



April 8, 2015

Ms. Monet Vela  
Office of Environmental Health Hazard Assessment  
P. O. Box 4010  
1001 I Street  
Sacramento, California 95812-4010

via email to [P65Public.Comments@oehha.ca.gov](mailto:P65Public.Comments@oehha.ca.gov)

Re: Comments of the American Chemistry Council on OEHHA's Proposed  
Clear and Reasonable Warning Regulation and Website Regulation

Dear Ms. Vela:

The American Chemistry Council (ACC)<sup>1</sup> appreciates the opportunity to comment on the Office of Environmental Health Hazard Assessment's proposal to amend the Proposition 65 warning regulations and the proposal for an affiliated website. Several of the changes OEHHA has made since the release of the pre-regulatory draft are encouraging; namely, the elimination of the requirement to include the Globally Harmonized System of Classification and Labeling of Chemicals Health Hazard pictogram and changing the language for the safe harbor warning from "will expose" to "can expose."

The proposed regulations, however, continue to retain problems such that they will not achieve any of their stated objectives. They will likely make many of the current problems with Proposition 65 worse: the proposed regulations will encourage more abusive bounty hunter suits, rather than reduce litigation; the proposal will generate more consumer confusion, not less. We appreciate that OEHHA would like to achieve more effective Proposition 65 warnings, but we believe that a number of features integral to the text of the statute preclude achieving this objective with the proposed regulations. We therefore urge OEHHA to withdraw the regulatory proposal in full. If the regulation is to move forward despite our recommendation, it is essential that both the "List of 12" proposal and the website proposal be removed. Our specific comments follow.

---

<sup>1</sup> 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<sup>®</sup>, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is an \$812 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for twelve 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.

## **I. Proposed Section 25601 Should Be Changed to Clarify that the Proposed Safe Harbor Provisions Are Optional, Rather than Mandatory.**

The safe harbor regulations provide warning language that OEHHA deems to comply with the statute's "clear and reasonable" requirement. The proposed rule goes on to state that regulated parties are not precluded "from providing a warning using content or methods other than those specified in this article that nevertheless complies with Section 25249.6 of this Act." OEHHA thus takes the view that the warnings outlined in Article 6, Sub article 2 of the proposed regulations supposedly are not mandatory.

But the Initial Statement of Reasons (ISOR) describes the proposed warning regulations in a manner that indicates that the safe-harbor provisions are not optional, but rather prescribe a mandatory floor that all warnings must meet. Specifically, OEHHA states that the safe harbor proposal "provides more clarity to the warning requirements and more specificity regarding the minimum elements for providing a "clear and reasonable warning." A proposed regulation that is somewhere described as optional and elsewhere described as having the "minimum elements" for a warning cannot stand. There is no rational, non-arbitrary basis for promulgating a regulation which is simultaneously characterized as optional and as a minimum requirement.

Assuming that OEHHA really intends the proposed regulations, including proposed Section 25602 (listing of specific chemicals discussed below), to be a mere safe harbor, this does not give OEHHA a free hand when it promulgates regulations. The regulations must be supported (including an evaluation of economic impact), cannot be misleading, must comply with the underlying statute, and must not violate other statutes or, as here, violate the protections afforded by the U.S. Constitution.

## **II. Proposed Section 25602 "Chemicals Included in the Text of a Warning" Should Be Eliminated.**

We are deeply concerned about the identification of 12 chemical/chemical "categories" (hereinafter referred to as the "List of 12," "superlist," or "hyperlist") which OEHHA proposes be specifically included in relevant warnings. This proposal is fundamentally flawed and must be removed. There is no statutory authority to create what, in effect, will function as a "superlist." The proposal will increase litigation; instill additional consumer confusion about relative hazard and product safety; and increase cost and compliance burdens on the regulated community.

### **II.A. The Statute Itself Offers No Authority to Differentiate Certain Chemicals as "Worse" than Others.**

The statute does not require that notice be provided of the presence of a specific chemical. It could have been drafted that way, but was not. The regulations cannot create a new obligation that does not exist in the statute itself. The List of 12 proposal exceeds OEHHA's statutory authority.

The statute is set up to be binary – either a chemical is listed or it is not. The statute does not offer a framework for ranking chemicals by hazard, exposure, or risk in order to support the strength of a warning. There is no basis for differentiating chemicals for identification in a listing because the statute itself does not anticipate such a basis. Chemicals are listed on the basis of hazard, and the statute does not rank listed chemicals based on any hazard or toxicological measure – not potency, mode of action, number of animal studies with positive results, quality of studies, number of epidemiology studies – nothing. The very design of the statute therefore does not warrant that a safe harbor distinguish among

chemicals. OEHHA has not proposed that all chemicals be identified (which would also raise serious regulatory issues) and the only other alternative is that none be identified. The statute offers no framework for the regulator to decide that certain chemicals merit mention in the text of warnings while others do not.

This provision is legally infirm for a second reason: It does more than give notice – it purports to “enhance the effectiveness of the warning and make it more understandable to the reader.”<sup>2</sup> But however well-meaning OEHHA’s intent, there is no statutory basis to “enhance the effectiveness of the warning.” The warning is a mere notice requirement that functions as an affirmative defense in litigation. The notice elements are met when the statutory elements are met: clear and reasonable warning of exposure to a carcinogen or reproductive toxicant (according to the State of California) prior to exposure.

### **II.B. The ISOR Offers No Evidence that Including the 12 Specific Chemical Names Will “Increase Warning Effectiveness and Understandability.”**

OEHHA recognizes that “it is not OEHHA’s intent to imply that any or all of these chemicals pose greater health risks to the public than other listed chemicals not included” in the list.<sup>3</sup> Even if one were to assume that OEHHA did have authority to require specific chemical names to be listed, it has come up with a hodgepodge of factors that neither support the differentiation of those chemicals to be listed from the other close to 900 chemicals, nor provide any basis for its conclusion that consumers won’t do exactly what OEHHA claims is not intended, namely, assume and conclude that listing a chemical means that it is a worse actor than others not listed. Indeed, one possible result of the superlist approach is that consumers will only pay attention to warnings that “name names” and include a specific chemical, and will begin to disregard everything else.

OEHHA offers no consumer focus data or literature of any kind to document consumer understanding or recognition of any of the chemicals proposed for inclusion on the List of 12. It never defines what an “effective” warning is with a rationale offered, and it never ties effectiveness to the names of the specific 12. For example, one of the compounds noted in the List of 12 is mercury. If consumer focus group testing indicates that the general public has existing beliefs and misperceptions about mercury, and would “overreact” to the inclusion of mercury by name on a label, then the listing of this particular chemical may invoke the kind of “overwarning” about which OEHHA professes to be concerned.

The phenomenon of the general public reacting in fear and panic to hearing the names of chemicals is well documented. Some have suggested that bloggers and others prey on the public’s general fear and lack of education about chemicals by converting it into a business strategy: “name a bunch of chemicals and count on the chemical illiteracy of your audience to result in fear at hearing their very names.”<sup>4</sup>

---

<sup>2</sup> 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, January 16, 2015, at 14.

<sup>3</sup> ISOR at 15.

<sup>4</sup> See post by David Gorski on Science-based Medicine, June 16, 2014 (available at [http://www.sciencebasedmedicine.org/vani-hari-a-k-a-the-food-babe-the-jenny-mccarthy-of-food/?utm\\_source=twitterfeed&utm\\_medium=facebook&utm\\_campaign=vani-hari-a-k-a-the-food-babe-the-jenny-mccarthy-of-food](http://www.sciencebasedmedicine.org/vani-hari-a-k-a-the-food-babe-the-jenny-mccarthy-of-food/?utm_source=twitterfeed&utm_medium=facebook&utm_campaign=vani-hari-a-k-a-the-food-babe-the-jenny-mccarthy-of-food)).

In short, to understand whether any specific chemical names listed on a warning would have a particular effect, OEHHA needs to study pre-existing consumer attitudes<sup>5</sup> and beliefs about the chemical, and consumer perception<sup>6</sup> in response to a specific chemical name on a label. None of this foundational work has been done, so it is not known what the impact of listing any particular chemical name will have on the “effectiveness” of a warning or whether the warning is “understandable.” If consumers are already misled or frightened about a chemical, it is possible that listing that specific chemical in a warning will have the effect of simply “overwarning”<sup>7</sup> them and groundlessly frightening them that much more.

OEHHA has no current basis for concluding and has not undertaken a valid, scientifically sound focus group testing of warning labels (including the proposed “List of 12” chemicals) to determine, in fact, how consumers perceive the inclusion of the new information. This testing, both qualitative and quantitative, should be performed against baseline testing of labels without specific chemicals listed. There is currently no adequate basis for OEHHA to conclude that listing of the chemicals will not cause consumers to believe that the listed chemicals do “pose greater health risks to the public than other” Proposition 65 chemicals, which is what OEHHA said was specifically not intended.

### **II.C. Use of Genericized Chemical Names Would Decrease Understandability.**

The proposed list of 12 does not accurately describe chemicals by recognized technical or scientific names. OEHHA asserts that it has “determined” that “in some cases” including the “simplified” names of the chemicals in the warning will enhance the “effectiveness of the warning” and make it more understandable to the reader” because “[i]ncluding the more technical chemical names ... would defeat the purpose of providing understandable and useful information.”<sup>8</sup> We see no evidentiary basis in the record to support such a determination. OEHHA offers no data to support its assertion that consumers will better recognize a “simplified” chemical name instead of a more technical one.

While we believe that specific chemical names need not be provided at all under the statute, if they are to be offered, it makes no sense, under any circumstance, to provide a deliberately incorrect and potentially misleading name. OEHHA’s entire proposal is premised on the notion of providing “more” information to consumers so consumers can be better informed. Offering half information, or inaccurate information, does not advance this purpose. Providing an inaccurate chemical name does not equip consumers with the information they need to conduct intelligent, informed research. OEHHA simultaneously notes complaints about the “lack of specificity” in warnings but then proposes chemical names that are imprecise and non-specific.<sup>9</sup> OEHHA cannot have it both ways.

A truly effective notice provision implemented pursuant to right-to-know principles would identify chemicals with this degree of precision, and would enable consumers wishing to learn more with an effective tool to do so. Absent that, use of the technical or scientific name for the chemical would be

---

<sup>5</sup> University of Southern California - Marshall, Consumer Attitudes, [http://www.consumerpsychologist.com/cb\\_Attitudes.html](http://www.consumerpsychologist.com/cb_Attitudes.html)

<sup>6</sup> University of Southern California – Marshall, Consumer Perception, [http://www.consumerpsychologist.com/cb\\_Perception.html](http://www.consumerpsychologist.com/cb_Perception.html)

<sup>7</sup> “Overwarning” is a term of art in the field of Risk Communication. Overwarning is “the notion that people encounter too many warnings, in the world, and it is thought that people will be less likely to attend to warnings as a consequence of this inundation.” Wogalter, Warnings and Risk Communication at 140. Overwarning should not be confused with the content of a warning and whether relevant information is being communicated about the severity and probability of a hazard (e.g., whether a “warning” is appropriate at all, and if so, how “loud” it should be).

<sup>8</sup> ISOR at 14.

<sup>9</sup> ISOR at 3.

absolutely essential to equipping consumers with the information they need to learn more about the specific chemical. OEHHA's own list of chemicals uses Chemical Abstracts Service (CAS) numbers and technical names, so consumers wishing to correlate the information on a product label with OEHHA's own list cannot do so without "matching" technical names.

OEHHA offers no evidence whatsoever that listing a chemical by name, or for that matter using a chemical name deemed to be "more familiar," would be more "understandable" or offer better information. To the contrary: consumer confusion about "genericized" chemical names is well documented. Arsenic is an excellent example. Consumer Reports wrote about consumer confusion in 2011 following a Dr. Oz show that instilled public fear about the presence of arsenic in apple juice.<sup>10</sup> But the U.S. Federal Food and Drug Administration then found itself needing to explain to the public that there are different kinds of arsenic: "[t]here are two general types of arsenic: organic and inorganic. The inorganic forms of arsenic are the harmful forms, while the organic forms of arsenic are essentially harmless."<sup>11</sup> Other experts have carefully made the same distinction.<sup>12</sup> Even the Organic Trade Association had to issue a fact sheet differentiating between inorganic and organic arsenic.<sup>13</sup>

#### **II.D. Use of Chemical "Category" Names Is Inappropriate and Arbitrary.**

OEHHA inappropriately and arbitrarily relies on categories rather than specific chemical names. Perhaps the most striking example of this is OEHHA's proposal to group phthalate esters into one category called "phthalates." There are, however, at least eighteen phthalate esters. 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. Phthalates in each of these subcategories have different toxicological properties.<sup>14</sup> On the Proposition 65 list itself, some phthalate esters are listed for carcinogenicity, some for reproductive toxicity, others for both health endpoints, and still others are not listed at all. Like the genericized chemical names discussed above, the use of groupings obscure accurate information and completely impede a consumer's ability to conduct additional research or learn more about the chemical at issue. It is the height of arbitrary action for the same regulatory package to justify new warning language as being helpful to the public because it is both "more specific" and "less specific."

Moreover, the U.S. Food and Drug Administration, as referenced by OEHHA, has noted that it is "not clear what effect, if any, phthalates have on human health."<sup>15</sup> No data reviewed by the FDA established an association between use of phthalates in cosmetic products and a health risk. Thus, the FDA determined there was not a "sound, scientific basis" to support taking regulatory action against cosmetics

---

<sup>10</sup> Getting the facts straight on arsenic and apple juice, Consumer Reports News: September 27, 2011, available at <http://www.consumerreports.org/cro/news/2011/09/getting-the-facts-straight-on-arsenic-and-apple-juice/index.htm>

<sup>11</sup> Federal Food and Drug Administration, Questions and Answers: Apple Juice and Arsenic, July 15, 2013, available at <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm271595.htm>

<sup>12</sup> James R. Coughlin, The Arsenic Debate Continues, JIFSAN 2014 Annual Spring Symposium, available at [http://jifsan.umd.edu/wp-content/uploads/2014/05/D1\\_1450\\_-\\_Coughlin.pdf](http://jifsan.umd.edu/wp-content/uploads/2014/05/D1_1450_-_Coughlin.pdf)

<sup>13</sup> Organic Trade Association, Fact Sheet on Organic and Inorganic Arsenic, available at [https://legacy.unfi.com/uploadedFiles/UNFI\\_ER-WR\\_Docs/FinalOTAFactSheet\\_InorganicOrganicArsenic%20copy.pdf](https://legacy.unfi.com/uploadedFiles/UNFI_ER-WR_Docs/FinalOTAFactSheet_InorganicOrganicArsenic%20copy.pdf)

<sup>14</sup> High Production Volume Chemical Challenge Test Plan for the Phthalate Esters Category (2001), <http://www.epa.gov/hpv/pubs/summaries/benzene/c13467tp.pdf>; IUCLID Data Set (2007), <http://www.epa.gov/hpv/pubs/summaries/benzene/c13467rr3c.pdf>

<sup>15</sup> <http://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm128250.htm#health>.

containing phthalates. Neither the studies nor reports available and “relied upon” by OEHHA warrant the target listing of “phthalates” as proposed by Section 25602. Federal agencies have repeatedly acknowledged insufficient data to confirm phthalates – in general – have detrimental human effects.

For specific information on certain phthalates, see Appendices A (discussing di(2-ethylhexyl) phthalate and why scientific data does not warrant it being listed as carcinogenic), B (discussing the exposure levels of diisodecyl phthalate are magnitudes lower than the MADL) and C (discussing diisononyl phthalate and its lack of carcinogenic risk or exposure).

## **II.E. The Criteria Selected for the “List of 12” Are Not Adequately Tied to the Purpose of the Statute.**

OEHHA lists five discrete criteria that it considered when selecting chemicals for the “List of 12.” These are:

- “Widespread prevalence” of the listed chemical in products and/or locations
- Potential for significant exposure
- Recent Proposition 65 enforcement activity
- Recognizability of the chemical name among the general public
- The “general availability” of additional information about the chemical

A sixth apparent criterion is added separately: a list of “scientific references relied upon by OEHHA in the selection of chemicals to be included in this section.”<sup>16</sup>

None of these criteria, however, is reasonably related to the purpose of the statute.

### **I.E.1. “Widespread Prevalence” of Chemical**

On its face, this criterion is ambiguous. It is unclear whether OEHHA means that the chemical is widely prevalent in consumer products, workplaces, or other facilities or something else altogether. More important, the widespread use of a chemical to manufacture a product – or in a product – does not mean that exposures would be widespread or significant. OEHHA offers no documentation of the methodology it used, modeling conducted, or data relied on to determine “widespread prevalence” for each of the 12 chemicals.

Further, this criterion is arbitrary on its face. If OEHHA is genuinely concerned about reducing “overwarning,” an argument can be made that obscure and little-used chemicals should be selected for superlisting, since selection of chemicals that have “widespread prevalence” will result in too many warnings. It does not make any rational sense that OEHHA proposes “widespread prevalence,” with its resultant overwarning, and yet rejects “little to no prevalence,” which is unlikely to result in overwarning. OEHHA’s reliance on contradictory positions is a hallmark of arbitrary and capricious action.<sup>17</sup> Circular conclusions are not rational ones.

---

<sup>16</sup> ISOR at 14.

<sup>17</sup> See, e.g., *National Association of Home Builders v. Defenders of Wildlife* 551 U.S. 664, 127 S.Ct. 2518 (2007).

### **II.E.2. Potential for Significant Exposure**

OEHHA does not define what it means by “significant exposure.” Does it mean that an individual could experience significant exposure, or that exposures could affect a significant percentage of the population? Does it mean a particular route of exposure? What if the potential for exposure to an individual is significant via one exposure pathway (e.g., dermal, ingestion) but the chemical is listed only for exposures via another pathway (e.g., inhalation)? What about exposures for limited durations? These are completely separate questions. This criterion is so broad that it is meaningless in application. That said, OEHHA offers no documentation of the methodology it used, modeling conducted, or data relied on to determine “potential for significant exposure” for each of the 12 proposed chemicals.

### **II.E.3. Recent Proposition 65 Enforcement Activity**

Proposition 65 “enforcement activity,” whether recent or not, bears no rational relationship with anything that could possibly justify “superlisting.” Enforcement activity could be related to the recency of a listing or the age of a listing. It could be related to the ease of detecting the presence of a listed chemical in a particular product due to the availability and cost of sample kits. It could be related to the experience and information base a particular enforcer already has accumulated. It could be related to how busy test labs are. And it could also be the case that enforcement activity has resulted in reformulations or settlements such that warnings are no longer required at all.

Even if there was some rational connection between recent enforcement activity and chemicals that warrant listing on a Prop 65 warning, the range of Prop 65 warning letters for the 12 chemicals is so vast as to render the criterion arbitrary, (the range is over 2300, the difference between a mere 2 for methylene chloride and 2351 for “phthalates,” although the record is silent as to which specific phthalates were the subject of warning letters).

### **II.E.4. Recognizability of the Chemical Name Among the General Public**

It is unclear from the general description whether OEHHA means that public familiarity with a chemical should be the basis for superlisting, or rather, public unfamiliarity; or, whether OEHHA means accurate public perception and knowledge of risk, or conversely, public ignorance. From a right-to-know standpoint, the less consumers know about something, the more important it is to tell them.

Assuming public familiarity is intended to be the case, this criterion is entirely opportunistic. It would seek, in part, to capitalize on pre-existing consumer fears and concerns. Such an approach would result in “overwarning” due to a “pile on” effect – adding more warnings where fear already exists.

Further, OEHHA’s application of this criterion appears to be inconsistent. For example, it seems to rationalize a superlisting of methylene chloride because the chemical is largely unknown and unrecognized, whereas acrylamide is widely recognized. This makes no sense.

### **II.E.5. “General Availability” of Authoritative Information and Resources**

This criterion, likewise, makes little sense. “General availability of information” is undefined, vague and overbroad. OEHHA neither defines what “authoritative” information is nor what “general availability” means.

In its chemical-specific discussions, OEHHA seems to suggest that the more information publicly available about a chemical, the more justified OEHHA is putting that chemical on a “superlist.” Again, one can easily argue the opposite: that “superlisting” a chemical where numerous expert bodies already offer comprehensive, consumer-facing information – the U.S. Occupational Safety and Health Administration, the Agency for Toxic Substances and Disease Registry, the National Institute for Occupational Safety and Health, the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration, the U.S. Department of Agriculture, the National Toxicology Program, the International Agency for Research on Cancer, the National Science Foundation, the National Institutes of Health, the U.S. Department of Transportation, California governmental bodies, and international bodies – serves no additional purpose. If, for example, the EPA has broadly communicated to the general public information about the risks and safety of mercury in compact fluorescent bulbs, it makes little sense to add a Prop 65 “superwarning” to light bulbs.

One of the critical features of a warning is that it offers an alert to something that is unknown or not readily apparent. In the product liability context, for example, it is axiomatic that warnings are not needed where the danger is obvious or well known to the user.<sup>18</sup> Piling on additional warnings where consumers already have awareness of the hazard defeats the purpose of a warning in the first place. It contributes to the kind of overwarning that OEHHA is trying to avoid.

#### **II.E.6. The Scientific References Relied Upon by OEHHA in the Selection of Chemicals to Be Included in the List of 12 Are Wholly Inappropriate to Support Selection**

The ISOR attaches a list of scientific references which, it says, was relied on “in the selection of chemicals” to the list of 12. This is puzzling, however, because OEHHA’s criteria are not based on the scientific merits of chemicals being listed, or on any measure that could support “ranking” chemicals by hazard. Moreover, as detailed in the Appendices, in several cases, the references cited would not support the listing in any event.

Setting aside our comment that none of the criteria identified are appropriate in the first place, OEHHA should have at least included references and documentation supporting its various assertions in the criteria; e.g., that certain chemicals in fact have “widespread prevalence” in products or facilities, or that certain chemicals are “recognizable” with the public. The ISOR offers no studies to support these claims.

We can discern no rational, non-arbitrary basis for selection of or use of the scientific citations supplied by OEHHA. For that matter, a detailed review of the citations offered for several chemicals reveals no consistent approach or pattern taken by OEHHA to inform a disciplined or scientifically-founded decision (see, e.g., Appendix A on di(2-ethylhexyl) phthalate, Appendix B on diisodecyl phthalate, and Appendix C on diisononyl phthalate). If OEHHA intends to rely on the scientific citations for any purpose, it should explain its approach and rationale fully in the rulemaking docket, and likewise, should subject its process to external peer review.

---

<sup>18</sup> See, e.g., *Billiar v. Minnesota Mining and Manufacturing Co.*, 623 F.2d 240, 243 (2d Cir. 1980) (warning not needed where danger is obvious or well known to the user).

## **II.F. OEHHA Inconsistently Applied – or Failed to Apply at All – Its Articulated Criteria When Selecting the List of 12.**

According to the ISOR, when selecting 12 chemicals in Section 25602, OEHHA “considered” five criteria, although the ISOR goes on to note that “some chemicals may not have information available for all of the criteria.” The ISOR, however, utterly fails to indicate which criteria or how many were relied on to select the 12 chemicals. Moreover, the ISOR is devoid of information to answer a litany of questions, which are fundamental to a rational, evidence-based approach for selecting chemicals to be included in Section 25602. Fundamental questions include, but are not limited, to the following:

1. Did OEHHA apply the criteria to all Proposition 65 listed chemicals, and if so what was the outcome?
2. How did OEHHA select the criteria, and were the criteria subject to scientific peer review?
3. Was each criterion given equal weight in its application to specific chemicals?
4. How does the application of each criterion provide sufficient evidentiary support for OEHHA’s selection of the twelve chemicals/categories?
5. Which of the five criteria were applied to each of the twelve selected chemicals?
6. What is the basis for OEHHA’s conclusion that “these [12] chemicals were selected using the above-mentioned criteria with the intent of making Proposition 65 warnings more informative and meaningful to the public”?
7. What was the purpose of listing scientific citations for the 12 chemicals/categories, how were these citations selected, which were excluded, and how were they relied upon for decision-making?

Table 1 depicts the extent to which OEHHA’s five criteria are applicable to each of the 12 chemicals listed in proposed Section 25602. As described in more depth in these comments, OEHHA provides wholly insufficient evidentiary support in the ISOR, as indicated by the red shading, for superlisting of specific chemicals/categories.

**Table 1: The extent to which the 5 enumerated criteria and their application provide adequate evidentiary support for selecting 12 chemicals/categories for superlisting.**

	Widespread prevalence <sup>19</sup>	Potential for significant exposure <sup>20</sup>	Recent P65 enforcement activity <sup>21</sup>	Recognizability of chemical <sup>22</sup>	Additional authoritative information <sup>23</sup>
Acrylamide					
Arsenic					
Benzene					
Cadmium					
Carbon monoxide					
Chlorinated tris					
Formaldehyde					
Hexavalent chromium					
Lead					
Mercury					
Methylene chloride					
Phthalates					

<sup>19</sup> Widespread prevalence of a chemical does not necessarily imply human exposure to that chemical. Several of the 12 proposed chemicals, for example, are elements on the periodic table, including arsenic, cadmium, lead and mercury, or are produced through normal metabolic processes of living organisms, as in the case of formaldehyde. Thus, widespread prevalence of these particular chemicals would be anticipated.

<sup>20</sup> OEHHHA fails to explain or offer any support as to what would be “significant exposure” for any of the 12 chemicals.

<sup>21</sup> OEHHHA provides no information whatsoever explaining how “recent Proposition 65 enforcement activity” provides any basis for selecting chemicals to be included in Section 25602. Even if there was some rational connection between recent enforcement activity and chemicals that warrant listing on a Prop 65 warning, the range of Prop 65 warning letters for the 12 chemicals is so vast as to render the criterion arbitrary, (the range is over 2300, the difference between a mere 2 for methylene chloride and 2351 for “phthalates,” although the record is silent as to which specific phthalates were the subject of warning letters).

<sup>22</sup> OEHHHA merely asserts throughout its proposal that each of the 12 chemicals is recognizable by the public, without providing any quantitative data of any kind to support this bold assertion.

<sup>23</sup> ACC is at a loss to understand the rationale for this criterion. There already undoubtedly exists voluminous information on all Proposition 65 listed chemicals, not just the 12 listed in Section 25602, easily accessible through the internet. OEHHHA proposes to further add to this vastness by creating a Lead Agency Website that will provide the public with information regarding warnings for potential exposures to all Proposition 65 listed chemicals. (As discussed elsewhere in the comments, ACC strongly objects to OEHHHA’s proposal.)

As an example, for methylene chloride, it is largely impossible to discern how the criteria were applied at all. Most methylene chloride use is in professional and occupational settings, so it is unclear why OEHHA thinks the general (non-worker) public could experience “widespread prevalence” of this chemical. OEHHA itself suggests that less methylene chloride is in use in consumer products, with its own website touting the fact that “reformulated paint strippers do not contain the carcinogen methylene chloride.”<sup>24</sup> The ISOR cites two 60-day notices over the past five years with no reported complaints or settlements, which is hardly significant or notable. OEHHA concedes (or perhaps merely asserts, since it makes this claim without any support) that methylene chloride is not well-known to the public (not surprising, since its use is not widespread or prevalent for ordinary consumers): “methylene chloride is less well-known to the public than some other chemicals in this section.”<sup>25</sup>

OEHHA does not mention that the California Safer Consumer Products program has selected methylene chloride for its pilot. OEHHA’s ISOR notes that the U.S. Consumer Product Safety Commission already requires a cautionary label on paint strippers that indicates potential cancer hazard, an explanation of factors that contribute to risk, and safeguards such as ventilation.<sup>26</sup> Concern about fatalities from acute exposure (not chronic exposure risks like carcinogenicity) has heightened interest and engagement of both federal agencies as well as California agencies. EPA has issued a fact sheet;<sup>27</sup> OSHA issued a hazard alert;<sup>28</sup> the U.S. Centers for Disease Control publishes extensive website materials<sup>29</sup> including a bulletin;<sup>30</sup> and the California Department of Public Health issued an alert.<sup>31</sup> The issue, as stated in a 2013 report from the California Department of Public Health, is that “consumers and workers may not understand that deadly levels of DCM vapors can quickly accumulate in closed rooms.”<sup>32</sup>

The methylene chloride discussion includes, as an apparent basis for superlisting, the observation that “there have been some well-publicized deaths in California in recent years due to methylene chloride exposure.” But these are incidents related to acute toxicity, and not chronic toxicity concerns of carcinogenicity or reproductive toxicity. This rationale makes no sense at all: that out of concern for workers are not following existing label and safety instructions that protect against acute hazards of using paint strippers containing methylene chloride, OEHHA believes an additional, special warning needs to be added. This creates more “noise” and competes with the acute toxicity warnings that the State of California believes are already being disregarded.

## **II.G. OEHHA Must Conduct an External Scientific Peer Review of the Scientific Basis for the Proposed Regulations, Including Any “List of 12” Criteria.**

The proposed regulations currently fail to meet the requirements of Health and Safety Code (HSC) Section 57004, which clearly requires that all aspects of the scientific basis of the proposed regulation must be subjected to external peer review. This has not yet occurred. As part of this review, OEHHA should bear in mind that HSC § 57004 states that “if the board, department, or office disagrees with any aspect of the finding of the external scientific peer review entity, it shall explain, and include as part of

<sup>24</sup> OEHHA, Proposition 65 in Plain Language, <http://www.oehha.ca.gov/prop65/background/p65plain.html>.

<sup>25</sup> ISOR at 21.

<sup>26</sup> California Department of Public Health, Dichloromethane (methylene chloride) in paint strippers: Survey of retail stores, January, 2013, p.1, available at <http://www.cdph.ca.gov/programs/ohsep/documents/MeClRetailSurvey.pdf>

<sup>27</sup> <http://www.epa.gov/oppt/existingchemicals/pubs/dcmfaq.pdf>

<sup>28</sup> OSHA-NIOSH Hazard Alert, [https://www.osha.gov/dts/hazardalerts/methylene\\_chloride\\_hazard\\_alert.html](https://www.osha.gov/dts/hazardalerts/methylene_chloride_hazard_alert.html)

<sup>29</sup> <http://www.cdc.gov/niosh/topics/methylenechloride/>

<sup>30</sup> <http://www.cdc.gov/niosh/docs/86-114/>

<sup>31</sup> <http://www.cdph.ca.gov/programs/ohb/Pages/methylenechloride.aspx>

<sup>32</sup> Id.

the rulemaking record, its basis for arriving at such a determination in the adoption of the final rule, including the reasons why it has determined that the scientific portions of the proposed rule are based on sound scientific knowledge, methods, and practices.” In such case, OEHHA must include as part of the rulemaking record its basis for disagreeing with, ignoring, or not addressing, the findings of the peer reviewers. A final regulation cannot be issued until such a scientific peer review has been completed.

HSC § 57004 makes clear that OEHHA must enter into an agreement with certain institutions (National Academy of Sciences, the University of California, the California State University or another appropriate body) when initiating a peer review process of scientific portions of proposed regulations. OEHHA should arrange to conduct a credible and robust peer review to comply with these regulatory requirements, ensuring, among other things, transparency about the specific criteria that are to be used to first identify potential peer reviewers, the process to select the final peer reviewers, the criteria used for and delivery of charge questions, the number of in-person meetings of peer reviewers with an appropriate opportunity for public comment during those meetings, and an opportunity to offer written responses to peer review comments.

A properly conducted peer review will help explain the basis for arriving at determinations in the adoption of a final rule, assuming OEHHA decided to proceed, and particularly the reasons why it has determined that the scientific portions<sup>33</sup> of the proposed rule are based on sound scientific knowledge, methods, and practices.<sup>34</sup> Peer review, at a minimum, should apply to any criteria selected to establish the proposed “List of 12” and information proposed for posting on a website.

#### **II.H. OEHHA’s Criteria for the “List of 12” Appear to be a Post-Hoc Rationalization of Decisions Already Made, and Are Thus Arbitrary and Capricious.**

The criteria used to select the “List of 12” are so overbroad, internally inconsistent, and inconsistently applied that they appear to be an exercise in justifying, after the fact, a chemical “wish list” from unknown quarters. There is no semblance of a deliberate and orderly approach to warn consumers about what they don’t know; the proposal, rather, seems to seek to warn them (again) of what they already do know, or to capitalize on what they already fear or are concerned. This is unfortunate. It is also entirely arbitrary.

#### **II.I. The Proposal Does Not Clearly Establish What Criteria Will Be Used in Future Rulemakings to Add or Remove Chemicals to or from the “List of 12.”**

The ISOR purports to list the criteria that OEHHA considered when selecting chemicals for this proposed rule. The proposed rule, however, does not state what criteria will be used going forward. The agency leaves open the possibility that it can add or remove criteria at random. Again, this is arbitrary. It offers no notice to the regulated community what might be listed in the future, resulting in serious due process concerns.

The proposed regulation gives no clear indication of how the criteria will be applied in the future. The proposal would apparently allow OEHHA unlimited discretion to choose any of the criteria as the basis

---

<sup>33</sup> California Health and Safety Code Section 57004(a)(2) states that ““Scientific basis” and “scientific portions” mean those foundations of a rule that are premised upon, or derived from, empirical data or other scientific findings, conclusions, or assumptions establishing a regulatory level, standard, or other requirement for the protection of public health or the environment.

<sup>34</sup> California Health and Safety Code Section 57004(d)(2).

for “superlisting” while ignoring other factors. Such a system fails to offer any regulatory predictability. Regulated entities would not be able to design and deploy new labels or signs because they will have no way of anticipating which chemicals might get added to the superlist. Additions to or deletions from the list would be subject to a highly discretionary and perhaps ever-changing process.

It is not clear how OEHHA plans to make superlist selections in a rational, predictable way that allows industry to plan, make investment decisions, and otherwise act in good faith. There is no process described at all, and we are not able to discern any process from the criteria set out. It must be made more systematic and predictable if the regulated community is to be bound or subject to enforcement. Otherwise, it will fail to meet the clarity standards of the Office of Administrative Law (OAL) review process.<sup>35</sup>

OEHHA tries to dispel worry that there will be a flood of requests to add new chemicals to the superlist by noting that “the addition or removal of a listed chemical from this section will require the adoption of an amended regulation and can only occur after a formal regulatory process that includes a public notice, hearing and opportunity to comment.” This is small comfort, however, given the unbounded discretion OEHHA has given itself to include any chemical it wishes, and on any basis it wishes, by simply pointing to one of the five listed criteria or creating additional criteria to justify inclusion. Moreover, interest groups and bounty hunters unable to have chemicals successfully added to the superlist through the regulatory process may seek to challenge OEHHA in court, increasing the litigation burden on OEHHA.

### **III. Provisions of Proposed Section 25600 Are Not Authorized by Statute.**

#### **III.A. Unlimited Petitioning For New Regulations Addressing Exposures**

OEHHA proposes in Subsection (c) of Section 25600 that “any interested party can petition OEHHA to adopt additional regulations that address exposures to listed chemicals in products or the environment that are not already sufficiently covered by the regulations.” As the rationale for this proposal, the agency explains that “it is intended to encourage businesses to continue to work with OEHHA to develop a tailored warning method or message where the existing regulatory provisions are not sufficient to address a particular exposure scenario.”<sup>36</sup> It is easy to conceive of a situation where those other than regulated entities – interest groups, bounty hunters, and others – could flood OEHHA with such petitions, creating an impossible burden for both the agency and businesses to be able to respond. The right to petition for warning language should belong solely to the statutory owners of the affirmative defense.

#### **III.B. “No Dilution” Provision for Supplemental Notice Information**

OEHHA proposes in Subsection (d) that the person giving a warning may provide information that is “supplemental” to the warning, because “[s]uch information may be useful in allowing a potentially exposed person to make informed decisions.”<sup>37</sup> Nonetheless, OEHHA then seeks to regulate the content of the warning through the backdoor by adding the restriction that any such supplemental information

---

<sup>35</sup> See Govt. Code section 11349.1, review of regulations, [https://www.dca.ca.gov/dca/publications/rulemaking/exhibit\\_12\\_gc\\_11349\\_1.pdf](https://www.dca.ca.gov/dca/publications/rulemaking/exhibit_12_gc_11349_1.pdf); OAL review process description (flowchart), [http://www.oal.ca.gov/res/docs/pdf/OAL%20Review%20Process\\_FINAL\\_June%202014.pdf](http://www.oal.ca.gov/res/docs/pdf/OAL%20Review%20Process_FINAL_June%202014.pdf)

<sup>36</sup> ISOR at 5.

<sup>37</sup> Id. at 6.

“may not contradict, dilute, or diminish the warning.”<sup>38</sup> This is inappropriate. The statute does not require that exposure or risk information be offered, and regulations cannot be made to so require.

Likewise, it cannot be the case that manufacturers are precluded by Proposition 65 from providing truthful, contextual information about product safety or relative risk. This is not only First Amendment protected commercial speech, it is exactly the kind of useful and informative information that OEHHA seems to want for consumers.

This provision, at a minimum, likely violates the First Amendment rights of manufacturers, and may likewise trigger a number of federal preemption problems. For example, a manufacturer may wish to label a product noting that a particular food additive has been approved as safe by the federal Food and Drug Administration, or to add this information to a Prop 65 “warning.” Likewise, it cannot reasonably be the case that Proposition 65 would be read to circumscribe safe use, safety, product instructions, and product warnings offered by manufacturers. This is useful information to a consumer, and places the Proposition 65 “warning” about the same chemical in context. A truthful statement such as this is both useful from a policy standpoint as well as legally protected.

Worse, this provision as proposed would invite still more frivolous bounty hunter litigation. Businesses should not be hauled into court to defend helpful, truthful, contextual information as long as the bare-bones notice required by the statute has been made.

### **III.C. Inclusion of Components in Definition of “Product Exposures”**

OEHHA proposes to change the definition in subsection (h) from “Consumer Product Exposure” to “Product Exposures,” intending to “clarify that a warning for an exposure to a listed chemical from any product, or component of a product ... may be provided using the methods and content described in the regulation.”<sup>39</sup> It is imperative that OEHHA clarify that a warning is made to consumers only with respect to a finished consumer good or article. While a component or material supplier may have a contractual or indemnification obligation to the manufacturer of the finished consumer good, upstream component or materials suppliers can have no independent liability under Proposition 65. Liability only attaches to persons who actually expose a person to a chemical. This clarification should be made in the definition.

### **IV. The Proposed Requirement to Include a Warning Symbol Is Not Authorized by Statute.**

Proposed Section 25604, Subsection (a)(1), would establish a warning symbol<sup>40</sup> to be used on all Proposition 65 warnings except where otherwise stated. We strongly object to the use of a warning symbol in any Proposition 65 warning. While we appreciate that OEHHA responded to stakeholder comments not to adopt a Globally Harmonized System (GHS) pictogram, the graphic now suggested is fraught with inherent problems.

---

<sup>38</sup> Id. at 6.

<sup>39</sup> Id. at 8.

<sup>40</sup> The current graphic proposed, which shows an exclamation point in a triangle, is better described as a “warning symbol” since there is no attempt to communicate a specific health hazard in the graphic itself. We therefore use “warning symbol” rather than “pictogram” in these comments.

The fact remains that presenting a statutorily compliant exposure warning is one of the few reliable ways to avoid liability under Proposition 65.<sup>41</sup> The statute does not require that a graphic or warning symbol be used and OEHHA does not have authority to require that a particular graphic or warning symbol now be used.

It should also be noted that the use and application of the “warning” language set out by statute is not consistent with risk communication principles or standards. Warnings “often contain specific words intended to alert people to the presence of a hazard and the level of danger involved (severity and probability).”<sup>42</sup> Proposition 65 does not itself offer information about hazard severity and probability (risk). In the U.S., the specific term “warning” is not used as an alert for the mere presence of a hazard; it is tied to hazards with “medium” levels of severity and probability.<sup>43</sup> More specifically, ANSI standards use the specific terms Danger, Warning and Caution as signal words to connote high to low levels of hazard, respectively. So the use of the term “warning” is intended for hazards that could result in severe personal injury or death with “medium” probability. Since ordinary consumers do not know the formally assigned definitions to signal words, the “effect” of these warnings is “mainly to alert people to the presence of a hazard and to produce an overall impression of the level of the hazard.”<sup>44</sup>

Proposition 65 uses “warning” across the board as a signal term, in all products and facilities without regard to severity and probability, thus delivering “warnings” in cases where a “warning” in accordance with risk communication principles would not be justified. Given this context – that the mere use of the term “warning” may already be offering too intense an alert for a specific product or facility, adding (across the board) an additional graphic will simply add to the problem, making an already “too intense” warning even more “over intense.” This is not advisable, because OEHHA here seeks to avoid what it has described as “overwarning,” i.e., consumers are disregarding Proposition 65 warnings, which is of apparent concern. However, offering warnings for safe consumer products (where there is no significant human health risk) and where consumers are familiar with those consumer products leads to disregard of the warning:

A substantial body of research shows that familiarity with a product is associated strongly with lower hazard perceptions and a reduced tendency to look for warnings. A problem related to familiarity is habituation. Habituation refers to the tendency for individuals to ignore stimuli after repeated exposure to the same stimulus ... Ideally, one would like to present reliably a warning only at the times necessary to prevent unsafe behavior that would otherwise occur.<sup>45</sup>

The solution is to avoid offering a “warning” where none is needed or justified (e.g., the use or consumption of a consumer product is safe), not (as OEHHA proposes here) to turn up the volume further on what is already a “too loud” warning by adding an attention-getting graphic.

---

<sup>41</sup> Of course, as many commentators have pointed out, bounty hunters may still try to challenge whether the warning is clear and reasonable and made in advance of actual exposure.

<sup>42</sup> M. Wogalter, D. DeJoy, and K. Laughery, eds., *Warnings and Risk Communication* (1999) at 251.

<sup>43</sup> *Id.* at 177.

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* at 180-181.

#### **IV.A. OEHHA Has Failed to Test Consumer Perception of the Proposed Warning Symbol**

OEHHA merely asserts that the warning symbol is “currently in use” by many businesses for current Proposition 65 warnings with no support for this claim.<sup>46</sup> Nor does OEHHA present any data to indicate that the pictogram “improves” the warning.

There is a tremendous body of scientific literature available with respect to warnings and risk communication.<sup>47</sup> OEHHA has completely disregarded this body of literature; it neither refers to it in any way nor is there any suggestion that consumer perception testing of either the proposed warning language or the symbol has occurred. For that matter, it is clear that the language and proposed symbol must be tested together, since together they comprise the communication. This has not occurred either. The body of evidence notes the elements of an effective warning, and OEHHA appears either to have ignored or is unaware of these elements. The consequences of a mistake are not insignificant.

#### **IV.B. The Proposed Design Is in Broad Use for a Variety of Other Purposes and Will Cause Consumer Confusion.**

OEHHA is not suggesting or offering a graphic specific to Proposition 65, such as a “P65” in a circle. Instead, it seeks to use graphics or symbols that are already known or in use. Despite the fact that this invites obvious confusion with other uses, and suggests that consumers may already have an understanding of what the graphic means that is inappropriate for Proposition 65 purposes, the agency offers no consumer focus group data to confirm how consumers will understand the graphic.

Similar symbols using an exclamation point are in wide use in consumer products such as automobiles and computers, where it can be expected that many consumers have been exposed to them. OEHHA should carefully consider that these external, preexisting uses of similar symbols could significantly add to consumer confusion about what the symbol means. These external uses further support the pressing need for OEHHA to conduct focus group testing of the proposed symbol, together with proposed narrative warning text, in a suite of different consumer products and facilities.<sup>48</sup>

#### **IV.C. OEHHA is Proposing the Use of a Safety Alert Symbol in a Manner Inconsistent with the ANSI Z535 Standard (and the Corresponding ISO Standard).**

ANSI Z535 outlines a system for presenting safety and accident prevention information. The ANSI Z535 standard comprises the following six individual standards:

- ANSI Z535.1 American National Standard for Safety Colors
- ANSI Z535.2 American National Standard for Environmental and Facility Safety Signs
- ANSI Z535.3 American National Standard for Criteria for Safety Symbols
- ANSI Z535.4 American National Standard for Product Safety Signs and Labels
- ANSI Z535.5 American National Standard for Safety Tags and Barricade Tapes (for Temporary Hazards)

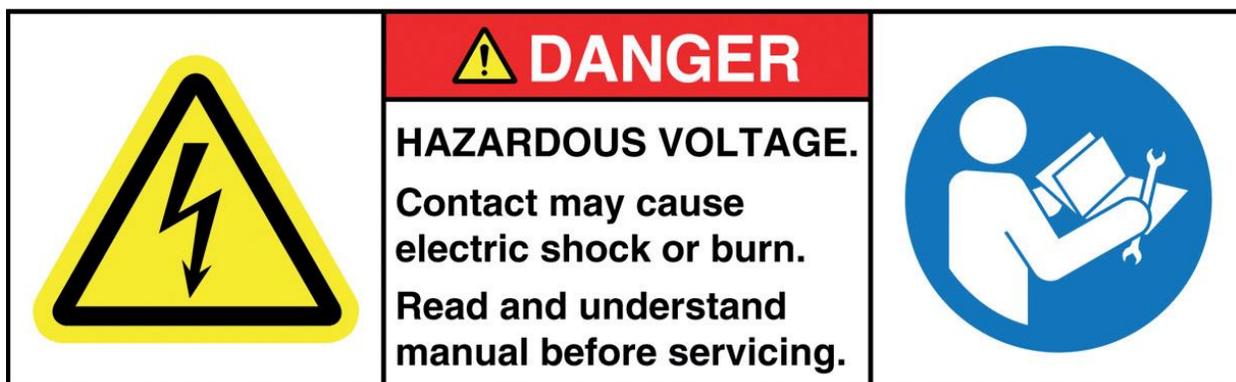
---

<sup>46</sup> Id. at 25.

<sup>47</sup> See, e.g., M. Wogalter, D. DeJoy, and K. Laughery, eds., *Warnings and Risk Communication* (1999).

<sup>48</sup> Live Science, *Not Too Bright: Dashboard Lights Baffle Drivers*, July 31, 2013, available at <http://www.livescience.com/38579-drivers-confused-dashboard-lights.html>

ANSI Z535.4 uses the same warning symbol that OEHHA proposes here, but in a much different manner. The warning sign is plainly intended for personal injury hazards – it is simply not appropriate for placement on everyday consumer products to communicate the mere presence of a chemical, or a long term chronic toxicity hazard.<sup>49</sup> In the ANSI standards, the safety alert symbol consists of a triangle with an exclamation mark and it appears to the left of the signal words DANGER, WARNING and CAUTION. The corresponding ISO standard, ISO 3864-2, refers to this same symbol as the "general warning sign" to indicate that a potential human risk of injury exists. The use of the safety alert symbol (triangle with exclamation mark) came into use in the U.S. with the 2002 revision to the standard, making this symbol "a universal element on all U.S. personal injury-related safety signs and labels."<sup>50</sup> The U.S. Occupational Safety and Health Administration adopted ANSI Z535 by reference in 2013.<sup>51</sup>



The use of a safety alert symbol in connection with personal injury hazards in the workplace is not new. The same symbol has been in use at least as far back as 1972 for Agricultural, Construction and Industrial Equipment.<sup>52</sup>

Under the ANSI standards, the use of the safety alert symbol together with the signal word "WARNING" is supposed to indicate a hazardous situation which, if not avoided, could result in death or serious injury. The use of the same safety alert symbol together with the Proposition 65 term "warning" would necessarily result in a massive "overwarning" problem. Exposure to Proposition 65 chemicals in products and facilities cannot be said to necessarily present either this type of hazard or this degree of risk that the hazard will materialize. It would create further consumer and worker confusion. And it creates a substantial compelled speech problem, since requiring businesses to warn of a risk that does not exist may be potentially challengeable under the First Amendment.

<sup>49</sup> NEMA, Your Guide to Effective Safety Labels, November 4, 2014, available at <http://www.nema.org/news/Pages/Your-Guide-to-Effective-Product-Safety-Labels.aspx>

<sup>50</sup> Geoffrey Peckham (Chair of both the ANSI Z535 Committee and the U.S. Technical Advisory Group to ISO Technical Committee 145-Graphical Symbols, Clarion Safety Systems), The ANSI Z535.4-2002 Revision Is Set for Release: Major changes are occurring in U.S. safety sign and label standards beginning July 1, 2002, available at <http://www.clarionsafety.com/assets/common/pdfs/whitepapers/ansi2002.pdf>

<sup>51</sup> 78 Fed. Reg. 66642 (November 6, 2013); see also NEMA, OSHA Validates ANSI Z535 Product Safety Labeling Formats, October 6, 2014, available at <http://www.nema.org/news/Pages/OSHA-Validates-ANSI-Z535-Product-Safety-Labeling-Formats.aspx>

<sup>52</sup> See, e.g., Safety Alert Symbol for Agricultural, Construction and Industrial Equipment, SAE, January, 1991, available at <http://www.doa.go.th/aeri/files/pht2008/lecture%20slides/mr%20viboon/grain%20drying/aeae-1998/pdfs/section2/246.pdf>

## V. OEHHA Must Conduct an Economic Impact Analysis.

OEHHA must also conduct an economic impact analysis. State agencies must consider their proposals' impact on business, including the ability of California businesses to compete with businesses in other states.<sup>53</sup> All state agencies must prepare an economic impact assessment that addresses:

- (A) The creation or elimination of jobs within the state.
- (B) The creation of new businesses or the elimination of existing businesses within the state.
- (C) The competitive advantages or disadvantages for businesses currently doing business within the state.
- (D) The increase or decrease of investment in the state.
- (E) The incentives for innovation in products, materials, or processes.
- (F) The benefits of the regulations, including, but not limited to, benefits to the health, safety, and welfare of California residents, worker safety, and the state's environment and quality of life, among any other benefits identified by the agency.

An agency's speculative belief does not substitute for an economic impact assessment. It must rely on facts, evidence, documents, and testimony to reach its conclusions.<sup>54</sup> Courts have invalidated regulations because of an inadequate economic analysis, even though they do not conflict with substantial evidence in the record.<sup>55</sup>

Furthermore, the fact that OEHHA recognizes a need for a two-year phase-in for these regulations strongly indicates that some portion of the business community will feel compelled to change their warnings. Accordingly, OEHHA must consider the economic impact resulting from the portion of the business community that will change its warnings in response to new regulations. Once again, OEHHA cannot have it both ways. It cannot on the one hand assert that no economic impacts will result from its regulatory proposal while at the same time providing the regulated community with a two-year phase in period to accommodate the economic impact of its proposal.

Finally, the labeling requirement may significantly increase costs for businesses, as they will be forced to periodically repackage their products due to the unstable nature of the list. Litigation may increase due to this new requirement too, as the failure to list all of the chemicals contained in the product may lead to more bounty hunter suits. A company that lists one chemical, but does not list another is in violation of the statute. OEHHA failed to take such economic impact into account.

We incorporate fully to our comments as if attached herein, a report entitled "The Business Cost of Proposed Changes to Article 6 of Proposition 65" prepared by Andrew Chang & Co., LLC, dated March 2015, and included with the California Chamber of Commerce's comments (to which ACC is also a signatory).

---

<sup>53</sup> Cal. Gov. Code § 11346.3(a)(2).

<sup>54</sup> California Assn. of Med. Products Suppliers v. Maxwell-Jolly, 131 Cal. Rptr. 3d 692, 708 (Cal. App. 2011).

<sup>55</sup> W. States Petroleum Assn., 159 Cal. Rptr. 3d 702 (striking down the California State Board of Equalization's regulation taxing petroleum refinery property because its economic impact analysis inadequately addressed fixture depreciation).

## **VI. OEHHA Should Not Launch a Stand-Alone Proposition 65 Website.**

We urge OEHHA to reconsider the need for and wisdom of a “lead agency” website. Consumers seeking additional information about the safety of consumer products and the chemicals in them should be referred, first and foremost, to the product manufacturer. Consumers seeking information about specific chemical concentrations in a product, or chemical exposures from that product, should likewise be referred to the product manufacturer. It is counterproductive for OEHHA to seek to independently offer such information. It can also present new and unintended health and safety issues if consumers with safe use, personal protective equipment, first aid, ventilation, or other questions about a specific product turn first to OEHHA’s website instead of the manufacturer’s instructions and information. (It should also be noted that OEHHA does not have the same incentive to maintain updated, accurate safety information and communicate it to consumers that a product manufacturer does. If OEHHA omits information or makes a mistake, even if someone is harmed, it will likely claim sovereign immunity from suit.)

The website is duplicative and unnecessary when other excellent sources of information are widely available. General information is available from a wide range of academic, professional, and trade organizations, as we note above, as well as government and regulatory bodies. The Proposition 65 website seems destined to, at worst, conflict with and, at best, duplicate web and information offerings from California’s Safer Consumer Products program. It would be a simple matter for OEHHA to refer those with inquiries to the product manufacturer and these other, existing authoritative resources rather than expand a new website.

Importantly, as these comments have discussed, consumers need product-based, complete, contextual information so they can understand product safety, benefits, risks, and safe use, including ways to reduce or control exposures if needed. It is a disservice for a website to provide incomplete, partial information. A website that presents only hazard information coupled with suggestions of ways to reduce exposure does not answer the consumer’s threshold question of whether the product is safe or can be safely used. Examples of these kinds of real-world inquiries that document the threshold question – is the product safe to use – are presented in Appendix D. If OEHHA cannot offer information about specific product use or safety, and cannot offer information about risk due to statutory limitations, it should leave these communications to others.

### **VI.A. Lack of Statutory Authority**

An important limitation to the proposal must be noted: Proposition 65 does not authorize OEHHA to require businesses to do more than meet their obligation to provide a statutorily-compliant warning. There is no statutory authority to compel businesses to provide any supplemental information to the agency about exposures or anything else.

While some have argued that OEHHA should remedy this problem by simply making responses to agency information requests voluntary, we suggest that OEHHA reconsider the need and value of an agency-managed website at all. Even a “voluntary” website will present serious issues.

### **VI.B. Lack of Opportunity to Review Information Prior to Posting**

OEHHA’s current proposal offers manufacturers the opportunity to review information and request correction after it has already been posted by the agency. Manufacturers, however, must be offered this opportunity before posting. It is important that manufacturers be able to preview the “public” information

on which OEHHA seeks to rely in preparing its web postings or fact sheets. Also, product composition and exposures to listed chemicals, as well as key safety and safe use information, may vary from product to product, and product manufacturers should be able to present specific, relevant, updated information about their products to the public. OEHHA should be cognizant that for particular consumer products, formulations may vary such that sweeping generalizations about chemical composition or chemical exposure cannot be made across the board.

#### **VI.C. Lack of Procedures for OEHHA to Ensure the Quality, Objectivity, Utility, and Integrity of Website Information**

If OEHHA is to offer information to the public via a website, it should take seriously the need to offer accurate, up-to-date, reliable information. Merely preparing information based on an internet review of “publicly available” data provides no assurance that the public will be offered quality information. For that matter, OEHHA should conduct both an agency-wide review and an interagency review to ensure that public communications about products, facilities, and chemicals are being made in an consistent manner across all California state agencies to avoid misleading or confusing the public.

#### **VI.D. Lack of Procedures to Make Timely Corrections to Incorrect Data**

We remain concerned that OEHHA is not offering procedures to allow prompt correction of incorrect or inaccurate information. For that matter, manufacturers who wish to offer integrated, complete, contextual information lack an opportunity to do so.

#### **VI.E. Lack of Legal Protection for Manufacturers Denied the Ability to Provide Complete and Contextual Information**

OEHHA presumably will not allow manufacturers to offer complete safety, safe use, first aid, personal protective equipment, ventilation, or other safety information, instructions, or warnings on the OEHHA website. It is not impossible to conceive of scenarios whereby site users or visitors seeking specific information (e.g., emergency or first aid information) are delayed in finding the information they need, confused by the information presented about chronic hazard, unable to quickly find (or find at all) information about acute hazard, or otherwise misled into thinking that no action need be taken. While OEHHA has given some thought into its potential liability and seeks to disclaim the same, if OEHHA is to control the information to be posted on its website and will block or control the supplemental information manufacturers wish to post, there should be a clear disclaimer that the site does not present complete information; that safety, safe use, warning, and use instructions are omitted; and that site content is controlled by OEHHA. Manufacturers should have no liability for failure to provide complete information or adequate warnings on acute hazards where OEHHA controls the information posted on the site.

#### **VI.F. OEHHA’s Disclaimer**

If OEHHA simply posts the information offered by a manufacturer (or other regulated entity), and the agency acts as a “pass through,” it might consider simply designating the information and the source. OEHHA should be careful not to disclaim the accuracy of information for which the agency is responsible – information the agency screened, edited, augmented, or changed.

There will inevitably be situations where information offered by multiple parties in a product value chain will be different. It is not helpful to the public for OEHHA to simply post, as is, facially inconsistent or even contradictory information. OEHHA should develop a deliberate and disciplined process to reconcile inconsistencies so that accurate and reliable information is presented. In our view, the better approach is set out in the first part of this discussion – OEHHA should reconsider the burden of administering the website in the first place and its relative value (or opportunity for confusion) to the public.

Any disclaimer should also be considered in the context of OEHHA’s broader obligation to conduct a peer review of the scientific basis for the regulations. OEHHA may seek to post scientific information that has not been peer reviewed, published, or otherwise validated or conducted in accordance with accepted scientific principles; if so (and assuming that this is consistent with OEHHA’s peer review obligation, which it may not be), this may be suitable for inclusion in a disclaimer.

\*\*\*

We appreciate the opportunity to comment. We strongly urge OEHHA to rescind or remove outright the “List of 12” proposal embodied in Proposed Section 25602, the “no dilution proposal” in Proposed Section 25600(d), and the website proposal in Proposed Section 25205.

Respectfully submitted,

A handwritten signature in black ink that reads "Michael P. Walls". The signature is written in a cursive, flowing style.

Michael P. Walls  
Vice President  
Regulatory & Technical Affairs

## APPENDIX A: DI(2-ETHYLHEXYL) PHTHALATE (DEHP)

OEHHA cites a number of scientific references it “relied upon” in selecting the “phthalates” category. However, including di(2-ethylhexyl) phthalate (DEHP) under the generically broad category of “phthalates,” as proposed by Section 25602 of the January 2015 draft regulation does not satisfy any of the five criteria “considered” by OEHHA.

### A. DEHP BACKGROUND

DEHP was listed as a chemical known to the State of California to cause cancer under Proposition 65 on January 1, 1988 (and later listed as a chemical known to the State to cause male developmental toxicity on October 24, 2003).<sup>1</sup> Initially, OEHHA adopted a No Significant Risk Level (NSRL) for DEHP of 80 µg/day based upon identification of male mice as the most sensitive sex and species for a hepatocarcinogenic effect, using a cancer potency value calculated by the U.S. Environmental Protection Agency (EPA) in 1986.<sup>2</sup> The current NSRL for DEHP is 310 µg/day.<sup>3</sup>

In its January 2015 ISOR, with respect to DEHP, OEHHA cited an outdated report prepared by its Pesticide and Environmental Toxicology Section from December 1997.<sup>4</sup> At that time, OEHHA adopted a public health goal (PHG) for DEHP of 12 parts per billion (ppb) in drinking water, calculated based on a linear method.<sup>5</sup> The PHG was based on research and studies (e.g., by the National Toxicology Program (NTP), International Agency for Research on Cancer (IARC), and the California Department of Health Services (DHS)) showing sufficient evidence for carcinogenicity and adverse reproductive and development effects in male and female B6C3F1 mice and F344 rats.

However, this 1997 PHG was superseded in June 2001 by a report prepared by OEHHA’s Reproductive and Cancer Hazard Assessment Section, indicating that carcinogenic hazards on mice and rats do not imply similarly carcinogenic hazards on people because of species differences between rodents and humans.<sup>6</sup> Accordingly, OEHHA amended the NSRL for DEHP, raising it to 300 µg/day based on science demonstrating that humans are less sensitive to DEHP than are rodents (i.e., mice and rats).<sup>7</sup>

The principal justification for raising the NSRL for DEHP was based on recognition by OEHHA that rodents are more sensitive to the effects of peroxisomal proliferating agents than humans. Evidence for species differences includes studies showing that DEHP has no effect on primate liver at levels well

<sup>1</sup> [http://www.oehha.ca.gov/prop65/prop65\\_list/Newlist.html](http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html).

<sup>2</sup> [http://www.oehha.ca.gov/prop65/law/pdf\\_zip/dehpnsrl.pdf](http://www.oehha.ca.gov/prop65/law/pdf_zip/dehpnsrl.pdf).

<sup>3</sup> <http://oehha.ca.gov/prop65/getNSRLs.html>. Current list of safe harbor levels dated August 2013. For DEHP, the intravenous MADLs for (i) adults, (ii) infant boys (age 29 days to 24 months), and (iii) neonatal infant boys (0 to 28 days) are respectively 4,200 µg/day, 600 µg/day, and 210 µg/day. The oral MADLs for the same three groups are respectively 410 µg/day, 58 µg/day, and 20 µg/day.

<sup>4</sup> Public Health Goal for Di(2-ethylhexyl) Phthalate (DEHP) in Drinking Water, available at [http://oehha.ca.gov/water/phg/pdf/dehp\\_c.pdf](http://oehha.ca.gov/water/phg/pdf/dehp_c.pdf).

<sup>5</sup> *Id.*

<sup>6</sup> No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen Di(2-ethylhexyl) Phthalate, available at [http://www.oehha.ca.gov/prop65/law/pdf\\_zip/dehpnsrl.pdf](http://www.oehha.ca.gov/prop65/law/pdf_zip/dehpnsrl.pdf).

<sup>7</sup> *Id.* at 2.

above effect levels in rodents (Kurata et al., 1998;<sup>8</sup> Pugh et al., 2000<sup>9</sup>). Comparative studies between rodent and human hepatocytes also reflect these same species differences (Elcombe and Mitchell, 1986;<sup>10</sup> Butterworth et al., 1989;<sup>11</sup> Bichet et al., 1990;<sup>12</sup> Dirven et al., 1993;<sup>13</sup> Elcombe et al., 1996;<sup>14</sup> Hasmall et al., 1999;<sup>15</sup> Hildebrand et al., 1999;<sup>16</sup> Goll et al., 1999;<sup>17</sup> Hasmall et al., 2000<sup>18</sup>). Based on these studies, OEHHA raised the DEHP NSRL value, finding that the species differences should be taken into account for human health risk assessment.

## B. SCIENTIFIC EVIDENCE DOES NOT SUPPORT OEHHA'S LISTING OF PHTHALATES SUCH AS DEHP AS CARCINOGENIC TO HUMANS

In its 2001 analysis, OEHHA calculated the DEHP cancer potency using a linear (non-threshold) model, basing this decision on the fact that cellular receptors (in rodents) may normally be saturated by endogenous ligands so that any amount of DEHP could have an additive effect. OEHHA's use of a linear model, however, ignores the basic physiological differences between rodents and humans with respect to blood levels of natural ligands (Vamecq and Latruffe, 1999<sup>19</sup>). Human hepatocytes do not increase metabolism of fatty acids to the extent that rodent hepatocytes do. Thus natural ligands are not likely to have an additive effect on DEHP exposures in humans. By applying a linear model, OEHHA incorrectly assumed that rodent-specific effects of DEHP exposure are applicable to humans. There is no

<sup>8</sup> Kurata, Kidachi, Yokoyama, Toyota, Tsuchitani, and Katoh. *Subchronic Toxicity of Di(2-ethylhexyl)phthalate in Common Marmosets: Lack of Hepatic Peroxisome Proliferation, Testicular Atrophy, or Pancreatic Acinar Cell Hyperplasia*. Toxicological Sciences. 42(1): 49-56 (1998), available at <http://toxsci.oxfordjournals.org/content/42/1/49.full.pdf>.

<sup>9</sup> Pugh, Isenberg, Kamendulis, Ackley, Clare, Brown, Lington, Smith, and Klaunig. *Effects of Di-isooctyl Phthalate, Di-2-ethylhexyl Phthalate, and Clofibrate in Cynomolgus Monkeys*. Toxicological Sciences. 56(1): 181-188 (2000), available at <http://toxsci.oxfordjournals.org/content/56/1/181.long>.

<sup>10</sup> Elcombe and Mitchell. *Peroxisome Proliferation Due to Di(2-ethylhexyl) Phthalate (DEHP): Species Differences and Possible Mechanisms*. Environmental Health Perspectives. 70: 211-219 (1986), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1474294/pdf/envhper00441-0199.pdf>.

<sup>11</sup> Butterworth, Smith-Oliver, Earle, Loury, White, Doolittle, Working, Cattley, Jirtle, Michalopoulos, and Strom. *Use of Primary Cultures of Human Hepatocytes in Toxicology Studies*. Cancer Research. 49: 1075-1084 (Mar. 1, 1989), available at <http://cancerres.aacrjournals.org/content/49/5/1075.short>

<sup>12</sup> Bichet, Cahard, Fabre, Remandet, Gouy, and Cano. *Toxicological Studies on a Benzofuran Derivative. III. Comparison of Peroxisome Proliferation in Rat and Human Hepatocytes in Primary Culture*. Toxicology and Applied Pharmacology, 106(3): 509-517 (Dec. 1990), available at <http://www.ncbi.nlm.nih.gov/pubmed/2260097>.

<sup>13</sup> Dirven, Van den Broek, Arends, Nordkamp, de Lepper, Henderson, and Jongeneelen. *Metabolites of the Plasticizer Di (2-ethylhexyl) Phthalate in Urine Samples of Workers in Polyvinylchloride Processing Industries*. International Archives of Occupational and Environmental Health. 64(8): 549-554 (Jan. 1993), available at <http://link.springer.com/article/10.1007/BF00517699>

<sup>14</sup> Elcombe, Bell, Elias, Hasmall and Plant. *Peroxisome Proliferators: Species Differences in Response of Primary Hepatocyte Cultures*. Annals of the New York Academy of Sciences. 804: 628-635 (Dec. 1996), available at <http://onlinelibrary.wiley.com/doi/10.1111/nyas.1996.804.issue-1/issuetoc>.

<sup>15</sup> Hasmall, James, Macdonald, West, Chevalier, Cosulich, and Roberts. *Suppression of Apoptosis and Induction of DNA Synthesis In Vitro by the Phthalate Plasticizers Monoethylhexylphthalate (MEHP) and Diisooctylphthalate (DINP): A Comparison of Rat and Human Hepatocytes In Vitro*. Archives of Toxicology. 73(8-9): 451-456 (Dec. 1999), available at <http://link.springer.com/article/10.1007/s002040050634>.

<sup>16</sup> Hildebrand, Schmidt, Kempka, Jacob, Ahr, Ebener, Goretzski, and Bader. *An in vitro Model for Peroxisome Proliferation Utilizing Primary Hepatocytes in Sandwich Culture*. Toxicology in Vitro. 13: 265-273 (1999), available at [http://www.uni-leipzig.de/~bader/departement/staff/publikationen/1999/in%20vitro%20model%20for%20peroxisome\\_1999.pdf](http://www.uni-leipzig.de/~bader/departement/staff/publikationen/1999/in%20vitro%20model%20for%20peroxisome_1999.pdf).

<sup>17</sup> Goll, Alexandre, Viollon-Abadie, Nicod, Jaeck, and Richert. *Comparison of the Effects of Various Peroxisome Proliferators on Peroxisomal Enzyme Activities, DNA Synthesis, and Apoptosis in Rat and Human Hepatocyte Cultures*. Toxicology and Applied Pharmacology, 160(1): 21-32 (1999), available at <http://www.sciencedirect.com/science/article/pii/S0041008X99987379>.

<sup>18</sup> Hasmall, James, Macdonald, Soames, and Roberts. *Species Differences in Response to Diethylhexylphthalate: Suppression of Apoptosis, Induction of DNA Synthesis and Peroxisome Proliferator Activated Receptor Alpha-mediated Gene Expression*. Archives of Toxicology. 74(2): 85-91 (Apr. 2000), available at <http://link.springer.com/article/10.1007/s002040050657#page-1>.

<sup>19</sup> Vamecq and Latruffe. *Medical Significance of Peroxisome Proliferator-Activated Receptors*. The Lancet. 354(9173): 141-148 (Jul. 10, 1999), available at <http://www.sciencedirect.com/science/article/pii/S0140673698103641>.

justification for application of a linear model to the nongenotoxic peroxisomal proliferation response in rodents; risk assessment for peroxisomal proliferation should utilize a threshold (non-linear) method (Fenner-Crisp, 1996;<sup>20</sup> Cattley et al., 1998;<sup>21</sup> CPSC, 2001;<sup>22</sup> Willhite, 2001<sup>23</sup>). The use of a threshold model to assess risk of peroxisomal proliferation would yield a much higher NSRL value than 300 µg/day.

C. OEHHA'S OWN CITED SCIENTIFIC REFERENCES DO NOT SUPPORT A LISTING OF DEHP SPECIFICALLY OR PHTHALATES IN GENERAL

In addition, OEHHA references the National Institutes of Health (NIH) Tox Town website,<sup>24</sup> which provides general information on phthalates. The website notes that the human health effects of phthalates are not yet fully known and that the NTP listed DEHP as “reasonably anticipated to be a human carcinogen” in its 13th Report on Carcinogens. Further, Tox Town provides phthalate information links to the Agency of Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC). Both of these sources indicate that while phthalates have affected laboratory animals, the human health effects from exposure are unknown.<sup>25</sup> Further, ATSDR specifically notes,

At the levels found in the environment, DEHP is not expected to cause harmful health effects in humans. Most of what we know about the health effects of DEHP comes from studies of rats and mice given high amounts of DEHP. Harmful effects in animals generally occurred only with high amounts of DEHP or with prolonged exposures. Moreover, absorption and breakdown of DEHP in humans is different than in rats or mice, so the effects seen in rats and mice may not occur in humans.<sup>26</sup>

Moreover, IARC has stated that DEHP cannot be classified as to its carcinogenicity to humans.<sup>27</sup>

The Food and Drug Administration (FDA) – also referenced by OEHHA – has noted that it is “not clear what effect, if any, phthalates have on human health.”<sup>28</sup> An expert panel convened from 1998 to 2000 by the NTP concluded that reproductive risks from exposure to phthalates were minimal to negligible in most cases. No data reviewed by the FDA established an association between use of phthalates in cosmetic products and a health risk. Thus, the FDA determined there was not a “sound, scientific basis” to support taking regulatory action against cosmetics containing phthalates.

Neither the studies nor reports available and “relied upon” by OEHHA warrant the target listing of “phthalates” as proposed by Section 25602. Federal agencies have repeatedly acknowledged insufficient data to confirm phthalates – in general – have detrimental human effects. Past assumptions of

<sup>20</sup> Fenner-Crisp. *Regulatory Implications: U.S. Environmental Protection Agency*. Annals of the New York Academy of Science. 804: 636-640 (Dec. 1996), available at <http://onlinelibrary.wiley.com/doi/10.1111/j.1749-6632.1996.tb18650.x/abstract>.

<sup>21</sup> Cattley, DeLuca, Elcombe, Fenner-Crisp, Lake, Marsman, Pastoor, Popp, Robinson, Schwetz, Tugwood, and Wahli. *Do Peroxisome Proliferating Compounds Pose a Hepatocarcinogenic Hazard to Humans?* Regulatory Toxicology and Pharmacology. 27(1): 47-60 (Feb. 1998), available at <http://www.sciencedirect.com/science/article/pii/S0273230097911636>.

<sup>22</sup> Bogen, Chronic Hazard Advisory Panel on DINP. Report to the U.S. Consumer Product Safety Commission. (June 2001), available at <http://www.cpsc.gov/PageFiles/98260/dinp.pdf>.

<sup>23</sup> Willhite. *Weight-of-evidence Versus Strength-of-evidence in Toxicologic Hazard Identification: Di (2-ethylhexyl) Phthalate (DEHP)*. Toxicology. 160: 219-226 (2001), available at <http://www.ask-force.org/web/Seralini/Wilhite-Weight-Evidence--versus-Strengh-Evidence-2001.pdf>.

<sup>24</sup> [http://toxtown.nlm.nih.gov/text\\_version/chemicals.php?id=24](http://toxtown.nlm.nih.gov/text_version/chemicals.php?id=24).

<sup>25</sup> [http://www.cdc.gov/biomonitoring/Phthalates\\_FactSheet.html](http://www.cdc.gov/biomonitoring/Phthalates_FactSheet.html).

<sup>26</sup> <http://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=377&tid=65>.

<sup>27</sup> *Id.*

<sup>28</sup> <http://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm128250.htm#health>.

the carcinogenicity of DEHP in rodents has been distinguished by studies indicating those effects would not be the same in humans. Literature also affirms that hazard effects experienced by rodents only occurred through prolonged exposure or high dosages of DEHP, neither of which reflects human exposures. Thus, the availability of information on DEHP is in direct opposition to OEHHA's criterion ("General availability of additional authoritative information and resources for the public on the toxicity and exposure to the chemical"), allegedly used to justify a specific listing for phthalates. OEHHA has failed to provide evidentiary support for identifying phthalates, including DEHP, as a category of chemicals that must be included in the text of a Proposition 65 warning.

**Additional References for Di(2-ethylhexyl) Phthalate (DEHP) Not Used by OEHHHA**

- [1] Choi, Joo, Campbell, Clewell, Andersen, and Clewell. *In Vitro Metabolism of Di(2-ethylhexyl) Phthalate (DEHP) by Various Tissues and Cytochrome P450s of Human and Rat*. *Toxicology In Vitro*. 26: 315-322 (2012), available at <http://www.sciencedirect.com/science/article/pii/S0887233311003183>. (Study aimed to determine relative contribution of hepatic and extrahepatic biotransformation of DEHP in humans and rats. Hepatic hydrolytic activity toward DEHP in rats is considerably greater than in humans.)
- [2] Staples, Adams, Parkerton, Gorsuch, Biddinger, and Reinert. *Aquatic Toxicity of Eighteen Phthalate Esters*. *Environmental Toxicology and Chemistry*. 16(5): 875-891 (1997), available at . <http://onlinelibrary.wiley.com/doi/10.1002/etc.5620160507/full>.
- [3] Cousins and Mackay. *Correlating the Physical–Chemical Properties of Phthalate Esters Using the 'Three Solubility' Approach*. *Chemosphere*. 41(9): 1389-1399 (Nov. 2000), available at <http://www.sciencedirect.com/science/article/pii/S0045653500000059>.

## APPENDIX B: DIISODECYL PHTHALATE (DIDP)

OEHHA cites a number of scientific references it “relied upon” in selecting the “phthalates” category, which presumably includes diisodecyl phthalate (DIDP). However, none of these documents, and none of OEHHA’s articulated criteria, support the inclusion of DIDP. Moreover, the fact that DIDP does not pose potential significant exposure via human interactions with products or locations frequented by the public directly contradicts one of the criteria.

### A. DIDP BACKGROUND

DIDP is mainly used as a plasticizer in polyvinyl chloride, and also used in rubbers, anti-corrosion paints, anti-fouling paints, sealing compounds, and textile inks. On April 20, 2007, OEHHA listed DIDP as a chemical known by the State of California to cause developmental toxicity under Proposition 65 via the Authoritative Bodies Mechanism pursuant to Title 22, California Code of Regulations, Section 12306.<sup>1,2</sup> OEHHA provided only one reference to support its listing of DIDP:<sup>3</sup> a study conducted by the National Toxicology Program (NTP)<sup>4</sup> Center for the Evaluation of Risks to Human Reproduction (CERHR)<sup>5</sup> in April 2003 on the potential human reproductive and developmental effects of DIDP.<sup>6</sup>

In its *Monograph on the Potential Human Reproductive and Developmental Effects of Di-Isodecyl Phthalate (DIDP)*, NTP-CERHR indicated that DIDP can possibly affect human development or reproduction. Specifically:

Although there is no direct evidence that exposure of people to DIDP adversely affects reproduction or development, studies with rats have shown that exposure to DIDP can cause adverse developmental effects, but it does not affect reproduction . . . . [R]ecognizing the lack of human data and the evidence of effects in laboratory animals, the NTP judges the scientific evidence sufficient to conclude that DIDP is a developmental toxicant and could adversely affect human development if the levels of exposure were sufficiently high. The scientific evidence indicates that DIDP will not adversely affect human reproduction.<sup>7</sup>

<sup>1</sup> [http://oehha.ca.gov/prop65/prop65\\_list/didp042007.html](http://oehha.ca.gov/prop65/prop65_list/didp042007.html). Title 22, Section 12306 has now been renumbered as Title 27, Section 25306.

<sup>2</sup> On August 26, 2004, ACC’s Phthalate Esters Panel (“Panel”) submitted comments in response to OEHHA’s Request for Relevant Information dated May 28, 2004. Further, on May 24, 2005 the Panel submitted comments in response to OEHHA’s Notice of Intent to List Chemicals dated March 4, 2005. ACC herein incorporates by reference the Panel’s 2004 and 2005 comments in full.

<sup>3</sup> See [http://oehha.ca.gov/prop65/CRNR\\_notices/admin\\_listing/intent\\_to\\_list/noilpkg21.html](http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/noilpkg21.html).

<sup>4</sup> Title 27, Section 25306 identifies the National Toxicology Program, solely as to final reports of the NTP’s Center for Evaluation of Risks to Human Reproduction, as an “authoritative body” for the identification of chemicals as causing reproductive toxicity.

<sup>5</sup> CERHR is now merged under the National Institute of Environmental Health Sciences (NIEHS) as part of the National Institutes of Health (NIH).

<sup>6</sup> National Toxicology Program – Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR, 2003e). *NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Di-Isodecyl Phthalate (DIDP)*, NIH Publication 03-4485 (Apr. 2003), available at [http://ntp.niehs.nih.gov/ntp/ohat/phthalates/didp/didp\\_monograph\\_final.pdf](http://ntp.niehs.nih.gov/ntp/ohat/phthalates/didp/didp_monograph_final.pdf) (last accessed on Apr. 1, 2015).

<sup>7</sup> *Id.* at 1.

NTP-CERHR further acknowledged that the DIDP exposure levels used in rodent studies were “generally far higher than those experienced by people,” and “[a]lthough no data are available on general population exposures to DIDP, its chemical properties and uses make it unlikely that human exposures are any greater than to DEHP.” NTP-CERHR offered the following conclusions, based on the assumption that the general U.S. population is exposed to DIDP at less than 30 µg/kg body weight/day:<sup>8</sup>

- There is minimal concern for developmental effects in fetuses and children.
- There is negligible concern for reproductive toxicity in exposed adults.

In April 2010, OEHHA set the maximum allowable dose level (MADL) for DIDP at 2,200 µg/day.<sup>9</sup> This value was calculated based on the developmental effects of DIDP as observed in the two-generation reproductive toxicity study in rats by Exxon Biomedical Sciences Incorporated (EBSI, 2000),<sup>10</sup> assuming a body weight of 58 kg for a pregnant woman. The MADL is derived from a No Observable Effect Level (NOEL)<sup>11</sup> based on the most sensitive study “deemed to be of sufficient quality.”<sup>12</sup> In its assessment, OEHHA only reviewed five animal studies<sup>13</sup> as cited by the NTP-CERHR monograph because “[t]he literature search conducted by OEHHA found no additional studies.” OEHHA acknowledged that “no relevant human data on the development effects of DIDP were identified.” From the EBSI study, OEHHA extracted a NOEL of 38 µg/kg/day as the appropriate basis for calculating the MADL.

**B. NTP-CERHR FOUND MINIMAL TO NEGLIGIBLE RISK OF HUMAN REPRODUCTIVE TOXICITY; ESTIMATED EXPOSURES TO DIDP ARE FAR BELOW OEHHA’S MADL OF 2,200 µG/DAY**

In finding minimal to negligible concern for human effects from DIDP, NTP used the conservative assumption that exposures would be less than the 3-30 µg/kg/day the NTP-CERHR Expert Panel deterministically estimated for DEHP. This is conservative because DIDP has a lower vapor pressure and water solubility than DEHP. Biomonitoring data from the Centers for Disease Control and Prevention (CDC)<sup>14</sup> indicate that exposures to DEHP are actually less than 3 µg/kg/day, and DIDP

<sup>8</sup> *Id.* at 2-3.

<sup>9</sup> [http://oehha.ca.gov/prop65/CRNR\\_notices/not042310.html](http://oehha.ca.gov/prop65/CRNR_notices/not042310.html).

<sup>10</sup> Exxon Biomedical Sciences Incorporated (EBSI, 2000). Two generation reproduction toxicity study in rats with MRD-94-775. Project Number: 1775355A. East Millstone, NJ: ExxonMobil Chemical Company, Inc.; ExxonMobil Chemical Europe, Inc.

<sup>11</sup> The NOEL is defined as the highest dose level which results in no observable reproductive effect expressed in milligrams of chemical per kilogram of bodyweight per day.

<sup>12</sup> OEHHA, Proposition 65 Proposed Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Diisodecyl Phthalate (DIDP). California EPA (April 2010) [http://www.oehha.ca.gov/Prop65/CRNR\\_notices/pdf\\_zip/DIDPMADLfinalrisk042310.pdf](http://www.oehha.ca.gov/Prop65/CRNR_notices/pdf_zip/DIDPMADLfinalrisk042310.pdf).

<sup>13</sup> (1) Hardin BD, Schuler RL, Burg JR, Booth GM, Hazelden KP, MacKenzie KM, Piccirillo VJ, Smith KN (1987). Evaluation of 60 chemicals in a preliminary developmental toxicity test. *Teratogen Carcinogen Mutagen* 7, 29-48; (2) Hellwig J, Freudenberger H, Jackh R (1997). Differential prenatal toxicity of branched phthalate esters in rats. *Food Chem Toxicol* 35, 501-512; (3) Waterman SJ, Ambroso JL, Keller LH, Trimmer GW, Nikiforov AI, Harris SB (1999). Developmental toxicity of diisodecyl and diisononyl phthalates in rats. *Reprod. Toxicol.* 13, 131-6; (4) Exxon Biomedical Sciences Incorporated (EBSI, 1997). Two generation reproduction toxicity study in rats with MRD-94-775. Project Number: 177535. East Millstone, NJ: Exxon Chemical Company; Exxon Chemical Europe, Inc.; and (5) EBSI, 2000, see *supra* note 10.

<sup>14</sup> CDC (2001). National Report on Human Exposure to Environmental Chemicals. U.S. Centers for Disease Control and Prevention (available at <http://www.cdc.gov/nceh/dls/report/default.htm>); CDC (2003). Second National Report on Human Exposure to Environmental Chemicals. U.S. Centers for Disease Control and Prevention (available at [www.cdc.gov/exposurereport](http://www.cdc.gov/exposurereport)). See also Blount, B.; Silva, M.; Caudill, S.; Needham, L.; Pirkle, J.; Sampson, E.;

exposures would be expected to be yet lower. Therefore, the concern for human reproductive or developmental effect should be even less than that expressed by the NTP-CERHR. Moreover, in a study by Kransler et al., 2013,<sup>15</sup> estimates of average human exposure based on urinary concentrations of DIDP metabolites are generally <1 µg/kg/day. This level of DIDP exposure is, again, far below the no observed adverse effect levels identified in animals (15–38 µg/kg/day) and also at least 2 orders of magnitude below health-based exposure guidance values identified by regulatory authorities and other authoritative bodies as acceptable levels; one for the general population and another specific for pregnant women and women of reproductive age.

A primary purpose of Proposition 65 listing is for consumers to be informed of potential hazards from chemicals in the products they use. Yet data demonstrate that exposures to DIDP are highly unlikely to result in the need for warnings, which brings into question the need to list DIDP in the first place, let alone including DIDP in the generic “phthalates” category as proposed in Section 25602. OEHHA cites a NOEL of 38 µg/kg/day (or an MADL of 2,200 µg/day assuming a pregnant woman with the body weight of 58 kg) but analysis of CDC data reveals that even in the 95th percentile of DIDP exposure, the measured level only ranges from 0.17-0.79 µg/kg/day (or 9.9-46 µg/day for a 58 kg pregnant woman). This is two orders of magnitude below OEHHA’s MADL.

Given that scientific data strongly suggest that reproductive and developmental effects seen in rodents treated with phthalates like DIDP are not relevant to humans (or at least much more refractory in humans), that NTP-CERHR found reproductive and developmental effects in humans from DIDP to be minimal to negligible, and that the level of exposure to DIDP would unlikely require a Proposition 65 warning, it makes little sense to incorporate DIDP in a “phthalates” category as proposed Section 25602.

---

Lucier, G.; Jackson, R.; and Brock, J. (2000). Levels of seven urinary phthalate metabolites in a human reference population. *Environmental Health Perspectives* 108:979-982; Kohn, M.; Parham, F.; Masten, S.; Portier, C.; Shelby, M.; Brock, J.; and Needham, L. (2000). Human exposure estimates for phthalates. *Environmental Health Perspectives* 108:2000;A440-442; Silva, M., Barr, D., Reidy, J., Malek, N., Hodge, C., Caudill, S., Brock, J., Needham, L., and Calafat, A. (2004). Urinary Levels of Seven Phthalate Metabolites in the U.S. Population from the National Health and Nutrition Examination Survey (NHANES) 1999-2000. *Environ. Health Perspec.* 112:331-338.

<sup>15</sup> Kransler, Bachman, and McKee. Estimates of Daily Di-isodecyl Phthalate (DIDP) Intake Calculated from Urinary Biomonitoring Data, *Regulatory Toxicology and Pharmacology*. 65(2013): 29-33.

## APPENDIX C: DIISONONYL PHTHALATE (DINP)

While OEHHA cites a number of documents it “relied upon” in selecting “phthalates” to be included in Section 25602, none of these documents support the inclusion of diisononyl phthalate (DINP) or satisfy the five criteria “considered” by OEHHA. In fact, inclusion of DINP contradicts OEHHA’s criterion that a listed chemical have the potential for significant exposure through human interactions with products. Nonetheless, since DINP is listed under Proposition 65, presumably it would be included in the “phthalates” category.

### A. DINP BACKGROUND

DINP is primarily used to soften or “plasticize” vinyl. In December 2013, the Carcinogen Identification Committee (CIC) recommended that OEHHA list DINP under Proposition 65. OEHHA subsequently listed DINP as a chemical known to the State of California to cause cancer on December 20, 2013, with its Proposition 65 warning requirement becoming effective December 20, 2014.<sup>1</sup>

On December 19, 2014, OEHHA issued an Initial Statement of Reasons (ISOR) for a proposed regulatory amendment to adopt a No Significant Risk Level (NSRL) for DINP of 146 µg/day “based on carcinogenicity studies conducted in rodents.”<sup>2</sup> In developing the proposed NSRL for DINP, OEHHA exclusively relied on an October 2013 report on the evidence of DINP carcinogenicity prepared by its Reproductive and Cancer Hazard Assessment Branch for purposes of the December 2013 CIC meeting (referred to as a Hazard Identification Document, or HID).<sup>3</sup> The HID purported to summarize available data from rodent carcinogenicity studies of DINP, as well as other information relevant to the carcinogenic activity of DINP.

In the October 2013 HID, OEHHA based DINP carcinogenicity primarily on four two-year diet studies conducted in male and female Fischer 344 (F344) rats, reported by Lington et al. (1997)<sup>4</sup> and Moore (1998a),<sup>5</sup> as reviewed by the U.S. Consumer Product Safety Commission (CPSC), 2001<sup>6</sup>). Other similar studies were conducted on Sprague-Dawley (SD) rats (Bio/dynamics et al., 1986,<sup>7</sup> as reviewed by CPSC, 2001) and B6C3F1 mice (Moore, 1998b,<sup>8</sup> as reviewed by CPSC, 2001). To calculate the NSRL,

<sup>1</sup> [http://www.oehha.org/PROP65/CRNR\\_notices/list\\_changes/122013P65list.html](http://www.oehha.org/PROP65/CRNR_notices/list_changes/122013P65list.html).

<sup>2</sup> [http://www.oehha.ca.gov/prop65/law/pdf\\_zip/121914\\_ISORA\\_25903.pdf](http://www.oehha.ca.gov/prop65/law/pdf_zip/121914_ISORA_25903.pdf).

<sup>3</sup> Reproductive and Cancer Hazard Assessment Branch, OEHHA, California EPA, Evidence on the Carcinogenicity of Diisononyl Phthalate (DINP), Oct. 2013, available at [http://www.oehha.ca.gov/Prop65/hazard\\_ident/pdf\\_zip/DINP\\_HID100413.pdf](http://www.oehha.ca.gov/Prop65/hazard_ident/pdf_zip/DINP_HID100413.pdf).

<sup>4</sup> Lington, A., et al. 1997. Chronic Toxicity and Carcinogenic Evaluation of Diisononyl Phthalate in Rats. *Fundamental and Applied Toxicology*. 36: 79-89, available at <http://toxsci.oxfordjournals.org/content/36/1/79.full.pdf>.

<sup>5</sup> Moore, M. 1998a. Oncogenicity study in rats with di(isononyl)phthalate including ancillary hepatocellular proliferation and biochemical analyses. Covance Laboratories Incorporated, Vienna, VA 22182. May 13, 1998. Covance 2598-104.

<sup>6</sup> Consumer Product Safety Commission. 2001. Report to the US Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP), available at <http://www.cpsc.gov/PageFiles/98260/dinp.pdf>.

<sup>7</sup> Bio\dynamics, Inc. 1986. A chronic toxicity carcinogenicity feeding study in rats with Santizer 900. Submitted to Monsonato Company by Bio\dynamics, Inc. Project No. 81-2572. June 20, 1986.

<sup>8</sup> Moore, M. 1998b. Oncogenicity study in mice with di(isononyl) phthalate including ancillary hepatocellular proliferation and biochemical analyses. Covance Laboratories Incorporated, Vienna, VA 22182. January 29, 1998. Covance 2598-105.

OEHHA used a default approach that relied on a linearized multistage model and, together with the U.S. Environmental Protection Agency's Benchmark Dose Software (BMDS),<sup>9</sup> which derived maximum likelihood estimates (MLE), calculated an animal cancer potency estimate for each of the four studies. Human cancer potency was then estimated by an interspecies scaling procedure and calculated to be 0.0048 µg/kg/day, which yielded a proposed NSRL of 146 µg/day.<sup>10</sup>

**B. SCIENTIFIC EVIDENCE DOES NOT SUPPORT OEHHA'S INCLUSION OF DINP IN SECTION 25602 BECAUSE IT IS NOT CARCINOGENIC TO HUMANS**

Under Proposition 65, animal carcinogens may not be listed where evidence demonstrates that the observed animal cancers are not relevant to people. "Cancer" as referred to in Proposition 65 means cancer in people, not substances carcinogenic only to animals. While reliance on animal testing is often useful and necessary, where evidence shows that animals and humans differ physiologically in significant ways, extrapolation to humans from animal studies is not appropriate.

A substantial body of scientific data and extensive evaluation of DINP by multiple regulatory bodies in the U.S. and Europe have concluded that rodent tumors associated with DINP are not induced in humans.<sup>11</sup> Moreover, no relationship between DINP exposure and cancer in humans has been demonstrated during its worldwide use in the last five decades.

The HID, on which OEHHA relied in proposing the NSRL of 146 µg/day, prefaces the findings of carcinogenicity studies in animals with the statement, "No carcinogenicity studies in humans were found in the published literature or referenced in government documents."<sup>12</sup> The HID further acknowledged that DINP has not been classified as to its potential (human) carcinogenicity by the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), the National Toxicology Program (NTP), the National Institute for Occupational Safety and Health (NIOSH), or the International Agency for Research on Cancer (IARC).<sup>13</sup> The U.S. Consumer Protection Safety Commission's Chronic Hazard Advisory Panel (CHAP) on DINP concluded in 2001 that "[t]he findings of mononuclear cell leukemia and renal tubular carcinoma in the rodent bioassay for DINP are of questionable relevance to humans."<sup>14</sup>

The U.S. EPA concluded with a "high degree of confidence" that tumors in rats resulting from the accumulation of alpha 2u-globulin in rat kidneys are not relevant to people because people do not produce alpha 2u-globulin.<sup>15</sup> DINP also satisfied IARC's criteria for determining whether cancer observed in male rats resulted from the alpha 2u-globulin mechanism, thus indicating DINP rat carcinogenicity is irrelevant to humans,<sup>16</sup> namely (1) lack of genotoxicity, (2) cancer limited to male rats, (3) alpha 2u-globulin accumulation in tubular cells, (4) reversible binding of DINP to alpha 2u-globulin, (4) sustained

<sup>9</sup> <http://www.epa.gov/NCEA/bmnds/index.html>.

<sup>10</sup> Details of the calculations are explained both in the ISOR, see *supra* note 2, and HID, see *supra* note 3.

<sup>11</sup> See, e.g., CPSC Toxicity Review of Diisononyl Phthalate (DINP) (Apr. 7, 2010), available at <http://www.cpsc.gov/PageFiles/126539/toxicityDINP.pdf>.

<sup>12</sup> HID, at 11.

<sup>13</sup> *Id.* at 62.

<sup>14</sup> CPSC, 2001, at 122.

<sup>15</sup> U.S. EPA. 1991. Alpha2u-globulin: Association with chemically induced renal toxicity and neoplasia in the male rat. EPA/625/3-91/019F. Risk Assessment Forum, U.S. Environmental Protection Agency, Washington, D.C., available at <http://www.epa.gov/osainter/raf/publications/alpha2u-globulin.htm>.

<sup>16</sup> See IARC Scientific Publications No. 147. International Agency for Research on Cancer, Lyon (1998). Available at <http://monographs.iarc.fr/ENG/Publications/pub147/IARCpub147.pdf>.

increased cell proliferation in the adrenal cortex, (5) similarities in dose response between tumor incidence and other outcomes like protein droplet accumulation and alpha 2u-globulin accumulation, and (6) induction of characteristic sequence of histopathological changes with protein droplet accumulation.

Tumors observed in rodents also do not support carcinogenic characteristics in humans because people and rodents have different physiologies. DINP is a peroxisome proliferator, i.e., a chemical that increases the number and size of peroxisomes, which are subcellular structures in the liver. Liver cancer observed in rodents exposed to high levels of DINP results from peroxisome proliferation, but liver cancer resulting from peroxisome proliferation is not relevant to humans.<sup>17</sup>

Mononuclear cell leukemia (MNCL) occurs spontaneously at a high level in Fischer 344 rats, which suggests that the increase in MNCL is species and strain-specific, and not relevant to people.<sup>18</sup> The only other species involved in DINP MNCL studies – mice – showed no increase in MNCL rates, which also suggests the effect is limited to Fischer 344 rats.<sup>19</sup> This, too, suggests that MNCL incidence has no relevance to people.

C. ESTIMATED EXPOSURES TO DINP IN CONSUMER PRODUCTS IS SO MINIMAL, IT IS UNLIKELY TO EXCEED EVEN OEHHHA'S OVERLY CONSERVATIVE NSRL OF 146 µG/DAY

ACC has calculated predicted exposure levels, including, where applicable, oral, dermal,<sup>20</sup> and/or inhalation<sup>21</sup> exposures, for four common scenarios:

- 1) consumer wearing PVC dishwashing gloves;
- 2) consumer exposure to vinyl flooring;
- 3) consumer installation of electric wiring; and
- 4) consumer installation of wall paper.

Using conservative assumptions, including, but not limited to, exposure time, all four scenarios result in exposure levels less than OEHHHA's proposed NSRL of 146 µg/day:

<sup>17</sup> See CHAP, 2001, at 122; IARC. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 77; Some Industrial Chemicals. World Health Organization. Lyon, France (2000), at 124, available at <http://monographs.iarc.fr/ENG/Monographs/vol77/mono77.pdf>.

<sup>18</sup> See, e.g., Lington et al., 1997; ECB (2003). European Chemicals Bureau: 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich and di-"isononyl" phthalate (DINP), CAS Nos: 68515-48-0 and 28553-12-0, EINECS Nos: 271-090-9 and 249-079-5, Summary Risk Assessment Report, Special Publication I.03.101, at 18. Available at <http://echa.europa.eu/documents/10162/0645f0cb-7880-4d23-acea-27b05ed7de39>.

<sup>19</sup> See Moore, 1998b.

<sup>20</sup> The dermal absorption rate for DEHP is cited as 0.24 µg/cm<sup>2</sup>/hour. (Deisinger. 1998. A combined in vitro/in vivo model for estimating dermal absorption of di(2-ethylhexyl) phthalate (DEHP) in man from contact with PVC film. Food and Chemical Toxicology. 36: 521-527.) However, DINP is absorbed ten times less rapidly than DEHP through rat skin (European Chemicals Agency (ECHA). 2013. Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to REACH Regulation (EC) No. 1907/2006. ECHA-13-R-07-EN. ISBN 978-92-9244-001-5) and human skin is four times less permeable than rat skin (Scott, et al. 1987. In Vitro Absorption of some o-phthalate diesters through human and rat skin. Environmental Health Perspectives. 74: 223-227; Mint et al. 1994. Percutaneous Absorption of Diethyl Phthalate through rat and human skin in vitro. Toxicology In Vitro. 8: 251-256). Based on the DEHP dermal absorption rate, with an adjustment factor for human skin, the DINP dermal absorption rate is 0.006 µg/cm<sup>2</sup>/hour.

<sup>21</sup> Given its low volatility, DINP has been measured indoors only in a few studies. A compilation of data sources gives a mean indoor concentration for DINP of 0.011 µg/m<sup>3</sup>. (Clark, et al. 2011. Modeling human exposure to phthalate esters: a comparison of Indirect and Biomonitoring Estimation methods. Human and Ecological Risk Assessment: An International Journal. 17(4): 923-965.) This concentration, along with an assumed average breathing rate of 20 m<sup>3</sup>/day for adults, results in an average daily exposure of 0.22 µg/day of DINP.

<b>Example</b>	<b>Estimated Exposure <i>μg/day</i></b>
1. consumer wearing PVC gloves	16
2. consumer exposure to vinyl flooring	29.4
3. consumer installation of electric wiring	0.4
4. consumer installation of wall paper	10

## **APPENDIX D: CONSUMER CONFUSION OVER PRODUCT SAFETY FROM EXISTING PROPOSITION 65 SAFE HARBOR WARNINGS**

Limited web searches suggest consumers do not know how to interpret the P65 warning and create confusion on the threshold question of whether the product is safe for use.

- Prop 65 labels, should I be concerned?

I was recently shopping on Hot Topic's website and after coming across a backpack I wanted to purchase I noticed a product notice for the state of California stating that the product contains harmful chemicals that may cause cancer/ birth defects. I know this is just an advisory, and the product may or may not have dangerous level of chemical in it, but I'm not really familiar with this. I'm a bit concerned, but I know this label has been listed on other products. Should I be concerned? I don't intend on chewing on or getting my mouth near it, but it's still unsettling. Any insight or knowledge on this is appreciated.

<https://answers.yahoo.com/question/index?qid=20110724003657AAmvaAW>

- My shoes have a prop 65 warning. Should I return them?

Hey all. I really appreciate the help. I ordered some T.U.K. heeled shoes, and they are fake leather. When they came, I saw that the bottom of the shoe has the classic Prop 65 label:

"Proposition 65 warning: this product contains chemicals known in the state of California to cause cancer and/or birth defects or other reproductive harm."

This obviously freaked me out a little bit. I definitely don't want cancer...and I have not have children yet, so it'd be nice to avoid the other part too.

I read up on Prop 65 and its history a little bit, but I still don't have a definitely answer. Will using this fake leather shoe and wearing it once in a while actually hurt ME? Should I return these?

I know this is trivial, but I adore the shoes and have wanted them forever. So I want to be sure. Thanks!

<https://answers.yahoo.com/question/index?qid=20111103220154AAJYThu>

- Proposition 65 Warning on Nautica Luggage, is it safe to use?

I just bought Nautica Luggage, and noticed this warning label attached: "WARNING: This product contains a chemical known to the State of CA to cause cancer. This product contains a chemical known to the Sate of CA to cause birth defects or other reproductive harm."

What the heck does this mean? I live in Maryland so does this even apply to me? Is it safe to keep/use?

<https://answers.yahoo.com/question/index?qid=20101023135920AA2qJyU>

## APPENDIX E: SELECTED CITATIONS OF SCIENTIFIC LITERATURE ON WARNINGS AND RISK COMMUNICATION

### I. Research on Target Audience, Their Knowledge or Level of Experience, and Context Yield Better Consumer Comprehension

- Wogalter et al 1987. Communication of a potential hazard may be more important than the provision of very specific information regarding nature and severity of hazard. [David W. Stewart & Ingrid M. Martin, Intended and Unintended Consequences of Warning Messages: A Review and Synthesis of Empirical research, 13 J. Pub. Poly' & Marketing (1994)]
- Relevant to do research on the comprehension of warning messages. Pyrczak and Roth 1976. [Stewart & Martin]
- Fischhoff 1993. People differ in how they interpret. There should be more focus on context effects. Depends on how knowledgeable an individual is. [Stewart & Martin]
- There has been “woefully inadequate” further research on design of warnings. But research thus far suggests that caution be exercised in the design and use of warnings. At a minimum, empirical research should be carried out on proposed formats and contents. [Stewart & Martin]
- Understanding how consumers evaluate everyday risks associated with consumer products would provide a basis for developing more effective warnings. [Stewart & Martin]
- To ensure risk messages are not distorted/appear to be distorted, those who manage the generation of risk assessments and messages should ... (2) consider review by recognized independent experts ... (3) subject draft messages ... to outside preview to determine if audiences detect any overlooked distortions. [Committee on Risk Perception and Communication, National Academy of Sciences, Improving Risk Communication (1989)].
- Research has shown that warnings can communicate benefits and risks to consumers successfully, but only if they are appropriately designed for target audience. [Baruch Fischhoff, Communicating Risks and Benefits: An Evidence-Based User's Guide, Food and Drug Administration, August 2011]
- To have effective consumer communication, 1] Determine from experts what information is most critical to understanding how risk is created and communicated, i.e. what matters? 2] Assess consumers' current beliefs regarding those facts. 3] Design messages focused on the critical gaps between what consumers know and what they need to know. 4] Consumer testing should be used to evaluate effectiveness of those messages in closing the gaps. 5] develop and evaluate a delivery mechanism capable of drawing actual consumers' interest. [Fischhoff, FDA Evidence-Based User's Guide.]
- Question of acceptable level of comprehension has been addressed in ANSI Z535 (2002). Standard suggests an acceptability criterion of 85% correct comprehension. [Laughery & Wogalter, Designing Effective Warnings]
- When audience was sophisticated, differences between hazard and risk were played out. But when audience was less knowledgeable, the “hazard” and “risk” are used interchangeably. Less knowledgeable the audience, greater confusion. The nature of hazards and risks under consideration must be put into context. Consumers or product users may misread and miscomprehend risk warnings or labels so that, through ignorance, they expose themselves to a larger risk than necessary. [E. Ulbig et al., editors, Evaluation of Communication on the Differences Between “Risk” and “Hazard,” Final Report, Federal Institute of Risk Assessment, Berlin 2010]

- More person knows about risk, more likely that person is to change their risk judgment and more likely that person is to follow warnings. (Viscusi et al. 1984.) [Ulbig et al., Federal Institute of Risk Assessment, Berlin 2010]
- Just presenting/sharing risk information is an inadequate goal. Want to change what people think, or change their behavior. [Fischhoff, FDA User's Guide]
- Hazard designations such as “carcinogenic” do not say anything about the actual risk; don't provide information about actual exposure. Good risk communication is dependent on scientific risk characterization which meets the quality criteria transparency, clarity, consistency and substantiation. [Ulbig et al., Federal Institute of Risk Assessment, Berlin 2010]

## **II. Effective Warning Provide Necessary Information at Relevant Times but in Manageable Quantities**

- In context of health/medical treatments: describing risks solely with words is ineffective. Does not provide details needed to make informed decisions. Increases risk perceptions. Should provide numerical estimates of risk. Simply providing information is not enough. Research suggests that, when provided information does not convey effective meaning, consumers are unable to use that information. [Fischhoff, FDA Evidence-Based User's Guide.]
- In three studies, researchers tested whether providing lay decision makers with less information, rather than more, could result in the best outcomes. Studies show that requiring less cognitive effort in hospital quality reports resulted in better decision making through improved comprehension and higher quality choices. (Peters E, Dieckmann NF, Dixon A, Hibbard JH, Mertz CK. Less is more in presenting quality information to consumers. *Medical Care Research and Review*. 2007; 64(2):169-190.) [Fischhoff, FDA Evidence-Based User's Guide.]
- Sheer omnipresence of warnings may undermine any single warning's effectiveness. A communication is adequate if most users can extract enough information to make sound choices. [Fischhoff FDA User Guide]
- Studies suggest that cognitive decision making skills actually degrade when consumers are overwhelmed with too much information. On this view, Prop 65 warnings are so commonplace that Californians will “dismiss them as white noise.” [35 Whittier L. Rev. 27 (2013)]
- Many everyday supermarket items contain some of the listed chemicals. Thus, a Prop 65 warning will not be unique as consumers peruse the aisles; over warning will abound and defeat the health benefits of Prop 65. Overwarning will (i) increase public anxiety or (ii) promote consumer ambivalence. [Wake Forest L. Rev. 367 (1989)]

## **III. Use of Accurately Researched and Well-Known Symbols Could Be Helpful**

- Urzic 1984. Use of pictures, larger letters, and words has no effect on either recall of warning or perceptions of safety. [David W. Stewart & Ingrid M. Martin, *Intended and Unintended Consequences of Warning Messages: A Review and Synthesis of Empirical research*, 13 *J. Pub. Poly' & Marketing* (1994)]
- Collins, Lerner, Pierman 1982. Symbols may be more effective than written communication when those symbols have well-known meanings. Without well-known meaning, it may fail to communicate potential for hazard, or communicate the opposite of what is intended. [Stewart & Martin]
- Pictorials that directly represent the information are preferred. Pictorials that require inference or learning are less likely to be recognized or understood. E.g., skull-and-crossbones are often accompanied by the signal word “poison.” [Laughery & Wogalter, *Designing Effective Warnings*]

- Pictorial should NOT communicate incorrect information, i.e., minimize probability of misinterpretation. Information should be provided at level of specificity or explicitness that will enable people to make informed judgments and decisions. Warnings should be presented when and where the information is needed. If warning is presented too distant from hazard in terms of location and time, people may not recognize connection or may not remember hazard. [Laughery & Wogalter]

#### **IV. Consumer Attendance and Response to Warning Labels or Communication of Hazard and/or Risk Vary**

- Consumers may not understand a warning or find it credible, or may choose not to act on a warning after evaluating the costs and benefits of complying, particularly if consequences of not complying are more distant in time, or if they believe themselves more careful or more skilled than the average consumer. [David W. Stewart & Ingrid M. Martin, Intended and Unintended Consequences of Warning Messages: A Review and Synthesis of Empirical research, 13 J. Pub. Poly' & Marketing (1994)]
- FTC study on efficacy of warnings on tobacco products. Consistently found very low percentages of adults who, when exposed to cigarette advertising, read the warning label. [Stewart & Martin]
- But other studies show consumers pay attention to particular warnings. U.S. Department of HHS 1987. Contradictory results suggest attributes of warnings and the target audience is relevant. [Stewart & Martin]
- Effectiveness of warnings depends on how consumers make trade-offs between potentially harmful consequences and costs/benefits of a given behavior. Consumers discount consequences more distance in the future. [Stewart & Martin]
- McCarthy et al 1984. Limited research demonstrates some consumers persist in potentially harmful activities when they are aware of the potentially harmful consequences. Orwin and Schucker 1984, 1983. Warning labels for saccharin. Sales of products declined over time, but so did the influence of the warning. [Stewart & Martin]
- Hyland Birrell 1979. England study found presence of warnings on cigarette packages increased desire to smoke among housewives who smoked, but had no effect on nonsmoking housewives. [Stewart & Martin]
- Even when individuals read and comprehend warnings, they often do not change their behavior in response to the information they receive. [Clifford Rechtschaffen, The Warning Game: Evaluating Warnings under California's Proposition 65, Ecology Law Quarterly (Mar. 1996); also Committee on Risk Perception and Communication, National Academy of Sciences, Improving Risk Communication (1989)]
- Different ways of presenting the same facts can create different impressions. When a risk estimate is uncertain, it can be described by a point or "maximum likelihood" estimate or by a range of possibilities around the point estimate. But estimates that include a wide range of uncertainties can imply that a disastrous consequence is "possible," even when expert opinion is unanimous that the likelihood of disaster is extremely small. The amount of uncertainty to present is a judgment that can potentially influence a recipient's judgment. [Committee on Risk Perception and Communication]
- Consumers may fail to attend to warnings because: 1) inadequate measures of attention or recall, 2) warning information is not personally relevant, 3) consumers may be already familiar with information, 4) distracted from information, 5) desensitized after repeated exposures, especially alarms being more extreme than necessary or no immediate harm. [Fischhoff, FDA Evidence-Based User's Guide]
- Many consumers in test ignored "may contain" label (MCL). Some felt taking the risk was more preferable. Participants made sense of MCL with reference to different context in which they manage

their nut allergy. Others did not think “may contain” was credible and thus ignored. [Barnett et al, Using ‘may contain’ labeling to inform food choice: a qualitative study of nut allergic consumers, BMC public health 2011]