UC Davis did not test Proposition 65 warnings on actual consumer products or at facilities to see if people had any difficulty, in real world conditions, noticing the warning or whether the addition of the pictogram helped them notice what they did not notice before.¹⁹ Without this baseline work, OEHHA assumes a problem (that people are not noticing Proposition 65 warnings or do not understand the statutory information being conveyed) but has not even slight, let alone substantial, evidence that the problem exists. There is no basis for concluding that people are not noticing or processing Proposition 65 notices in real world conditions, or understanding the information being conveyed.²⁰

As we noted in our prior comments, this particular symbol is particularly ill advised. The symbol is in wide use in cars, on electronics, and other applications. Further, it is being deployed nationally by the food industry to signify allergens as part of the Grocery Manufacturers Associations’ new SmartLabel™ program – raising the distinct possibility that a food product might bear the same pictogram twice with completely different meanings.²¹ When used in accordance with the ANSI standard itself, as the Chamber notes, it is “clearly intended for potential accident situations where death or a serious potential injury is possible.” More accurately, it is intended where the danger being warned of is imminent – notably, acute (short term) hazard rather than chronic (long term) hazard.

Other commentators have previously suggested that OEHHA consider a “P65” designation or logo. While we believe this is neither needed nor required, such an approach would be an improvement over the current “ANSI” pictogram Proposal. It would signify that the information to follow is specific to the Proposition 65 program without misusing a logo.

IV. Requirements to List Specific Chemicals for Certain Products/Exposures Should Be Removed.

In addition to the warning requirements for consumer products and environmental exposures in general, the Proposal dictates safe harbor warning requirements for a number of specific products and area exposures. In most cases, the warning content follows the format of the consumer product warning, requiring inclusion of the name of one or more chemicals, but with those chemicals unspecified by the regulation. In some cases, the types of activities that can cause exposure are listed, but without naming specific chemicals. For several of these specific provisions, however, specific chemicals are listed by the regulations to be included in the safe harbor warning. If OEHHA does not revert to the current safe harbor

established a continuum of warnings – danger/warning/caution/notice – “based on a respective decreasing degree of hazard.” See Drake, Conzola, and Wogalter, Discrimination among Sign and Label Warning Signal Words, *Human Factors and Ergonomics in Manufacturing*, (1998) at 289. As the authors note, “danger” is perceived to have a greater connoted hazard than “warning.” If the UC Davis results were to be reliable, the huge number of participants who misinterpreted the pictogram as meaning “danger” would be sufficient to disqualify use of this pictogram as inconsistent with the statutory “warning” language.

¹⁹ See Attachment A at 8-11.

²⁰ The statute does not require (and OEHHA cannot under this statute force) manufacturers to offer the exposure and risk information that would, at least, help make the “notification” being offered more meaningful and less misleading. On the other hand, with its proposed restriction on supplemental information, OEHHA would tie the hands of manufacturers wishing to offer such information. Because the use of the safe harbor warning is the most certain way to avoid private enforcement, this virtually assures that some businesses will choose to “warn” where the risk of the noted health endpoint does not justify a warning at all. This feedback loop assures that meaningless “warnings” will continue to be made under this statute.

²¹ See illustration at Progressive Grocer, December 2, 2015, at <http://www.progressivegrocer.com/industry-news-trends/cpgs-trading-partners/gma-unveils-smartlabel-initiative?nopaging=1>

warning language, as we believe would be appropriate, then it should amend these specific product/area exposure provisions to give the obligated party discretion over which chemical or chemicals to include in the warning. This would be consistent with Proposed Section 26301, which provides that “a warning meets the requirements of this article if the name of one or more of the listed chemicals for which the warning is being provided is included in the text of the warning” (emphasis added).

OEHHA’s previous proposal would have required specific listing of 12 chemicals. Our previous comments explained in depth that creation of such a “superlist” was inappropriate and unauthorized by the statute.²² While we applaud OEHHA for eliminating the “list of 12” approach from the current Proposal, remnants of the mindset behind that list linger in some of the facility/industry-specific provisions in the current Proposal, and should be removed for the same reasons we previously articulated for the list of 12 needed to be removed.

For example, Proposed Section 25607.17, Vehicle Exposure Warnings – Content, gives the following safe harbor language:

*WARNING: Operating, servicing and maintaining a passenger vehicle or off-road vehicle can expose you to chemicals such as, **engine exhaust, carbon monoxide, phthalates and lead**, that are known to the State of California to cause cancer and birth defects or other reproductive harm. To minimize exposure, avoid breathing exhaust, service your vehicle in a well-ventilated area and wear gloves or wash your hands frequently when servicing your vehicle. For more information go to [www.P65Warnings.ca.gov/passenger vehicle](http://www.P65Warnings.ca.gov/passenger_vehicle).*

First, it is not a given that there will be exposures to all of engine exhaust, carbon monoxide, phthalates and lead. Second, even if there are such exposures, it is not a given that they will be at a level greater than the level below which no warning is required. Third, a list like this is a new “superlist.” In this case it is a list of only four Proposition 65 substances, rather than 12. This can serve only to more greatly, and inappropriately, focus attention on these particular chemicals as being “worse” than all the other Proposition 65 chemicals. Further, other Proposition 65 chemicals may be present, but the specific list of the regulatory language may well mislead exposed individuals into believing that need be concerned only with those four specific chemicals.

There is no support given for listing these specific chemicals in the ISOR. It states only, “The content for the warning message was developed based on discussions with industry stakeholders and a review of the warning language currently in use.”²³ That sentence does not even indicate that these four specific chemicals were brought up by industry stakeholders or are included in current warning language. It certainly provides no evidence that all those chemicals are present for all vehicles, that they are present at levels that would require warning, and that there are no other Proposition 65 chemicals likely to be present at levels with equal or greater risk for exposed persons.

The language quoted above and that for the following Proposed Section 25607.19, Recreational Vessel Exposure Warnings – Content, is particularly egregious because of the inclusion of the term “phthalates.” As explained above, Section I.B., this term is overinclusive and misleading, because only six of the multitude of phthalate esters are on the Proposition 65 list. Further, not all of those phthalate esters are likely to be present in any given vehicle, if indeed any are.

²² ACC comments, April 8, 2015, section II.

²³ ISOR at 49.

For these reasons, and all those stated before with regard to the list of 12, no specific chemicals should be designated for any particular product or area of exposure. Rather, if any chemical(s) must be named, the choice of which chemicals should be in the discretion of the warning party, as per Proposed Section 26301.

V. Expert Review Reveals that The UC Davis Study Cannot Be Relied Upon to Support the Proposal.

In response to the previous regulatory proposal, ACC commented that OEHHA had failed to test consumer perception of the proposed warning labels.²⁴ For the revised regulatory proposal, “OEHHA contracted with the UC Davis Extension Collaboration Center to conduct a study to better assess the effectiveness of the existing and proposed new warnings.”²⁵ The study, however, does not demonstrate that the proposed changes would “improve” the statutorily required warning to make them either more “clear” or more “reasonable” (notably, the statute does not require that warnings be “effective” -- just clear and reasonable). The study does not support OEHHA’s regulatory proposal due to the flawed charge instructions and design of the survey itself; an unrepresentative survey sample; improper survey instrument design; and flawed execution of the survey.²⁶ These shortcomings are described more fully in Attachment A; we highlight several key points here.

According to OEHHA, “[t]he purpose of the study was to assess whether the existing or proposed safe harbor warnings more clearly communicate that the chemical in question is known to the State of California to cause cancer, birth defects or other reproductive harm.”²⁷ The stated purpose, then, is misplaced, because the statute does not require that the “chemical in question” be identified in the warning in order to satisfy the statutory elements of a warning.²⁸ The statute only requires that the communicated “warning” be clear and reasonable; the statute does not require or speak to whether the communicated “warning” delivers perceived “helpful” information. OEHHA claims that “[t]he results showed that over 75 percent of the participants selected the warnings based on the proposed regulations as being more “helpful” than the existing regulations.”²⁹ (emphasis added). But the researchers did not probe what the respondents intended “more helpful” to mean; or how the “more helpful” response connected with the warning being “more clear” or “more reasonable,” and in particular, whether they better understood (because the warning was “more clear” or “more reasonable” any of the statutory elements of the warning offered.³⁰ Another way to say this: had OEHHA included a URL on an option to get a free ice cream cone, the participants might very well have said they liked that option “better;” had OEHHA shown an option to the survey participants in rainbow colors, the participants may very well have said it made them “feel better,” and had OEHHA included an option with a full page of assembly

²⁴ ACC comments, April 8, 2015.

²⁵ ISOR at 9.

²⁶ See Attachment A.

²⁷ ISOR at 9.

²⁸ The statute has never been interpreted to mean that “clear and reasonable warning” requires the specific identification of the chemical at issue. (On the other hand, many courts have approved agreed warning language attendant to settlements in which the defendant agreed to name a particular chemical, but that is another matter). If, of course, that is what the statute actually were to mean, it would necessitate including the name of every Proposition 65 listed chemical in the “warning.”

²⁹ ISOR at 9.

³⁰ If the sole purpose of this study was to determine whether the respondents could better identify the chemical “at issue” when the warning named a chemical, this design remains horribly flawed because it assumes – improperly – that merely identifying a chemical at issue improves a warning or makes it more effective, has any salutary effect on public health, or assists consumers with consumer choice. As we noted above, it would have been essential to any study design testing product, food, or facility warnings to test the warning as deployed on the product, food, or facility, which was not done. A properly done study would likely have revealed that a statutorily compliant Prop 65 warning with no chemical name is no better than with a specific name (and that both warnings are ineffective and meaningless).

instructions for a product, participants may have said the option was more “helpful.” None of this is relevant unless it answers the question, “more helpful to what,” and the “to what” needs to be tied to the statutorily required elements of the Proposition 65 warning. The UC Davis study did not do this.

Further, the results cannot be used to support any conclusions about public opinion in California because the population sampled is biased and unrepresentative. The researchers did not survey a representative sample of California citizens. Instead, they surveyed only those people present at one of 19 Department of Motor Vehicle (DMV) locations, an already unrepresentative population. Moreover, the DMV locations chosen over represent or underrepresent distant regions of the state.³¹

In addition, the design and delivery of the survey instrument biased the results. The survey used live interviews, which allowed the researchers to communicate to respondents the results they expected to receive and likely resulted in inconsistent administration.³² The survey also included a number of questions that influenced respondents to give certain answers to other questions, especially by including justifications for the proposed warnings in questions about their “helpfulness.”³³ Moreover, several of the questions contained biased wording or provided biased response options, particularly in questions concerning the proposed warning symbol.³⁴

The survey was long and repetitive, which may have led to respondent fatigue. This fatigue also renders the data unreliable.³⁵

The UC Davis study also asked respondents to self-predict how they would respond to the inclusion of a URL, even though social science research has established the difficulties of predicting future behavior with poll questions of this type. Interest in future behavior (e.g., researching for more information, going to a URL) should have been gauged with a different study design that monitored actual behavior.

Finally, we note that OEHHA is now pursuing the development of a website with supplemental information on Prop 65 chemicals in a separate rulemaking. OEHHA’s study, however, was not performed in time to inform or be incorporated into the “website” rulemaking. OEHHA should reopen the website docket and include its UC Davis study, and allow further comment, if it intends to rely on the UC Davis study as part of its evidentiary basis for the website rulemaking.

³¹ See Attachment A at 2-4.

³² Id. at 4-5.

³³ Id. at 5-6.

³⁴ Id. at 6-8.

³⁵ Id. at 9.

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ACC appreciates OEHHA’s consideration of our comments and would welcome working with the Agency on any issues raised here. Should you have questions, please feel free to contact me or Karyn Schmidt, Senior Director, Regulatory & Technical Affairs, 202-249-6130, or Tim Shestek, Senior Director, State Affairs.

Respectfully submitted,

A handwritten signature in black ink that reads "Michael P. Walls". The signature is written in a cursive style and is centered on a light blue rectangular background.

Michael P. Walls
Vice President
Regulatory & Technical Affairs

Attachment A (pdf): Alexander J. Oliver, MA, Adam B. Schaeffer, PhD, Evolving Studies LLC, *An Assessment of “Proposition 65 Clear and Reasonable Warning Regulations Study*, January 14, 2016.

All other attachments public record/OEHHA dockets (URLs provided).