

July 17, 2008

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*Via Email and Overnight Delivery*

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Re: Response to Request for Public Participation, Notice of Public Workshop,  
Proposition 65 Regulatory Update Project — Labor Code Mechanism Regulatory  
Concepts (“Request”)<sup>1</sup>

Dear Ms. Monahan-Cummings:

These comments are submitted on behalf of a coalition that represents companies that manufacture, distribute, and sell many of the foods, beverages, over-the-counter medications, nutritional supplements, and personal care products consumed or used by Californians every day (the “Coalition”) in response to the above-referenced Request.<sup>2</sup> The Coalition thanks OEHHA for extending until July 17, 2008 the time to respond.

## **I. INTRODUCTION AND SUMMARY**

While the Coalition generally applauds OEHHA’s efforts to review and update Proposition 65’s implementing regulations, it cannot, for several reasons, support the conceptual regulation set forth in the Request. First, OEHHA’s proposal is premised on a fundamental misreading of the statute—the belief that section 25249.8(a) mandates an automatic listing of chemicals without any requirement of public input or opportunity for OEHHA to consult with the State’s qualified experts on scientific issues before a listing decision is made.

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<sup>1</sup> *OEHHA*, Request for Public Participation, Notice of Public Workshop, Proposition 65 Regulatory Update Project - Labor Code Mechanism Regulatory Concept (May 16, 2008), available at <http://www.oehha.ca.gov/prop65/law/workshop051608.html>.

<sup>2</sup> The Coalition includes the Grocery Manufacturers Association, the Personal Care Products Council, the Consumer Healthcare Products Association, the American Beverage Association, the National Coffee Association, and the Council for Responsible Nutrition.

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OEHHA's interpretation is legally and logically untenable for the following reasons:

- it is contrary to the plain language of the statute and appellate court interpretation of that language;<sup>3</sup>
- it conflicts with the administrative history of Proposition 65 regulations implementing section 25249.8;
- it represents a radical change in OEHHA's own long-standing interpretation of the statute; and,
- it ignores the Governor's [OEHHA's] mandatory and ongoing duty under section 25249.8(d) to "consult with the state's qualified experts as necessary to carry out his [listing] duties" under the statute.

Second, the proposed new listing process is completely unnecessary. Any chemicals that could be listed pursuant to a proper incorporation of chemicals identified under Labor Code sections 6382(b)(1) or 6382(d) can be managed efficiently through the already-streamlined authoritative bodies mechanism, which imposes a limited burden on OEHHA. Indeed, unless a member of the public brings forth scientific evidence compelling enough to convince the Director of OEHHA to exercise her discretion to refer the matter to the state's qualified experts, listings through this mechanism are nearly automatic already.

Finally, even if OEHHA had the authority to adopt a regulation that expressly eliminates any possibility for consultation with the state's scientific experts during the listing process, such a policy seems to fly in the face of everything in which OEHHA takes pride: public input, sound science, and individual actions that produce a public benefit. OEHHA's conceptual regulation would bar the state's qualified experts from considering scientific information, *no matter how compelling*, demonstrating that a chemical should be listed subject to a qualifier, not listed at all, or delisted once it is added. It would also bar consideration of new scientific data obtained by anyone—OEHHA, the state's qualified experts or the public—calling into question the conclusions underlying the chemical's presence in the Labor Code.

It is difficult to see any public health benefit to OEHHA's proposed approach. Rather, the likely result will be either more litigation or, to avoid such litigation, an increase in defensive warnings on products even where the majority of scientists agree they pose no actual health risk. This result is contrary to the purpose of Proposition 65's "clear and reasonable

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<sup>3</sup> *AFL-CIO v. Deukmejian*, 212 Cal. App. 3d 425 (1989) ("*Duke P*").

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warning” requirement, and is inconsistent with the voters’ expectations when the statute was passed.<sup>4</sup>

## II. DISCUSSION

### A. Section 25249.8(A) Does *Not* Create a Current Mandatory Duty to Automatically List Chemicals From the Labor Code.

Section 25249.8 of Proposition 65 sets forth four mechanisms through which chemicals may be added to the list of carcinogens and reproductive toxicants governed by the statute. Subsection (a) describes how the first list—required to be published on March 1, 1987 (i.e., before the organization of a panel of qualified scientific experts)—was to be compiled. Specifically it utilizes lists already compiled under two sections of the California Labor Code at the time Proposition 65 was passed, so as to quickly and efficiently populate the initial list:

On or before March 1, 1987, the Governor shall cause to be published a list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter, and he shall cause such list to be revised and republished in light of additional knowledge at least once per year thereafter. Such list shall include at a minimum those substances identified by reference in Labor Code Section 6382(b)(1) and those substances identified additionally by reference in Labor Code Section 6382(d).<sup>5</sup>

Labor Code section 6382(b)(1) references chemicals identified as carcinogens by the U.N.’s International Agency for Research on Cancer (“IARC”).<sup>6</sup> Cal. Labor Code § 6382(d) references chemicals listed pursuant to the federal Hazard Communications Standard (“HCS”), under regulations found at 29 C.F.R. § 1910.1200.<sup>7</sup> The HCS includes known and probable carcinogens identified by IARC, substances identified as known or probable

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<sup>4</sup> *Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652, 661 (1992); Proposition 65 Voter Pamphlet, at 54 (“Proposition 65 singles out *chemicals that are scientifically known* to cause cancer or reproductive disorders such as birth defects. . . . Chemicals that are only suspect are not included.”) (emphasis added).

<sup>5</sup> Cal. Health & Safety Code § 25249.8(a).

<sup>6</sup> Cal. Labor Code § 6382(b)(1).

<sup>7</sup> *Id.* § 6382(d).

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carcinogens by the National Toxicology Program (“NTP”), and a few chemicals listed pursuant to the federal Occupational Safety and Health Act (“OSHA”).<sup>8</sup>

OEHHA’s proposal posits that section 25249.8(a) creates an ongoing non-discretionary duty to automatically list chemicals from each of these sources.<sup>9</sup> This is incorrect as a matter of law.

**1. The mandatory duty created in section 25249.8(a) pertains only to the initial list.**

Section 25249.8(a), in its language, by judicial interpretation, and with reference to other provisions of the statute, applies to the initial list only. OEHHA is correct that section 25249.8(a) conveys a mandatory duty.<sup>10</sup> However, OEHHA is mistaken about the *time* that the duty created in subsection (a) was owed.

The rules of statutory construction depend on ascertaining the intent of the drafters “so as to effectuate the purpose of the law.”<sup>11</sup> Where the language of a statute is susceptible to more than one interpretation, legislative intent

must be gathered from the terms of the statute construed as a whole, from the nature and character of the act to be done, and from the consequences which would follow the doing or failure to do the particular act at the required time.

*Cal. Corr. Peace Officers Ass’n v. State Pers. Bd.*, 10 Cal. 4th 1133, 1143 (1995) (internal quotations and citations omitted). Timing is critical to the understanding of Section 25249.8, which sets forth four mechanisms for adding chemicals to the list of carcinogens and reproductive toxicants governed by the statute. The first, quoted above, describes the chemicals that were required to be on the March 1, 1987 list.

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<sup>8</sup> 29 C.F.R. § 1910.1200.

<sup>9</sup> Request, at 1 (“[A]ll Chemicals or substances identified by reference to Labor Code sections 6382(b)(1) or 6382(d) as known to cause cancer or reproductive toxicity *must be* included on the Proposition 65 list.”) (emphasis added).

<sup>10</sup> *People v. Standish*, 38 Cal. 4th 858, 869 (2006).

<sup>11</sup> *Mejia v. Reed*, 31 Cal. 4th 657, 663 (2003).

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The other three mechanisms are found in subsection (b).<sup>12</sup> Two of these three mechanisms require that “the state’s qualified experts” be designated and have an opportunity to consider and provide their opinions. Specifically, these are the mechanisms for listing a chemical when: 1) “in the opinion of the state’s qualified experts it has been clearly shown through scientifically valid testing according to generally accepted scientific principles to cause cancer or reproductive toxicity,” or 2) “a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity.”<sup>13</sup> As a practical and historical matter, the number of chemicals listed by these two mechanisms far outnumber those listed by the “formally required to be labeled” mechanism.

Given the drafters’ requirement that the initial list be published within four months of the vote on Proposition 65, it is no surprise that the *first* list would be populated by reference to a list in being at the time. That is the only way it could have been compiled in such a short time period.

Subsection 25249.8(d) establishes another mandatory duty. This subsection requires that the Governor “*shall . . . consult with the state’s qualified experts as necessary to carry out his duties*” under section 25249.8.<sup>14</sup>

In the first Proposition 65 case to be decided by a California Court of Appeal, the court harmonized all of these provisions by concluding that the purpose of subsection (a) was to populate the *initial* list that was to be adopted in 1987.<sup>15</sup> As to this list, the mandate to add Labor Code chemicals was “etched in stone,” but the Governor and his scientific advisors were required to exercise discretion to determine subsequent listings.<sup>16</sup>

Proposition 65 was not intended to produce a one-time list of known carcinogenic chemicals, but rather requires revision of the initial list annually or even more frequently. Section

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<sup>12</sup> Subsection (b) says: “A chemical is known to the state to cause cancer or reproductive toxicity within the meaning of this chapter if in the opinion of the state’s qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity, or if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity, or if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity.” Cal. Health & Safety Code § 25249.8(b).

<sup>13</sup> Cal. Health & Safety Code § 25249.8(b).

<sup>14</sup> Cal. Health & Safety Code § 25249.8(d) (emphasis added).

<sup>15</sup> *Duke I*, 212 Cal. App. 3d at 440.

<sup>16</sup> *Id.*

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25249.8 subdivision (a) insures the minimum content of the initial list and section 25249.8(b) directs both [the Governor] *and* [his scientific experts] *to engage in a diligent, thorough and continuing search for additional chemicals which evolving scientific knowledge demonstrates are subject to the Act.* Viewed in this light, the provisions of section 25249.8, subdivisions (a) and (b) are not inconsistent, but complementary.<sup>17</sup>

As implied by this language and expressed in subsections (b) and (d), the state's qualified experts were intended to be the sources (or at least the gatekeepers) of the "additional knowledge" used in updating the original list.<sup>18</sup>

This is also the interpretation that proponents of Proposition 65 made to the voters in the ballot pamphlet prior to the election in which it was enacted. They told voters that the Governor would, under the Proposition, be required to list chemicals "*already listed as known carcinogens*" by IARC and NTP in 1986. It described other listings as follows:

Proposition 65's new civil offenses focus only on chemicals that are *known to the state* to cause cancer or reproductive disorders. Chemicals that are only suspect are not included. The Governor must list these chemicals, *after full consultation with the state's qualified experts.*<sup>19</sup>

The pamphlet further assured voters that determinations about carcinogenicity and reproductive toxicity would be based on "known" scientific risks: "Proposition 65 singles out chemicals that are *scientifically known* to cause cancer and reproductive disorders such as birth defects."<sup>20</sup>

**2. OEHHA's interpretation impermissibly bars the Governor from performing his mandatory role under section 25249.8(d).**

The Governor is required by section 25249.8(d) to consult with the State's qualified experts in carrying out his listing duties under the statute. OEHHA's interpretation disregards this language as well as *Duke I* by ignoring the prescribed roles of the Governor and his experts.

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<sup>17</sup> *Id.* (emphasis added).

<sup>18</sup> Cal. Health & Safety Code § 25249.8(d).

<sup>19</sup> Voter Pamphlet, at 54 (emphasis added).

<sup>20</sup> *Id.* (emphasis added).

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If the word “shall” creates a mandatory duty in subsection (a), it does so in subsection (d) as well, meaning that the Governor’s duty described therein—to consult with the state’s qualified experts as necessary to carry out his duties—is mandatory.<sup>21</sup>

Under California law, the word “necessary” has long meant “that which is reasonably convenient, and appropriate for carrying out the purposes” of a statute or contract.<sup>22</sup> In the context of determining the scope of government discretion, California courts have construed the term in favor of flexibility to allow the government to respond to changing circumstances.<sup>23</sup> As articulated by the court in *Duke I*, subsections (b) and (d) work together to require the Governor and his experts to respond to just such changing circumstances in the form of “evolving scientific knowledge.”<sup>24</sup> Viewed as a whole, the plain words of subsection (d) require the Governor, in doing what is needed to implement the listing provisions, to consult his experts.

**B. Even If OEHHA Has the Authority to Adopt a Rule Automatically Listing Labor Code Chemicals, There Is No Reason to Do So.**

Automatic listing of chemicals at this point (after the 1987 creation of the initial list) does not advance the purposes of the statute. OEHHA has stated that the purpose for this regulation was to clear up public confusion regarding what OEHHA believes to be its mandatory duty under section 25249.8(a). If this is the only reason for the proposed rulemaking, it will be entitled to little deference by a court, since it amounts to little more than an interpretation of a statutory provision.<sup>25</sup>

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<sup>21</sup> Cal. Health & Safety Code § 25249.8(d); *Standish*, 38 Cal. 4th at 870 (“Terms ordinarily possess a consistent meaning throughout a statute.”).

<sup>22</sup> *Danley v. Merced Irrigation Dist.*, 66 Cal. App. 97, 105 (1924); *San Francisco Fire Fighters Local 798 v. City and County of San Francisco*, 38 Cal. 4th 653, 671 (2006) (defining the term to mean “that which is ... convenient, useful, appropriate, suitable, proper or conducive” to the purposes of the statute at issue).

<sup>23</sup> *San Francisco Fire Fighters Local 798 v. City and County of San Francisco*, 38 Cal. 4th 653, 671 (2006); *Zack v. Marin Emergency Radio Authority*, 118 Cal. App. 4th 617, 663 (2004) (“Moreover, “[w]hat is indispensable to the attainment and maintenance of the declared objects and purposes of a municipality has been said to be subject to ‘change with changing circumstance . . . .’”).

<sup>24</sup> 212 Cal. App. 3d at 440.

<sup>25</sup> *Yamaha Corp. of America v. State Bd. of Equalization*, 19 Cal. 4th 1, 8 (1998) (“Considered alone and apart from the context and circumstances that produce them, agency interpretations are not binding or necessarily even authoritative. To quote the statement of the Law Revision Commission in a recent report, ‘The standard for judicial review of agency interpretation of law is the *independent*

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Even under the most deferential scope of review, a regulation must be “reasonably necessary” to effectuate the purpose of the statute it purports to implement.<sup>26</sup> Indeed, were OEHHA to propose a regulation, it would be required to publish an initial statement of reasons clearly explaining the reason and necessity for the regulation.<sup>27</sup> Other than the faulty legal interpretation already addressed in these comments, no such necessity has been articulated to date by the Agency or by any participants at the workshop held on June 17 in Oakland (“Workshop”). Nor does such necessity exist. In fact, the rule described in the Request is *not* necessary to effectuate the purpose of Proposition 65.

Any chemical that is properly incorporated through the Labor Code can be easily managed through the authoritative bodies mechanisms. The authoritative bodies process is efficient, streamlined, and nearly automatic already — perhaps too much so in some instances.

When OEHHA identifies a chemical for listing through the authoritative bodies mechanism, the burden shifts to the public to come forward with scientific evidence demonstrating that the listing should not proceed.<sup>28</sup> Based on that showing, OEHHA may refer the chemical to the state’s qualified experts on the Developmental and Reproductive Toxicants Identification Committee (“DART IC”) or the Carcinogen Identification Committee (“CIC”) for further scrutiny.<sup>29</sup> However, short of that, the process assures that the listing will proceed, saving OEHHA and the science panels time and resources.

As a result of this streamlined process, instances where such challenges resulted in a decision by the DART IC or the CIC not to list a chemical proposed for an authoritative bodies listing, or to list it with appropriate science-based qualifications, are rare. However, they *have* happened, always in instances where the is scientific evidence requires it.

For example, carbon black appears on the IARC list as a 2B chemical, or possible human carcinogen, based on “sufficient evidence” that it causes cancer in animals.<sup>30</sup> However, the opportunity for review built into the authoritative bodies listing process allowed OEHHA to

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*judgment* of the court, giving *deference* to the determination of the agency *appropriate* to the circumstances of the agency action.”).

<sup>26</sup> *Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d at 658 (“Where a statute empowers an administrative agency to adopt regulations, such regulations must be consistent, not in conflict with the statute, and reasonably necessary to effectuate its purpose.”).

<sup>27</sup> Cal. Govt. Code § 11350(b)(1).

<sup>28</sup> Cal. Code Regs., tit. 27, § 25306(l).

<sup>29</sup> *Id.*

<sup>30</sup> IARC, *Overall Evaluations of Carcinogenicity to Humans, Group 2B: Possibly carcinogenic to humans*, available at <http://monographs.iarc.fr/ENG/Classification/crthgr02b.php>.



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consider evidence that what IARC had actually reviewed and evaluated was a specific *form* of carbon black to which, as it happens, there is very little human exposure. The forms of carbon black that are virtually ubiquitous in consumer products are permanently bound up in a matrix, and have not been found to pose the risks identified by IARC.<sup>31</sup> The result was a qualified listing that correctly captures the nature of the chemical.

The ability to conduct such a review and to reflect it in a qualified listing was very important to furthering Proposition 65's goal of providing clear and reasonable warnings. Under the Labor Code mechanism proposed by OEHHA, both qualifications like that on carbon black and conclusions that the chemical should not be listed at all would be impossible. Had OEHHA's conceptual regulation been put into place, OEHHA would not have had the opportunity to review the data demonstrating that the form of carbon black found in consumer products poses no risk, and the chemical would be listed without a qualifier. Companies that sell products made with carbon black would have to provide warnings on these products for a non-existent health risk or risk being sued, an outcome that would have undermined the purpose of providing consumers with clear and reasonable warnings.<sup>32</sup>

As the Agency recognized, there may also be instances where information developed subsequent to listing by IARC or NTP demonstrates that the original conclusion regarding carcinogenicity was in error:

The science of hazard identification is not static. Studies relied upon today may, in the light of new data, be unreliable tomorrow. The identification of chemicals under the Act was intended by the voters to be based on scientific testing. It would make little sense to have chemicals listed under the Act where the data relied upon by an authoritative body is outdated and clearly contradicted by newer data. . . . [T]he regulatory implications of listing under the Act require a consideration of new data.<sup>33</sup>

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<sup>31</sup> OEHHA, *Notice to Interested Parties: Chemical Listed Effective February 21, 2003 as Known to the State of California to Cause Cancer*, (Feb. 21, 2003), available at [http://www.oehha.ca.gov/prop65/prop65\\_list/files/22103not.pdf](http://www.oehha.ca.gov/prop65/prop65_list/files/22103not.pdf).

<sup>32</sup> Cal. Health & Safety Code § 25249.6; *Nicolle-Wagner*, 230 Cal. App. 3d at 661.

<sup>33</sup> Final Statement of Reasons for Cal. Code Regs., tit. 22 § 12306 (February 1990) ("12306 FSOR"), at 20.

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OEHHA's concerns have been borne out by the facts. For example, saccharin was listed by IARC and NTP as a carcinogen.<sup>34</sup> On this basis, it was among the chemicals listed in 1989 by order of the court in *Duke I*.<sup>35</sup> However, subsequent to its listing, epidemiological and mechanistic data cast doubt on the relevance of animal data that caused saccharin to be classified by NTP as a probable carcinogen.<sup>36</sup> Thus, in response to a private entity's request to reconsider, NTP delisted the chemical in December 1998.

Under OEHHA's conceptual regulation, there would be no mechanism for the state's experts or agency staff to receive or consider new information about chemicals adopted by this automatic process, unless and until the original listing agency took action. That could be a long wait, as OEHHA acknowledged in connection with the provision of the authoritative bodies mechanism regulations allowing for post-listing review of new data: "The authoritative body . . . may not have a legal duty or need to expeditiously re-evaluate its conclusions in the light of new data, especially when its resources are limited."<sup>37</sup> In fact, although both IARC and NTP have "delisting" mechanisms, it sometimes takes years for each of them to decide to reevaluate a chemical, convene the appropriate review group, and publish the conclusions.

Precluding the opportunity to take recent scientific work into account in listing chemicals would mean that for some potentially extended period of time, California consumers would receive cancer or reproductive toxicity warnings that no longer have any scientific justification. This is contrary to the science-based determinations to which OEHHA has devoted itself, and inconsistent with what voters were promised.<sup>38</sup>

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<sup>34</sup> OEHHA, *Summary of Proposition 65 Activity* (August 15, 2001), available at <http://www.oehha.org/prop65/background/81601jdl.html>.

<sup>35</sup> *Id.*

<sup>36</sup> See, e.g., National Toxicology Program, Appendix B, Agents, Substances, Mixtures, or Exposure Circumstances Delisted from Report on Carcinogens, Report on Carcinogens, Eleventh Edition (2000), available at <http://ntp.niehs.nih.gov/ntp/roc/eleventh/append/appb.pdf>.

<sup>37</sup> 12306 FSOR, at 20, discussing 12306(f).

<sup>38</sup> Voter pamphlet, at 55 ("Proposition 65 is based strictly on scientific testing, more than any existing toxics law."). Moreover, forcing a company to provide warnings to consumers about non-existent risks raises constitutional issues. First, the First Amendment of the U.S. Constitution forbids the State from compelling a company to provide warnings that contain false information. Compelled speech may be permissible only where the government is acting to require disclosure of "purely factual and uncontroversial information" necessary to prevent the commercial speech at issue from misleading consumers. See *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985) (emphasis added). However, a compelled statement *that is false* cannot meet this exception. Indeed, the State can never establish a substantial interest in compelling Defendants to speak falsely. See

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**C. OEHHA'S Break With the *Duke I* Interpretation Is Inconsistent with Existing Proposition 65 Regulations, Past Agency Action, and the Conclusions of Its Qualified Experts.**

OEHHA's proposed actions are inconsistent with OEHHA's prior actions and regulations. Indeed, OEHHA expressed its current interpretation publicly for the very first time in the listing process in connection with the response to comments received in relation to listing "Areca Nut" and "Betel Quid without Tobacco" in 2005.<sup>39</sup>

The history of Proposition 65's implementing regulations does not support this recent view. As set forth in the *Duke I* case, the Governor appointed a panel of scientific experts in early 1987.<sup>40</sup> On February 27, 1987, the Governor published a list of 29 chemicals derived from the lists maintained under sections 6382(b)(1) and 6382(d) of the California Labor Code.<sup>41</sup> The chemicals on the Governor's list were limited to those designated by the agencies used as a source for Labor Code designation as "known" human carcinogens and reproductive toxicants.<sup>42</sup> *Id.* The Governor was sued, and the court held that he had an obligation to list all known human and animal carcinogens.<sup>43</sup>

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*McCauley v. Howard Jarvis Taxpayers Assn.*, 68 Cal. App. 4th 1255, 1259 n.4 (1998) ("Surely if the First Amendment precludes anything, it precludes compelled false speech."). Second, Proposition 65 warnings provided under these circumstances would conflict with — and be preempted by — the Federal Food, Drug, and Cosmetic Act ("FDCA"), which prohibits introducing into interstate commerce a food item which has a false or misleading label. 21 U.S.C. §§ 331, 343(a).

<sup>39</sup> See OEHHA, *Request For Comments on Proposed Listing of Areca Nut and Betel Quid Without Tobacco as Known to Cause Cancer* (October 21, 2005), available at [http://www.oehha.ca.gov/prop65/CRNR\\_notices/admin\\_listing/requests\\_info/pdf/Arecanutbetelnotice.pdf](http://www.oehha.ca.gov/prop65/CRNR_notices/admin_listing/requests_info/pdf/Arecanutbetelnotice.pdf); OEHHA, *Responses to Comments Received from the American Herbal Products Association (AHPA) Objecting to the Listing of "Areca Nut" and Betel Quid without Tobacco" as Known to Cause Cancer* (hereinafter, "Areca Nut Response to Comments"), available at [http://www.oehha.ca.gov/prop65/docs\\_admin/betel%20quid\\_areca%20nutresponses.pdf](http://www.oehha.ca.gov/prop65/docs_admin/betel%20quid_areca%20nutresponses.pdf).

<sup>40</sup> *Duke I*, 212 Cal. App. 3d at 432.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> *Id.* at 430. In the Areca nut proceedings, OEHHA characterized *Duke I* as determining that "all known and probable human carcinogens identified by IARC and NTP are presumed conclusively by HCS [federal Hazard Communication Standard] to be carcinogens and must be included on the initial list." See *Areca Nut Response to Comments*, at 3. This raises a question of whether chemicals characterized by IARC only as "possible" carcinogens fall within the holding of *Duke I*. The Coalition does not address this issue in these comments.

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In the years immediately following passage of Proposition 65, the Health & Welfare Agency (“HWA”), OEHHA’s predecessor and the agency charged with implementing the statute at that time, adopted several regulations, including those governing the authoritative bodies mechanisms established in section 25249.8(b).<sup>44</sup> Among other things, these early regulations reflect the decision by the Panel to designate NTP and IARC as authoritative bodies, despite the fact that the Labor Code sections used to populate the initial Proposition 65 list also refer to chemicals that have been identified as carcinogens and reproductive toxicants by IARC and NTP.<sup>45</sup>

In addition, HWA—with the assistance of the Governor’s science panel—set controls over which bodies could be designated “authoritative,” to ensure against “uncontrolled listing of chemicals.”<sup>46</sup> Among those controls were rules put in place to guarantee that the Agency and its qualified experts had access to new data that could change the listing determination.<sup>47</sup>

[T]he Panel has serious concerns that the listing of chemicals as the result of such a designation should be controlled. . . .

If the Panel has discretion in designating authoritative bodies, it may condition its designation. One of the Panel’s primary concerns is that the designation of authoritative bodies will result in the uncontrolled listing of chemicals. Therefore, to satisfy its own concerns, it makes sense for the Panel to condition its designation upon the application of suitable controls. This section simply affirms that this solution is available. . . . Thus, chemicals will be listed only in a controlled manner. . . .<sup>48</sup>

None of these actions is consistent with the position that section 25249.8(a) mandates continuing nondiscretionary listing of IARC and NTP chemicals. Had the Agency been of that view, it would not have adopted regulations designating these agencies as authoritative bodies, when those very regulations subject listing decisions to scientific challenge.<sup>49</sup>

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<sup>44</sup> 12306 FSOR.

<sup>45</sup> Cal. Code Regs., tit. 27 § 25306; 12306 FSOR, at 28 (the regulation governing authoritative bodies mechanism was adopted under title 22 of the Code of Regulations, but has been moved to title 27, along with all other Proposition 65 regulations).

<sup>46</sup> *Id.* at 2, 27.

<sup>47</sup> Cal. Code Regs., tit. 27, § 25306(f), (i).

<sup>48</sup> 12306 FSOR at 26-28.

<sup>49</sup> Cal. Code Regs., tit. 27 § 25306(i).

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Interpretations of a statute or regulation that render its provisions a nullity are to be avoided.<sup>50</sup> Similarly, the Panel's adoption of regulations adopted to address concerns about uncontrolled and scientifically insupportable listings is not consistent with an Agency interpretation of Proposition 65 that requires ongoing automatic, scrutiny-free listing of Labor Code chemicals.

Further, without reviewing the data underlying a decision by ACGIH to identify a chemical as a reproductive toxicant, OEHHA cannot be sure that the data addressing developmental toxicity were derived from studies involving prenatal exposures. Automatically listing ACGIH chemicals without such scrutiny is thus inconsistent with longstanding OEHHA policy.<sup>51</sup>

Finally, OEHHA's new interpretation is inconsistent with its failure to have ever listed a chemical based on its identification by the the American Conference of Government Industrial Hygienists ("ACGIH") as a carcinogen or reproductive toxicant. Indeed, after the Panel rejected ACGIH as an authoritative body, the issue of ACGIH chemicals does not appear to have entered into the conversation or in OEHHA's view of Proposition 65 listings until 2006, when a private organization petitioned OEHHA to list several reproductive ACGIH.<sup>52</sup>

For these reasons, it is surprising for OEHHA to argue that the public has misunderstood the Agency's position of Proposition 65 with respect to the Labor Code. While an administrative agency is free to change its interpretation, such a reversal should be clear and unambiguous. OEHHA and its predecessors did not invoke section 25249.8(a) or assert the meaning that OEHHA now claims for the provision for the first 19 years of the statute. The

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<sup>50</sup> *Troppman v. Valverde*, 40 Cal. 4th 1121, 1135 n.10 (2007).

<sup>51</sup> See, e.g., OEHHA, *Candidates for Proposition 65 Listing via the Authoritative Bodies Mechanism Found Not to Meet the Scientific Criteria* (22 CCR 12306(g)), at 3 (Mar. 19, 1999).

<sup>52</sup> 2006 Petition to OEHHA by Natural Resources Defense Counsel, available at <http://www.oehha.ca.gov/prop65/pdf/NRDCtoOEHHA121506.pdf>. The position taken in this petition was new, even for NRDC, who participated in several OEHHA workshops in 1998, in which neither OEHHA nor NRDC advocated for listing chemicals based on ACGIH identification. See, e.g., [http://www.oehha.ca.gov/prop65/public\\_meetings/698abwks.html](http://www.oehha.ca.gov/prop65/public_meetings/698abwks.html); <http://www.oehha.ca.gov/prop65/pdf/abslide.pdf>; [http://www.oehha.ca.gov/prop65/public\\_meetings/717ipltr.html](http://www.oehha.ca.gov/prop65/public_meetings/717ipltr.html); <http://www.oehha.ca.gov/prop65/pdf/727trans.pdf>; and <http://www.oehha.ca.gov/prop65/pdf/925trans.pdf>. The 2006 petition was not originally based on Labor Code listings, but rather on NIOSH as an authoritative body. NRDC later amended the petition <http://www.oehha.ca.gov/prop65/pdf/NRDCtoOEHHA121506.pdf> and used ACGIH Labor Code rationale for these 18 chemicals.

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authoritative bodies mechanism has evolved as *the* streamlined process for listing chemicals that have been studied by recognized federal and international scientific bodies.

The statute and its implementing regulations concerning listing have evolved over the past twenty years based on the nature of the statute, past activity by OEHHA and the panels, and public participation in rulemaking activity. OEHHA should exercise extreme caution in disrupting the system based on a shaky legal interpretation that is due very little deference by a court.<sup>53</sup>

**D. In Any Event, Section 25249.8(A) Applies Only to IARC and NTP Chemicals, *Not* To ACGIH Chemicals.**

OEHHA's conceptual language proposes to automatically list chemicals identified by the ACGIH because the Labor Code references the HCS, and because the HCS mentions ACGIH — just as it mentions IARC and NTP and OSHA chemicals. This is a misreading of the HCS, which does not treat ACGIH hazard identification with the same dignity provided to determinations by IARC, NTP, and OSHA. *Only* a chemical identified by IARC, NTP, and OSHA is designated under section 1910.1200(d)(1) as a carcinogen or reproductive toxicant under the HCS.<sup>54</sup>

**1. ACGIH is not considered a source for carcinogen or reproductive toxicant identification under the HCS.**

The HCS does not identify ACGIH as a definitive source for the identification of chemicals as either carcinogens or reproductive toxicants. Indeed, values identified by ACGIH are subject to a unique qualifier in the HCS. Specifically, employers are instructed not to rely on ACGIH's characterization of chemicals for inclusion in their hazard communication system without further investigation through use of materials derived from other sources: "The chemical manufacturer, importer, or employer *is still responsible for evaluating the hazards associated with the chemicals in these source lists in accordance with the requirements of this standard.*"<sup>55</sup>

To make this further evaluation, employers are directed to Appendix A, which "provides further definitions and explanations of the scope of health hazards covered by this section . . . ."<sup>56</sup> As to the two endpoints relevant to Proposition 65—carcinogenicity and

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<sup>53</sup> *Yamaha Corp. of America v. State Bd. of Equalization*, 19 Cal. 4th 1, 8 (1998).

<sup>54</sup> 29 C.F.R. § 1910.1200(d)(1).

<sup>55</sup> *Id.* § 1910.1200(d)(3)(ii) (emphasis added).

<sup>56</sup> *Id.* 1910.1200(c).

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reproductive toxicity—Appendix A specifically identifies only NTP and IARC carcinogens.<sup>57</sup> There is no corollary in Appendix A (or any other appendix) by which an employer can find a definitive identification verifying an ACGIH determination as to reproductive toxicants. Under this provision, chemicals identified by ACGIH that are also classified as carcinogens by IARC, NTP, or OSHA are carcinogens under the HCS. The same simply cannot be said for ACGIH characterizations with respect to reproductive toxicants.

Where the drafters of HCS wanted to definitively designate a source, they did so expressly. Section 1910.1200(d)(4) of the HCS expressly defines NTP, IARC, and OSHA as sources for the identification of carcinogens: “Chemical manufacturers, importers and employers evaluating chemicals shall *treat the following sources as establishing that a chemical is a carcinogen or potential carcinogen* for hazard communication purposes:

- (i) National Toxicology Program (NTP), “Annual Report on Carcinogens” (latest edition);
- (ii) International Agency for Research on Cancer (IARC) “Monographs” (latest editions); or
- (iii) 29 CFR part 1910, subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration.<sup>58</sup>

In other words, IARC, NTP, and OSHA are *the* listed sources for identification of carcinogens under the Labor Code. By contrast, ACGIH is not designated by the HCS as a definitive source “establishing that a chemical is a carcinogen or potential carcinogen”. While ACGIH characterizations are mentioned in the HCS rule, they are not mentioned in section 1910.1200(d)(1), the part of the HCS rule clearly identifying IARC, NTP and OSHA chemicals as carcinogens or reproductive toxicants. ACGIH is found only under section 1910.1200(d)(3), which classifies chemicals as “hazardous,” but doesn’t identify a particular endpoint. The number of hazards potentially covered by this designation extends well

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<sup>57</sup> 29 C.F.R. § 1910.1200 Appx. A.

<sup>58</sup> 29 C.F.R. § 1910.1200(4)(d) (emphasis added).

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beyond cancer or reproductive toxicity.<sup>59</sup> ACGHI is not identified as a definitive determinant for the identification for any of these endpoints without resort to other sources.<sup>60</sup>

HCS rules governing material safety data sheets (“MSDS”) provide further evidence that the HCS does not treat ACGIH as a definitive source for characterizations of carcinogenicity or reproductive toxicity.<sup>61</sup> Unlike IARC, NTP, and OSHA, the MSDS rules mention ACGIH only in the context of establishing permissible exposure levels, not for the identification of carcinogens or reproductive toxicants.<sup>62</sup> An OSHA MSDS, which instructs manufacturers to specifically incorporate lists of carcinogens, only incorporates IARC, NTP, and OSHA for any endpoints, not ACGIH.<sup>63</sup>

**2. Voters could not have understood or intended that ACGIH chemicals were to be automatically listed under the Labor Code.**

OEHHA’s proposal to include ACGIH in its Labor Code Listing regulations also runs afoul of what voters could have understood when they voted to enact Proposition 65. Indeed, ACGIH was unlikely to have been within the consciousness of voters who passed Proposition 65.

A voter initiative must be construed by ascertaining the meaning that an ordinary voter would have attached to the language of an initiative and the materials presented with it:

In the case of a voters’ initiative statute . . . we may not properly interpret the measure in a way that the electorate did not contemplate: *the voters should get what they enacted, not more and not less . . .*”<sup>64</sup>

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<sup>59</sup> *Id.* § 1910.1200(c) (“The term ‘health hazard’ includes chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic system, and agents which damage the lungs, skin, eyes, or mucous membranes.”).

<sup>60</sup> *Id.* § 1910.1200(d)(3)(ii).

<sup>61</sup> *Id.* § 1910.1200(g)(2)(vi). (referring to “OSHA permissible exposure limit, ACGIH Threshold Limit Value, *and any other exposure limit* used or recommended by the chemical manufacturer, importer, or employer preparing the material safety data sheet, where available . . .”) (emphasis added.)

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

<sup>63</sup> *Id.*

<sup>64</sup> *People v. Singleton*, 155 Cal. App. 4th 1332, 1339 (2007) (emphasis added).



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First, ACGIH is mentioned nowhere in the statute or in the ballot materials that accompanied it. The ballot pamphlet argument in favor of Proposition 65 mentions only IARC and NTP, characterizing them as “organizations of the most highly regarded national and international scientists” whose work would be reflected in the initial list.<sup>65</sup> Second, as discussed above, even if a voter had decided to track down HCS regulations from Labor Code section 6382(d), he or she would have seen only language that treated ACGIH as a screening provision.

Finally, the ACGIH lists were not publicly available. Even a highly motivated voter who read all of the ballot materials and attempted to review the materials cited in the initiative in order to make an informed vote would have been unable to acquire the list of ACGIH chemicals, which are available only through subscription..

For all of these reasons, voters would have been hard pressed to understand that ACGIH chemicals were to be included, and in any event, would have been unable to review the ACGIH list prior to casting her ballot.

### **3. OEHHA’s proposal is not supported by the *Duke I* case.**

The *Duke I* case neither compels nor provides authority for OEHHA’s proposal to incorporate ACGIH chemicals into Proposition 65. The court in *Duke I* did not analyze ACGIH chemicals because none were on the record before it. In fact, the plaintiff’s complaint in that case did not mention ACGIH at all.

The lower court decision in that case included an appendix containing all of the carcinogens and reproductive toxicants that plaintiff was demanding to add to the list pursuant to section 25249.8(a).<sup>66</sup> The appendix does not mention ACGIH or list any ACGIH chemicals.<sup>67</sup>

#### **E. Automatic Uncontrolled Listing of Chemicals Without Any Possibility for Further Scientific Scrutiny Is Bad Public Policy.**

At the Workshop, OEHHA’s Chief Counsel said that OEHHA did not intend for any rule that came out of this process to affect existing qualified listings. There is no language in the

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<sup>65</sup> Voter Pamphlet, at 54.

<sup>66</sup> The trial court’s opinion in *Duke I* is attached hereto as Exhibit A.

<sup>67</sup> *Id.*

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current draft that would prevent this result.<sup>68</sup> Squandering work already done by the Agency or the state's experts would be irresponsible.

Moreover, as explained above, OEHHA's proposal would tie the Agency's hands with respect to scientific evidence that should prevent listing or result in a qualified listing. The potential effects of these chemicals remaining on the Proposition 65 list are very real to companies doing business in California. Because these chemicals would still be on the list even after the science that caused it to be listed is known to be outdated or proven wrong, they would still be subject to the statute's warning requirement, and would therefore be fair game for lawsuits by private and public enforcers.<sup>69</sup>

As long as a plaintiff could find one scientist willing to testify in opposition to new studies, it could likely satisfy the certificate of merit requirement under the statute, survive the pleading stage of litigation, and possibly create enough of a factual dispute to escape summary judgment. Putting a warning on products containing any detectable amount of such chemical—even though the chemical should not be listed at all—would be the only protection against a protracted legal battle. In addition to placing unreasonable (and potentially unconstitutional) burdens on companies, such warnings would be misleading to the consumer and contrary to the “clear and reasonable warning” provision of the statute.<sup>70</sup>

### III. CONCLUSION

For all of the reasons stated above, the Coalition asks OEHHA not to proceed with this proposal. It is not required by law, it is unnecessary, and it is bad public policy.

Respectfully submitted,



Michele B. Corash

cc: Dr. Joan Denton  
Cynthia Oshita (via Email)

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<sup>68</sup> OEHHA, Request for Public Participation, Notice of Public Workshop, Proposition 65 Regulatory Update Project - Labor Code Mechanism Regulatory Concept (May 16, 2008), available at <http://www.oehha.ca.gov/prop65/law/workshop051608.html>.

<sup>69</sup> Cal. Health & Safety Code §§ 25249.6, 25249.7.

<sup>70</sup> Cal. Health & Safety Code § 25249.6.