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April 6, 2012

Ms. Cynthia Oshita  
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Submitted by e-mail: [P65Public.Comments@oehha.ca.gov](mailto:P65Public.Comments@oehha.ca.gov)

**RE: Notice of Intent to List (NOIL) Chemicals by the Labor Code Mechanism:  
Diethanolamine**

Dear Ms. Oshita:

The American Cleaning Institute (ACI)<sup>1</sup> appreciates the opportunity to provide comments on the *Notice of Intent to List Chemicals by the Labor Code Mechanism*, issued on January 20, 2012 by the California Office of Environmental Health Hazard Assessment (OEHHA). ACI members use Diethanolamine (DEA) and mixtures containing DEA in the cleaning products they manufacture and the ingredients supplied for those products.

ACI opposes the listing of Diethanolamine (DEA) on two fundamental grounds: 1) the weight of the scientific evidence demonstrates that DEA is not a human carcinogen and does not meet the listing criteria under Proposition 65; and, 2) the Office of Environmental Health Hazard Assessment (OEHHA) does not have the legal authority to list DEA pursuant to the Labor Code references.

Regarding the first point, carcinogenicity findings in studies using mice are not relevant to humans and are weakened by serious limitations in their design. ACI supports the comments of the Alkanolamines Panel of the American Chemistry Council (ACC) which present a review the pertinent studies in the context of criteria for listing under Proposition 65.<sup>2</sup>

Regarding the second point, OEHHA does not have the legal authority to list DEA pursuant to the Labor Code references based on the following observations.

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<sup>1</sup> The American Cleaning Institute (ACI) is a trade association representing the \$30 billion U.S. cleaning products industry. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers.

<sup>2</sup> American Chemistry Council, Letter to Cynthia Oshita, California Environmental Protection Agency, April 6, 2012.

- A. Health and Safety Code Section 25249.8 Limits the Labor Code References to the Initial List.
- B. OEHHA Cannot Predicate the Listing of DEA on Labor Code References Without Formally Adopting Its Interpretation As a Regulation In Accordance With the California Administrative Procedure Act.
- C. OEHHA's Refusal to Consider the Scientific Data With Respect to DEA Is Inconsistent With the Clear Intent of Proposition 65.
- D. OEHHA Admits That IARC Identification of a Chemical As a Carcinogen Does Not Occur Until the Monograph Is Released.
- E. Listing DEA Will Compel Companies to Provide False Warnings About Their Products, Violating Those Companies' First Amendment Rights.

The following sections provide more details on these scientific and legal grounds for rejecting the listing of DEA under Proposition 65.

### **I. DEA Is Not a Human Carcinogen.**

The following is a summary of the evidence demonstrating DEA is not a human carcinogen. Details on the studies supporting this conclusion are contained in the comments from the ACC to OEHHA.

Chronic (2 year) dermal exposure studies in rodents reported by the National Toxicology Program (NTP) in 1999 indicated that chronic dermal exposures to DEA (using ethanol as a vehicle) increased the incidence of liver tumors in male and female mice and kidney tumors in male mice. No tumors were observed in rats. In their report, NTP concluded, using their standard criteria, that there was *No Evidence* of carcinogenicity in male and female rats, and *Clear Evidence* of carcinogenicity in male and female mice

It is important that OEHHA recognize that the study findings in mice are not relevant to humans and are weakened by serious design limitations. Thus, they do not support listing under the criteria under Proposition 65.

#### A. Studies Demonstrate that the Mode of Tumorigenesis of DEA in Mice is not Relevant to Humans

The mechanistic data for DEA demonstrate that the mode of tumorigenesis in mice is not relevant to humans. Experimental evidence is consistent with a mode of action involving the development of intracellular choline deficiency. Since rodents are far more sensitive to choline deficiency than humans, the hepatocarcinogenic effect of DEA in mice is not predictive of similar susceptibility in humans.

Several potential non-genotoxic mechanisms of action have been considered for DEA: the disruption of choline metabolism, the disruption of phospholipid metabolism, and the *in-situ*

formation of nitrosodiethanolamine (NDELA). However, several independent research investigations support a weight of evidence conclusion that the carcinogenicity mechanism of action for DEA is the ability to induce a choline deficiency (disruption of choline metabolism) in the treated animals. Experimental evidence supporting this hypothesis is:

- DEA administration decreased the hepatic choline metabolites and S-adenosylmethionine levels in mice, similar to those observed in choline-deficient mice. In contrast, DEA had no effects in the rat, a species in which it was not carcinogenic at a *maximum* tolerated dose level.
- A consistent dose-response relationship has been established between choline deficiency and carcinogenic activity, since all DEA dosages that induced tumors in the NTP studies were also shown to cause choline deficiency in mice.
- DEA administration decreased phosphatidylcholine synthesis by blocking the cellular uptake of choline *in-vitro*, but these effects did not occur in the presence of excess choline.
- DEA administration induced transformation in the Syrian Hamster Embryo (SHE) cells, increased S-phase DNA synthesis in mouse hepatocytes, and decreased gap-junction intracellular communication in primary cultured mouse and rat hepatocytes. All of these effects were prevented with choline supplementation to the test system.

B. Limitations of the NTP Chronic Mouse Carcinogenicity Study Invalidate its Use as the Basis for Assessing DEA

OEHHA should not overlook the significant limitations of the NTP chronic mouse study of DEA, which was the basis for the 2011 IARC evaluation. The following are significant limitations in the NTP study:

*1. The dermal absorption of DEA for mice does not represent dermal absorption in humans*

In the NTP bioassays, carcinogenicity was observed in mice but not in rats. The difference in carcinogenic response in the rodents may be explained by differences in dermal absorption kinetics. Since DEA was more readily absorbed through the skin of mice than rats and the dosages employed in the NTP bioassays were higher in mice than rats, the total DEA exposure was markedly different between these two species. A no observed effect level for DEA-induced choline deficiency in mice has been established to be 10 mg/kg/d, and this indicates that there is a threshold level of DEA that must be reached in order to affect choline metabolism. The lack of a carcinogenic response in rats suggests that exposure to DEA did not reach this critical level. Since absorption of DEA across human skin had been demonstrated to be even less than observed in rats, the levels required to alter choline metabolism are not likely to be achieved following human exposures to DEA.

*2. A biologically active vehicle was used in the bioassays.*

In the NTP bioassays, ethanol was used as a vehicle for the dermal dosing of DEA, with a dermal dosage reaching as much as 1500 mg ethanol/kg/day. Bioavailability studies replicating the same dosing conditions as the NTP chronic bioassays demonstrate that such a dosage of ethanol would give rise to an ethanol body burden of about 50-62 mg/kg/day. Chronic ethanol ingestion has been shown to increase hepatic choline requirements. It is plausible that the hepatic effects of DEA observed in the NTP bioassay were exacerbated by the use of ethanol as a vehicle for DEA.

*3. The routes of administration were confounded*

The animals in the NTP bioassays had free access to the unoccluded dermal application site during normal grooming activities, and the effective DEA dosage would be a combination of both dermal and oral exposures, resulting in significantly increased blood DEA concentrations from dermal absorption and oral ingestion.

*4. Choline deficiency may have caused observed renal tubular adenomas*

While most of the experimental data has focused on the effects of DEA in the liver, it is conceivable that a similar mode of action involving choline deficiency is responsible for the renal tubular adenomas observed in the NTP bioassay. Choline deficiency is known to compromise renal functions and cause kidney toxicity in laboratory animals.

## **II. OEHHA Lacks Legal Authority to List DEA Under the Labor Code References.**

### A. Health and Safety Code Section 25249.8 Limits the Labor Code References to the Initial List.

*1. The Plain Language of Section 25249.8 Applies the Labor Code Listings Only to the Initial List.*

The Proposition 65 provisions that govern the listing of chemicals are set out in Health and Safety Code section 25249.8. Subdivisions (a) and (b) are the most relevant. They provide as follows:

(a) 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).

(b) 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.

The Office of Environmental Health Hazard Assessment (“OEHHA”) and others involved in the implementation and enforcement of Proposition 65 construed subdivisions (a) and (b) of Health and Safety Code section 25249.8 consistently with the court’s decision in *AFL-CIO v. Deukmejian*, 212 Cal.App.3d 425 (1989). In that case, the court was construing the relationship between subdivisions (a) and (b), and said:

“Proposition 65 was not intended to produce a one-time list of known carcinogenic chemicals, but rather requires a revisions of the initial list annually or even more frequently. (§ 25249.8, subd. (a).) Section 25249.8, subdivision (a), insures the minimum content of the initial list, and section 25249.8, subdivision (b) directs both defendant and the Panel 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.”

Hence, the universal understanding was that the references to the Labor Code in subdivision (a) applied to the initial list, and the initial list was to be updated, at least annually, based on additional knowledge as set out in subdivision (b). That interpretation persisted for over 15 years until OEHHA, for administrative convenience, began to propose listing actions relying directly on the references to the Labor Code provisions, thus giving this mechanism priority at the expense of the clear obligation of the State to consider “scientifically valid testing according to generally accepted principles.”

Today, OEHHA rationalizes its decision to use the Labor Code to update the initial list on the court’s decision in *California Chamber of Commerce v. Brown*, 196 Cal.App.4th 233 (2011). In that case, the Court of Appeal, First District, dismissed the Court of Appeal, Third District, decision in the *Deukmejian* case, saying that the issue in the *Deukmejian* case did not involve the question of whether the Labor Code references were to be used to upgrade the list. The First District Court, in a desire to reach a result, ignored the fact that the Third District Court, in the *Deukmejian* case was construing the relationship between subdivisions (a) and (b) in the context of adding chemicals to the Proposition 65 list and reached a logical result based on the plain meaning of the statutory language.

The First District Court also engaged in legal gymnastics with the statutory language to support its decision. The first sentence of subdivision (a) requires the Governor to publish a list of chemicals by March 1, 1987. The second sentence begins “Such list” shall include those chemicals identified by reference to the Labor Code. The plain meaning of the language is that “Such list” refers to the list the Governor is to publish by March 1, 1987. Yet, the First District

Court construed “Such list” to mean “the Proposition 65 list,” reading the March 1, 1987 date right out of the first sentence.

Further, the First District Court misconstrued a key portion of the ballot argument. The argument provides, “At a minimum, the Governor must include the chemicals **already** listed as known carcinogens by two organizations or most highly regarded national or international scientists: . . .” (Emphasis added.) The First District Court concluded that this language demonstrates an intent to continue to use the Labor Code references to add chemicals to the Proposition 65 list. That conclusion ignores the fact that the ballot argument states, “already listed.” It does not say simply “listed” or “listed now and in the future.” Modifying the word “listed” with “already” obviously demonstrates that the intent was to include those chemicals as they existed on the initial list, and not to use it 25 years later with chemicals that might be swept in subsequently under the Labor Code references.

Fortunately, the First District Court decision is binding only on trial courts in that district. Other trial courts may follow the Third District Court decision in the *Deukmejian* case and reach a decision contrary to the *Brown* decision. This is more likely, given the First District Court’s tortured reading of section 25249.8 and misreading of the ballot argument.

*2. The Ballot Argument In Favor of Proposition 65 Applies Section 25249.8(a) Only to the Initial List.*

The ballot argument stresses that Proposition 65 lists only those “certain chemicals known – *not merely suspected but known* – to cause cancer and birth defects.” The ballot argument continues:

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 suspected are not included. The Governor must list these chemicals, after full consultation with the state’s qualified experts. At a minimum, the Governor must include the chemicals already listed as known carcinogens by two organizations of the most highly regarded national and international scientists: the U.S.’s National Toxicology Program and the U.N.’s International Agency for Research on Cancer. [Original emphasis.]

Thus, the recent intent to list DEA defeats the clear intent provided to citizens of the State who supported Proposition 65 and sidesteps the responsibility of the State and the responsible agency to meet the expectations of those citizens prior to listing.

*3. Under OEHHA’s Long-Standing Interpretation of Section 25249.8, Only Subdivision (b) Authorizes Subsequent Listings.*

For many years, OEHHA acknowledged that subdivision (b) provides the only authority to “supplement the initial list.” This is important because courts give great weight and respect to an

administrative agency's interpretation of the statute that governs its powers and responsibilities.<sup>3</sup> (*County of Santa Barbara v. Connell* (1999) 72 Cal.App.4th 175, 185.) As the court explained in *Mason v. Retirement Bd. of City and County of San Francisco* (2003) 111 Cal.App.4th 1221, 1228:

Such deference is particularly warranted when an agency's interpretation is of long standing. (*Yamaha Corp. of America v. State Bd. of Equalization* (1998) 19 Cal.4th 1, 13.) This rule is supported by practical considerations. "When an administrative interpretation is of long standing and has remained uniform, it is likely that numerous transactions have been entered into in reliance thereon, and it could be invalidated only at the cost of major readjustments and extensive litigation." (*Whitcomb Hotel, Inc. v. Cal. Emp. Com.* (1944) 24 Cal.2d 753, 757.)

In OEHHA's 1999 status report, Director Dr. Joan Denton correctly reviews the "three mechanisms ... available for adding chemicals to the Proposition 65 list," and distinguishes the "qualified experts" mechanism based on the experts' chemical-specific findings from the "administrative" mechanisms used by OEHHA to list chemicals without specific findings by the experts. Conspicuously absent is any reference to a fourth mechanism authorizing OEHHA to add chemicals to the Proposition 65 list pursuant to Labor Code section 6382:

Three mechanisms are available for adding chemicals to the Proposition 65 list. *These listing mechanisms provide a comprehensive approach to identify chemicals which may qualify for listing.* One listing mechanism results from findings of the "state's qualified experts" (panels of scientists from outside of state government) following their consideration of evidence compiled and analyzed by the OEHHA scientists. The other two listing mechanisms are administrative in nature. ... Under one administrative listing mechanism, a chemical may be added to the Proposition 65 list if another body, one considered to be an "authoritative body" by the state's qualified experts, has formally identified the chemical as causes cancer or reproductive toxicity. ... Under the other administrative listing mechanism, chemicals are listed under Proposition 65 if a state or federal agency has "formally required" that the chemical be labeled or identified as causing cancer or reproductive toxicity. [Emphasis added.]

Dr. Denton's 1999 report echoes other OEHHA documents that, for many years, referred to only "the three listing mechanisms" set forth in section 25249.8(b). One such document, "Mechanisms for Listing Chemicals Under Proposition 65," was posted on OEHHA's Policy and Procedure website for 11 years, from May 22, 1996, through May 15, 2007. The document states:

[Proposition 65] ... defines *three mechanisms* by which carcinogens and reproductive toxicants are listed. First, the state's qualified experts may render an

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<sup>3</sup> OEHHA's change of position does not affect this rule of statutory construction. "An agency interpretation which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference' than a consistently held agency view." (*INS v. Cardoza-Fonseca* (1987) 480 U.S. 421, 446, fn. 30.)

opinion that the chemical has been clearly shown to cause cancer or reproductive toxicity “through scientifically valid testing according to generally accepted principles.” Second, the statute requires the listing of chemicals formally identified as carcinogens or reproductive toxicants by a body considered authoritative under Proposition 65. Third, the statute requires chemicals to be listed that are required by a state or federal agency to be ... labeled as carcinogens or reproductive toxicants. [Emphasis added]

Similar explanations of the “three mechanisms” for supplementing the Proposition 65 list were included in numerous other OEHHA public notices, including both Notices of Intent to List chemicals under the various mechanisms, and regulatory notices announcing changes to the listing regulations.

In 2006, OEHHA used and posted a document entitled “Proposition 65 in Plain Language.” In this document, OEHHA not only describes the “three principal ways” for listing chemicals, but also mentions the Labor Code reference, explaining, “This method was used to establish the initial chemical list following voter approval of Proposition 65 in 1986.” As with the other documents, this document does not indicate that OEHHA may continue to list chemicals pursuant to the Labor Code reference.

OEHHA’s more recent interpretation of section 25249.8 conflicts with the statute’s plain meaning, with standard rules of statutory construction, with the intent revealed by the Ballot Argument, and with the long-standing OEHHA interpretation on which the public has relied for more than 15 years. Implementing this new interpretation by adding DEA to the Proposition 65 list as a carcinogen is unlawful.

#### *4. Proposition 65 Incorporates the 1986 Version of the Labor Code.*

In *Palmero v. Stockton Theaters, Inc.* (1948) 32 Cal.2d 53, 58, the California Supreme Court held that “It is a well-established principle of statutory law that, where a statute adopts by a specific reference the provisions of another statute, regulation, or ordinance, such provisions are incorporated in the form in which they exist at the time of the reference and not as subsequently modified.” In contrast, “where the reference is general instead of specific, such as a reference to a system or body of laws or to the general law relating to the subject in hand, the referring statute takes the law or laws referred to not only in their contemporary form, but also as they may be changed from time to time. . . .” (*Id.*, at 59.)

Applying the *Palmero* rule, the court in *People v. Domaglowski* (1989) 214 Cal.App.3d 1380 construed the incorporation to be specific because the incorporating statute referred specifically to subdivisions (a) through (f), omitting the balance of the section, that is, subdivisions (g) through (i). In contrast, the court in *Fireman’s Benevolent Assn. v. City Council* (1959) 168 Cal.App.2d 765, held an incorporation to be general because it referred to “all provisions of the State Employees’ Retirement Law.”

Here, section 25249.8(a) incorporates two specific Labor Code subsections, omitting other subsections within the same statute. Section 25249.8 makes no reference to the Hazardous

Substances Communication and Training Law generally. Nor does the balance of Proposition 65 include general reference to that law or to the Labor Code. Therefore, the specific subsections must be given the meaning they had in 1986, when Proposition 65 was enacted –that is, they refer only to the substances then described in those subsections, and not to any substances that may have been added in the past 25 years.

*5. The Labor Code Referenced Chemicals Are “Presumed to be Potentially Hazardous,” Not “Known to Cause Cancer or Reproductive Toxicity.”*

Health and Safety Code section 25249.8(b) defines the term, “known to the state to cause cancer or reproductive toxicity” for purposes of Proposition 65. The Labor Code reference is not within the definition. If the Labor Code reference in subsection (a) were employed continuously, it would conflict with the requirement to add to the list only chemicals “known” to cause cancer or reproductive toxicity.

Health and Safety Code section 25249.8(b) provides:

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.

Labor Code section 6360 et seq., the Hazardous Substances Information and Training Act, requires the Director of Industrial Relations to adopt a list of hazardous substances, which must include specified substances “presumed to be potentially hazardous” unless the director finds that they are not “potentially hazardous to human health.” See Labor Code section 6382(a). Labor Code section 6382(b) governs the chemicals to be reviewed by the Director for inclusion on the list. Thus, a chemical may be described in Labor Code section 6382(b) even though it never appears on the Director’s list of hazardous substances.

In contrast, Proposition 65 does not apply to chemicals that are merely “presumed” to be “potentially” hazardous. As the ballot argument in favor of Proposition 65 stated, the list is for “certain chemicals that are scientifically known -- not merely suspected, but known -- to cause cancer and birth defects.” (Ballot Pamp., Gen. Elec. (November 4, 1986), argument in favor of Prop. 65, p.54.; see also *Nicolle-Wagner v. Deukmejian*, (1991) 230 Cal. App. 3d 652, 661.) The definition of a chemical “known” to cause cancer or reproductive harm notably does *not* include any reference to the Labor Code. Rather, under Proposition 65, a chemical is not “known” to require listing unless either the state’s qualified experts, a body regarded as authoritative by the state’s experts, or an agency of the U.S. or California has made a determination about its toxicity.

The Labor Code reference is not within any of these categories. Nothing in the Labor Code requires them to be reviewed by the state’s qualified experts to determine whether they are

“clearly shown” or “formally identified by an authoritative body” to be toxic. Nor does the Labor Code require them to be “labeled or identified;” rather, section 6382 requires them to be *reviewed by the Director for potential hazard*.

Listing chemicals based on the Labor Code presumption would undermine the careful, science-based practices that OEHHA has followed for more than 15 years, as the Ballot Pamphlet promised. At p. 54, the Argument in Favor of Proposition 65 stated:

Proposition 65 ...focus[es] 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. [Original emphasis.]

And at p. 55, the Rebuttal to Argument Against Proposition 65 assured voters:

Proposition 65 is based strictly on scientific testing, more than any existing toxics law.

Courts must harmonize statutes dealing with the same subject, and avoid interpreting a statute in a way which renders another statute nugatory. (*Peltier v. McCloud River R.R. Co.* (1995) 34 Cal.App.4th 1809, 1816.) Well-established canons of statutory construction preclude a construction which renders a part of a statute meaningless or inoperative. *Manufacturers Life Ins. Co. v. Superior Court* (1995) 10 Cal.4th 257, 274.

If Health and Safety Code section 25249.8(a) applies to the subsequent updated lists, then the requirement to include the Labor Code referenced chemicals conflicts with 25249.7(b)’s requirement to list only chemicals “known” to cause cancer or reproductive toxicity. If chemicals could be listed through the Labor Code, without “full consultation with the state’s qualified experts,” then Proposition 65 listing will not be more science-based “than any existing toxics law.” Rather, listing will include chemicals merely “presumed” to be “potentially” hazardous under the Labor Code.

The subsections can be reconciled only by acknowledging that the initial list was governed with its own unique starter provision that allowed chemicals merely “presumed” to be “potentially” hazardous a place on the initial list until they could be reviewed by the state’s experts “in light of additional knowledge.” The court in *AFL-CIO v. Deukmejian, supra*, harmonized these subsections by recognizing that the Labor Code reference applies only to the initial list. That court construed the statute correctly. OEHHA should not propose a contrary regulation.

*6. Applying the Labor Code to Current Listings Undermines the Authoritative Body Listing Mechanism.*

OEHHA’s original interpretation is further supported by the designation of the International Agency for Research on Cancer (“IARC”) and the National Toxicology Program (“NTP”) as “authoritative bodies” under section 25249.8(b). If subsection (a) still applied, there would be no reason to designate IARC and NTP as authoritative bodies. Chemicals identified as carcinogens

or reproductive toxicants by IARC or NTP would be listed pursuant to the ongoing “mandatory duty” OEHHA now proposes to discern in subdivision (a). The “authoritative bodies” mechanism could never be utilized with respect to IARC and NTP. Stated differently, IARC and NTP would never have the opportunity to contribute via the discretionary mechanisms set forth in subdivision (b) because chemicals identified by these two organizations would already have to be included via the mandatory mechanism set forth in subdivision (a). The designation of IARC and NTP shows just how strongly OEHHA believed it lacked authority to add chemicals to the proposition 65 list pursuant to subdivision (a).

B. OEHHA Cannot Predicate the Listing of DEA on Labor Code References Without Formally Adopting Its Interpretation As a Regulation In Accordance With the California Administrative Procedure Act.

OEHHA’s determination to add DEA to the Proposition 65 list involves substantial interpretations of Health and Safety Code section 25249.8, subdivisions (b)(1) and (d) of Labor Code section 6382, and 29 CFR Sec. 1910.1200. The interpretations OEHHA is giving to those provisions of law have regulatory effect. However, OEHHA has not formally adopted any of the interpretations pursuant to the California Administrative Procedure Act.

OEHHA recognized in 2008 that it was obligated to adopt regulations before adding chemicals to the Proposition 65 list based on the so-called Labor Code mechanism. It admitted in May 2008, 22 years after beginning to enforce Proposition 65, that “there are currently no regulations discussing the Labor Code mechanism for listing chemicals.” OEHHA even conducted a workshop on a set of draft regulations. However, it has taken no steps since that time to adopt formally those regulations.

No basis exists for OEHHA to conclude that it is not obligated to adopt regulations setting out its interpretations and proposed implementation of the many provisions involved in the Labor Code listing mechanism. Certainly, no exception in the Administrative Procedure Act applies to OEHHA’s interpretation and implementation of those provisions of law. While OEHHA might assert that its interpretations “embody the only legally tenable interpretation,” the discussion below demonstrates that to be far from true.

The first significant interpretation applies to the specific language of Proposition 65. Section 25249.8(a) provides that, “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...” The subdivision also provides that, “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).”

For nearly 20 years, OEHHA and its predecessor lead agencies construed the reference to the Labor Code provisions to apply only to the initial list. Explicit statements setting out that interpretation were included in attachments to the comments that we submitted to OEHHA in response to the draft regulations in July 2008.

Given that OEHHA and its predecessor lead agencies construed the provision as applying only to the list that the Governor was to complete by March 1, 1987 and no further implementation was contemplated, neither OEHHA nor the other lead agencies had an obligation to adopt that interpretation by regulation. However, once it changed that interpretation and concluded that it will begin implementing that provision, it becomes obligated to set out that new interpretation formally in a regulation.

While ACI disagrees with OEHHA's current interpretation, that is not the point that is being emphasized in this argument. The point is that OEHHA cannot implement its current interpretation without adopting that interpretation after giving notice to the public and an opportunity for the public to comment on that proposed regulation. As noted above, that has not been done. Accordingly, any further action by OEHHA to add any chemical to the Proposition 65 list based on the so-called Labor Code mechanism is invalid.

The first Labor Code reference is to subdivision (b) of section 6382. That reference includes only one of five paragraphs contained under that subdivision. The paragraph that is referenced provides, "Substances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC)." That provision in subdivision (b)(1) is inherently ambiguous when viewed in the context of what IARC does.

First, IARC does not list chemicals as carcinogens. It prepares monographs where it characterizes the evidence and classifies the hazard.

Second, IARC does not classify chemicals as animal carcinogens. It classifies chemicals in terms of their hazard to humans. The classifications are Group 1, "the agent is carcinogenic to humans," Group 2A, "the agent is probably carcinogenic to humans," Group 2B, "the agent is possibly carcinogenic to humans," Group 3, "the agent is not classifiable as to its carcinogenicity to humans," Group 4, "the agent is probably not carcinogenic to humans."

Third, IARC characterizes the evidence. It characterizes both human and animal evidence as either "sufficient evidence of carcinogenicity," "limited evidence of carcinogenicity," "inadequate evidence of carcinogenicity," or "evidence suggesting lack of carcinogenicity."

Hence, OEHHA, to implement the so-called Labor Code mechanism, is obligated to interpret the provision in subdivision (b)(1). What does IARC do that can be interpreted to mean a substance listed is a human carcinogen? Does it mean a Group 1 chemical in which there is sufficient evidence of carcinogenicity in humans could cause IARC to say that the agent is carcinogenic to humans? Does it mean a Group 2A chemical in which there is limited evidence of carcinogenicity in humans but sufficient evidence of carcinogenicity in animals? Or, does a Group 2A chemical constitute a listing as an animal carcinogen?

OEHHA has interpreted the Labor Code language to include Group 2B chemicals, in which there is limited evidence of carcinogenicity in humans and limited evidence in animals, resulting in a classification that the agent is only possibly carcinogenic to humans. Does OEHHA characterize such a chemical as a listed human or animal carcinogen? Again, while ACI disagrees with that

interpretation, that 2B chemicals are listed as either human or animal carcinogens, the point here is that the interpretation to be implemented has to be adopted formally pursuant to the Administrative Procedure Act. We believe that OEHHA must demonstrate why this Labor Code listing mechanism should void the obligation of the agency to provide a clear scientific justification for the stated intent of “known by the State of California” in the Proposition.

OEHHA has also apparently concluded that IARC’s classification of Group 3 chemicals, agents not classifiable as to its carcinogenicity to humans does not constitute a listing of human or animal carcinogens. This, despite the fact that a Group 3 classification can be based on limited evidence in animals. Accordingly, on one hand, OEHHA concludes that limited evidence in animals constitutes the listing of either a human or animal carcinogen, but in the instance of Group 3 chemicals, it does not. While that interpretation may be logical, it is an interpretation of the Labor Code provision that should be set out in a regulation.

Similarly, subdivision (d) of Labor Code section 6382 references substances “within the scope of the federal Hazard Communication Standard (29 CFR Sec. 1910.1200)...” Subdivision (d)(4) of section 1910.1200 identifies three sources as establishing that a chemical is a carcinogen.

The first of those sources is the National Toxicology Program (NTP) Annual Report on Carcinogens. The second is IARC monographs. The third refers to subpart Z of 29 CFR part 1910. The reference to NTP’s Annual Report on Carcinogens is specific and does not require an interpretation. However, that is definitely not true with respect to the other two sources.

The first of those is IARC’s monographs. When IARC considers the carcinogenicity of a chemical, it prepares a monograph. The monograph can result, as noted above, in a finding that the agent is carcinogenic to humans, the agent is probably carcinogenic to humans, the agent is possibly carcinogenic to humans, the agent is not classifiable as to its carcinogenicity to humans, and the agent is probably not carcinogenic to humans.

Does the reference to IARC monographs mean that every chemical for which a monograph is prepared is intended to be included? Such an interpretation would result in an absurd result, in particular with respect to its application to Proposition 65. Such an interpretation would mean that chemicals for which the agent is not classifiable or is probably not carcinogenic to humans would have to be added to the list.

Accordingly, it is clear that OEHHA has made an interpretation that chemicals referenced in only some of the monographs should be added to the Proposition 65 list. It has obviously concluded that chemicals in Group 1, “carcinogenic to humans”, and Group 2A “probably carcinogenic to humans” are to be included. OEHHA has also concluded that chemicals that are only possibly carcinogenic to humans are to be included as well.

ACI disagrees strongly with OEHHA’s interpretation to include chemicals that are only possibly carcinogenic. Nonetheless, the point here is that OEHHA has made an interpretation from five possible outcomes set out in IARC’s monographs. OEHHA has drawn the line between the third and fourth. The line could just as easily have been drawn between the second and third, or the

first and second. That is an interpretation requiring the adoption of a regulation before that interpretation can be lawfully implemented.

While DEA is not affected by the third source listed in subdivision (d)(4) of 29 CFR Sec. 1910.1200, that is subpart Z, other chemicals proposed for listing are. As noted in *AFL-CIO v. Deukmejian, supra*, the Hazard Communication Standard referenced in Labor Code section 6382 subdivision (d) “includes thousands of substances that are not carcinogens or reproductive toxicants.” The court noted that, “it is true that ‘any substance within the scope of the federal [HCS](§ 3682, subd. (d)) includes chemicals other than known carcinogens.’” The court went on to say that “the list need not include all substances under HCS, but only known carcinogens . . . listed there.” How does OEHHA determine, from among the thousands of chemicals listed in the Hazard Communication Standard, those chemicals that are “known to cause cancer”? That interpretation is unknown. However, whatever that interpretation is, for it to be implemented, it has to be adopted formally as a regulation pursuant to the Administrative Procedure Act.

C. OEHHA’s Refusal to Consider the Scientific Data With Respect to DEA Is Inconsistent With the Clear Intent of Proposition 65.

OEHHA construes its authority to list chemicals based on the Labor Code references to be ministerial that is, it cannot consider the evidence to determine whether it is sufficient to conclude that a chemical is a known carcinogen or reproductive toxicant. This interpretation contrasts with the process OEHHA follows in determining whether to add a chemical to the Proposition 65 list pursuant to the authoritative body mechanism. There, OEHHA will determine whether the authoritative body had sufficient evidence to conclude that a chemical is a known carcinogen or reproductive toxicant, and it will consider scientific data that was not taken into account by the authoritative body.

The authoritative body process is consistent with the promise of Proposition 65 as set out in the ballot argument. That is, to list only those chemicals known to cause cancer, and not those that are only suspected. Moreover, subdivision (a) of section 25249.8 provides that the initial list is “to be revised and republished in light of additional knowledge at least once per year thereafter.” OEHHA, in implementing the Labor Code provisions, is ignoring additional knowledge and acting inconsistently with specific language in Proposition 65.

ACI does not agree that OEHHA has authority to add chemicals to the Proposition 65 list based on the Labor Code references. However, if it is to do so, it must certainly consider scientific information that was not considered by the International Agency for Research on Cancer at the time it characterized DEA. To refuse to consider that scientific information is to undermine the promise of Proposition 65 and specific language in that measure.

D. OEHHA Admits That IARC Identification of a Chemical As a Carcinogen Does Not Occur Until the Monograph Is Released.

OEHHA is proposing to add DEA to the Proposition 65 list even though the IARC monograph has not been released. OEHHA itself has taken the position that it has no obligation to add

chemicals to the Proposition 65 list until the IARC monograph is complete and released. In opposing a Motion for Summary Judgment filed by the Sierra Club in a case still pending in Alameda County, OEHHA made the following argument:

IARC makes available on its website the summaries and evaluations that have been prepared for forthcoming monographs, prior to publication, with the following notation presented in bold text: **“The text of these Summaries and Evaluations may be edited for language and clarity during the checking of the main text of the Monographs.”** While the final publication can take several years, until the monograph is published, IARC may edit the language with which it identifies the chemical or the identification in some manner. Since it is the text of the Evaluations section which contains the IARC conclusions regarding carcinogenic risk for the agent under evaluation, OEHHA has determined that it is appropriate to propose listings based on IARC Monographs only after the final text of the Summaries and Evaluations section is published. [Citation omitted.] This determination is an appropriate exercise of discretion by the agency that should not be disturbed by this Court. (See *Sklar v. Franchise Tax Board* (1986) 185 Cal.App.3d 616, 622 [writ of mandate “cannot invade the area of discretion with which an administrative agency is vested over a given subject matter”]; *Banning Teachers Assoc. v. Public Employee relations Board* (1988) 44 Cal.3d 799, 804-5 [court defers to agency when agency has specialized knowledge and experience not possessed by court]; *California Hotel and Motel Assn. v. Industrial Welfare Commission* (1979) 25 Cal. 3d 200, 212 [courts “will uphold the agency action unless the action is arbitrary, capricious, or lacking in evidentiary support.”].)

Defendants request that the Court deny Plaintiffs’ motion on the ground that OEHHA need not list chemicals where the IARC monograph is in preparation and has not yet been published.

As noted above, the references to the Labor Code are ambiguous in light of IARC’s activities. It does not identify chemicals as carcinogens. Whatever it does, it does only through its monographs. Hence, the reference in the Labor Code cannot contemplate some preliminary activity short of the release of a monograph as the triggering event. Accordingly, OEHHA cannot add DEA to the Proposition 65 list, if ever, until after IARC issues its final monograph on DEA.

E. Listing DEA Will Compel Companies to Provide False Warnings About Their Products, Violating Those Companies’ First Amendment Rights.

The Court, in *ARP Pharmacy Services, Inc. v. Gallagher Bassett Services, Inc.*, 138 Cal.App.4<sup>th</sup> 1307 (2006), said it best:

“Because speech results from what a speaker chooses to say and what he chooses not to say, the right in question comprises both a right to speak freely and also a

right to refrain from doing so at all, and is therefore put at risk both by prohibiting a speaker from saying what he would otherwise say and also by compelling him to say what he otherwise would not say.”

Moreover, the United States Supreme Court has recognized that the right not to speak is just as important as the right to speak. *West Virginia State Board of Education v. Barnett*, 319 U.S. 624 (1943), *Wooley v. Maynard*, 430 U.S. 705 (1977). Certainly, government-compelled speech cannot survive if it runs counter to scientific fact. *Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67.

The very speech condemned in the *Int’l Dairy Foods Ass’n* case would result if OEHHA adds DEA to the Proposition 65 list. Within a year after listing DEA, ACI member companies that market products containing DEA will be obligated to label their products, stating:

**“Warning:** This product contains a chemical known to the State of California to cause cancer.”

As noted above, the scientific data do not demonstrate that DEA is a human carcinogen. The mechanism by which animals develop cancers following exposure to DEA is not relevant to humans. Accordingly, the imposition by the State on companies to include a warning on their label that their product contains a chemical known to the State of California to cause cancer is inherently false and misleading. The imposition of such a warning violates ACI member companies’ free speech rights under both the California Constitution and the First Amendment of the United States Constitution.

### **III. Conclusion**

OEHHA should refrain from adding DEA to the Proposition 65 list as a carcinogen. Scientific evidence confirms that DEA does not cause cancer in humans. Therefore, DEA is not a carcinogen within the definition intended by Proposition 65.

Moreover, adding DEA to the Proposition 65 list as a carcinogen would be unlawful. OEHHA has made numerous interpretations of the provisions of Proposition 65, the Labor Code provisions referenced in Proposition 65, and the federal regulations referenced in the Labor Code provisions. OEHHA cannot act validly without formally adopting these interpretations as regulations pursuant to the California Administrative Procedure Act. Any step to implement those interpretations prior to their formal adoption would constitute an invalid underground regulation. Moreover, the proposal to add DEA to the Proposition 65 list as a carcinogen is inconsistent with the statutory language in Proposition 65, the ballot argument explaining that measure, and a court decision interpreting it. OEHHA’s interpretation that the so-called Labor Code mechanism can be used to augment the Proposition 65 list is contrary to the plain meaning of the statute, the rules of statutory construction, and OEHHA and its predecessor lead agencies’ 15-year interpretation.

Finally, we believe that using Labor Code listing frustrates the clear intent of Proposition 65 in its passage and thus provides a false warning to the citizens of the State. Indeed, it compels

Ms. Cynthia Oshita  
Office of Environmental Health Hazard Assessment

April 6, 2012

companies to falsely warn citizens that DEA contained in any products is “known by the State of California to be a human carcinogen” violating commercial free speech and subjecting the company to Federal Trade Commission action.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Sedlak". The signature is written in a cursive, flowing style.

Richard Sedlak  
Executive Vice President, Technical & International Affairs

cc: Gene Livingston, Greenburg Traurig