

April 4, 2014

***Via Electronic Mail***

Ms. Monet Vela  
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**Re: Comments on Notice of Proposed Rulemaking, Title 27, California Code of Regulations Proposed Section 25904 Listings by Reference to the California Labor Code**

Dear Ms. Vela:

The Styrene Information and Research Center (SIRC)<sup>1</sup> appreciates the opportunity to submit comments on the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment's (OEHHA) proposed regulation to implement the Labor Code Mechanism (hereinafter referred to as the "Proposed Rule") of the Safe Drinking Water and Toxic Enforcement Act of 1986, known as Proposition 65.<sup>2</sup> We support OEHHA's efforts to define criteria for listing chemicals pursuant to Health and Safety Code section 25249.8(a), the Labor Code Mechanism, by proposing a new section 25904 under Title 27 of the California Code of Regulations (27 CCR). As reflected by this rulemaking effort, it is important that OEHHA, the regulated community and the general public understand and agree to the regulatory process by which OEHHA will list a Proposition 65 chemical under the Labor Code Mechanism.

**I. Introduction and Summary**

The U.S. Occupational Safety and Health Administration (OSHA) initially promulgated the Hazard Communications Standard (HCS) in 1983.<sup>3</sup> Three years later, California adopted the Safe Drinking Water and Toxic Enforcement Act. Section 25249.8 of the Act provides that the Governor's list of chemicals known to the state to cause cancer or reproductive toxicity shall

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<sup>1</sup> SIRC was formed in 1987 as the principal focal point for public information and research on styrene. SIRC is a non-profit organization consisting of voting member companies involved in the manufacturing or processing of styrene, and associate member companies that fabricate styrene-based products. Collectively, SIRC's membership represents approximately 95% of the North American styrene industry. SIRC has gained recognition as a reliable source of information and scientific research on styrene that supports reasoned regulatory decisions. For more information, visit <http://www.styrene.org/>.

<sup>2</sup> CAL. HEALTH & SAFETY CODE § 24249.5 et seq.; *Initial Statement of Reasons*, Title 27, California Code of Regulations, Proposed section 25904, Listings by Reference to the California Labor Code (Jan. 27, 2014).

<sup>3</sup> 29 C.F.R. § 1910.1200.

contain "those substances identified by reference in Labor Code Section 6382(b)(1) and . . . (d)." Health and Safety Code section 25249.8 (a) reads:

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).

Labor Code section 6382(b)(1) reads: "Substances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC)."

Labor Code section 6382(d) reads: ". . . any substance within the scope of the federal Hazard Communication Standard (29 C.F.R. Sec. 1910.1200) is a hazardous substance subject to this chapter."

OEHHA's effort to adopt a regulation for listing carcinogens and reproductive toxins via the Labor Code Mechanism began in 2008. The Proposed Rule currently advanced by OEHHA reflects the agency's consideration of the comments filed on the 2013 pre-proposal regulations, the judicial decisions of several cases related to Proposition 65 listing decisions, and the 2012 amendments of the HCS. While SIRC generally supports the current proposal, there remains a singular and critical concern, that is OEHHA's proposed implementation of Labor Code section 6382(d) and its interpretation of what chemicals are "within the scope" of the HCS.

Although Labor Code section 6382, subdivision (b)(1) was not without some controversy, OEHHA's current proposed regulatory text under section 25904(a)(1) is not in question — a chemical determined to be a carcinogen by IARC based on sufficient animal or human evidence may be listed as a Proposition 65 chemical.<sup>4</sup> Labor Code section 6382, subdivision (d), however, is more complicated and requires a clear understanding of the 2012 amendments to the HCS (HCS 2012) to align HCS with three aspects of the United Nations' Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

As detailed below and also discussed in our 2013 comments, substances identified as human or animal carcinogens by IARC and the National Toxicology Program's (NTP) Report on Carcinogens (RoC) are not within the scope of the HCS 2012 for purposes of classifying carcinogens. OEHHA's position that chemicals are within the scope of the HCS simply because U.S. OSHA requires employers and importers to provide informational references to IARC and NTP classification of chemicals on safety data sheets (SDS) conflicts with:

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<sup>4</sup> As a general matter, we urge OEHHA to consider new information that may bring into question prior classifications by IARC or other authoritative bodies, regardless of the listing mechanism. Consideration of new information is a best practice from both scientific and public policy perspectives.

1. the purpose of the Labor Code provision, which is to conform the state law to federal law;
2. the fundamental finding necessary to fall “within the scope” of the HCS, which is a specific finding by OSHA, and not any other entity or person, that a chemical is a carcinogen; and
3. OSHA’s repeal of the requirement that the HCS treat chemicals listed on NTP’s RoC and IARC’s Monographs as carcinogens.

Section 6382 (d) is part of the state Hazardous Substances Information and Training Act. (Labor Code sections 6360 et seq.) Section 6380 requires the director of the Department of Industrial Relations to compile a list of hazardous substances. Section 6382 calls for the director to presume substances on certain lists to be hazardous. Included are carcinogens identified by IARC, water and air pollutants designated by the U.S. Environmental Protection Agency, airborne contaminants listed by OSHA, and restricted materials designated by the director of Food and Agriculture (today Pesticide Regulation). Subdivision (d) was added to include substances designated as hazardous by federal OSHA in the HCS. Under the HCS 2012, the only chemicals that meet the listing criteria of section 6382(d) are those chemicals determined to be carcinogens by OSHA and listed under 29 C.F.R. part 1910, subpart Z.

Until 2012, the HCS mandated that employers treat substances as carcinogens if the substances were: (1) identified as carcinogens in an OSHA substance-specific standard, or (2) classified as a carcinogen or potential carcinogen by the IARC Monograph or the NTP RoC. In 2012, the HCS was amended to align with certain aspects of the GHS. HCS 2012 continues to mandate that employers automatically treat substances as carcinogens if they are so-identified in an OSHA substance-specific standard, but mandatory treatment as a carcinogen based on an IARC or RoC listing is no longer required. Rather, HCS 2012 directs the domestic manufacturer or importer to self-classify each chemical based on a strength/weight of evidence analysis. While an employer or manufacturer may be required to disclose the IARC or NTP classification on a chemical SDS, it is improper to characterize this as bringing the chemical within the scope of the HCS for purposes of listing under Proposition 65.

Accordingly, the agency must amend the “Summary and Rationale of Regulation” section of its *Initial Statement of Reasons* and delete all discussions suggesting that the requirements to disclose on a SDS that that a workplace chemical is listed in the NTP RoC or has been found to be a carcinogen in the IARC Monographs brings that substance within the scope of the HCS. OEHHA is attempting to establish a Labor Code listing mechanism process that is outside the realm of what the California legislature contemplated or authorized when it enacted Labor Code section 6382(d). OEHHA also attempts to interpret the provisions of HCS 2012 in a manner that flies in the face of both the regulatory text and OSHA's intent in adopting HCS 2012. As reasoned by OEHHA, the Proposition 65 rule is inconsistent with the language, the intent and the underlying principles of the HCS 2012 and Labor Code section 6382(d).

## **II. The Proposed Rule is a Great Improvement from the 2013 Pre-Proposal Draft**

In its effort to develop a body of regulations to implement the Labor Code Mechanism, OEHHA held two public pre-regulatory workshops on June 17, 2008 and June 17, 2013, and provided two related comment periods. These efforts have been successful in our opinion and have resulted in a more refined proposed rule than OEHHA initially advanced.

### **A. The Proposed Rule Correctly Excludes the California Director's List**

OEHHA has appropriately abandoned its proposal to refer to the California Director's List of hazardous substances when updating and amending the Proposition 65 list. SIRC supports this decision because OEHHA's authority to use the Director's List is constrained by the language of Proposition 65 and the Labor Code provisions.

Proposition 65 limits the chemicals to be listed by the Labor Code Mechanism to "substances identified by reference" in the Labor Code. In *AFL-CIO v. Deukmejian*, 212 Cal. App. 3d 425 (1989), the Court explained that Labor Code section 6382, subdivision (d), refers to "... any substance within the scope of the federal Hazard Communication Standard (HCS) (29 C.F.R. Sec. 1910.1200). . . ." <sup>5</sup> It did not mention the Director's List as a source in section 6382(d), and it left out the phrase "in addition to those substances on the director's list of hazardous substances" in its discussion. The Court also found that the initial Proposition 65 list, which was created by reference to Labor Code section 6382(b)(1) and (d), contained substances from the IARC's list, the NTP's list and OSHA's list. <sup>6</sup> There is no mention of substances from the Director's List. Similarly, the Courts of Appeal in *California Chamber of Commerce v. Brown*, 196 Cal.App.4<sup>th</sup> 233 (2011), and *SIRC v. OEHHA*, 210 Cal. App. 4<sup>th</sup> 1082 (2012), did not cite the Director's List as an authorized Proposition 65 listing source.

The 1986 Ballot Argument in favor of Proposition 65 stated, "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.' National Toxicology Program, and the U.N.'s International Agency for Research on Cancer." <sup>7</sup> The obvious reference is to the Proposition 65 provision requiring the Governor to include, "at a minimum, those substances identified by reference in Labor Code section 6382(b)(1) and . . . (d)." No other provision includes the concept of "at a minimum," and no other provision implicates NTP or IARC. Further, no reference is made in the Ballot Argument to the Director's List.

OEHHA has appropriately corrected the 2013 pre-proposal and applies section 6382(d) of the Labor Code in context of the entire chapter.

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<sup>5</sup> *AFL-CIO v. Deukmejian*, 212 Cal. App. 3d at 433-35, 437 (1989) (the Court's omitted the first part of sentence).

<sup>6</sup> *Deukmejian*, 212 Cal. App. 3d at 430.

<sup>7</sup> See Proposition 65 1986 Ballot Initiative, including the Legislative Analyst analysis and arguments and rebuttals for and against the Proposition, available at [http://oehha.ca.gov/prop65/law/pdf\\_zip/Prop65Ballot1986.pdf](http://oehha.ca.gov/prop65/law/pdf_zip/Prop65Ballot1986.pdf).

**B. Correctly, the Proposed Rule Only Allows the Listing of Chemicals with Sufficient Evidence of Carcinogenicity or Reproductive Toxicity in Humans or Animals**

During the June 17, 2013, workshop, OEHHA raised the question whether the *SIRC v. OEHHA* decision should be construed to require sufficient evidence of carcinogenicity in humans or animals only for IARC 2B chemicals. OEHHA's question implied that the agency might rely on limited or inadequate evidence to add chemicals to the Proposition 65 list if some authoritative body other than IARC listed them, including the Director's List, NTP's Annual Report on Carcinogens, and 29 C.F.R. part 1910, subpart Z. Under the current Proposed Rule, OEHHA properly applied the decisions of *SIRC, v. Deukmejian*, and *Western Crop Protection Ass'n v. Davis*, 80 Cal. App. 4th 741 (2000), which all held that any regulatory provision or action taken by OEHHA to list a chemical under Proposition 65 must be based on sufficient evidence of carcinogenicity.

When summarizing its holding in both *Deukmejian* and *Western Crop*, the Court said, "Our analysis in *Western Crop*, like that in *Deukmejian*, was based on a recognition that chemicals may be included on the Proposition 65 list only if there is a sufficient showing that they in fact cause cancer or reproductive toxicity. This interpretation is consistent with the legislative history underlying Proposition 65 and does not conflict with the minimum requirements language of section 25249.8, subdivision (a)." Hence, any listing under the Labor Code, regardless of the authoritative body list that OEHHA may use, requires that authoritative body to have based its listing decision on sufficient evidence demonstrating that the substance is known to cause cancer or reproductive toxicity. We commend OEHHA for its careful consideration and application of these judicial decisions.

**III. The 2014 Proposed Rule**

Our primary concern with the current Proposed Rule is proposed section 25904(a)(2) and OEHHA's interpretation of the phrase "within the scope of the Federal Hazard Communications Standard" as set forth in Labor Code section 6382(d). OEHHA's proposed language under section 25904 (a)(2) reads:

A chemical shall be included on the list if it is within the scope of the Federal Hazardous Communications Standard and is identified in the most recent version of Title 29 of the Code of Federal Regulations, part 1910.1200, adopted by the federal Occupational Safety and Health Administration, as causing cancer or reproductive toxicity based on sufficient animal or human evidence.

There are two critical clauses to this provision and OEHHA's ability to list a chemical: (1) the chemical must be "within the scope" of the federal HCS; and (2) the chemical must be "identified in the most recent version of 29 CFR, part 1910.1200 . . . as causing cancer or reproductive toxicity based on sufficient animal or human evidence." In its "Summary and Rationale of Regulation" in the *Initial Statement of Reasons*, OEHHA provides its rationale for how clause 1 is implemented but essentially disregards clause 2. As discussed below, the only

chemicals that meet the listing criteria of section 6382(d) (clauses 1 and 2) are those chemicals determined to be carcinogens by OSHA and listed under 29 C.F.R. part 1910, subpart Z.

**A. “Within the Scope”**

According to OEHHA, because the HCS, Appendix D requires a reference on a hazardous substance’s SDS that the substance is listed on the NTP RoC or has been found to be a potential carcinogen in the IARC Monographs that chemical falls “within the scope” of the HCS.<sup>8</sup> This statement reflects OEHHA continued misapplication or misunderstanding of HCS 2012. Under HCS 2012, substances listed in NTP’s Report on Carcinogens and IARC’s Monographs are not “within the scope of the HCS.” To hold otherwise is to ignore the fact that the Labor Code provision exists to conform state law to federal law; that to be “within the scope” of the HCS, there must be a specific finding by OSHA by operation of the HCS, and not any other entity or person, that a chemical is a carcinogen. HCS 2012 does not treat NTP’s RoC or IARC’s Monographs as a default finding that a chemical is a carcinogen, and this precludes OEHHA’s proposed approach.

**1. Labor Code Section 6382(d) Must be Read to Conform State Law to the Federal Law**

Every indication is that the California Legislature intended that subdivision (d) of section 6382 conform California law to the federal HCS. Nothing in that subdivision can be construed to imply that the reference includes substances other than those covered by the federal HCS. Hence, when OSHA deletes from the hazard classification requirements the established lists of chemicals that are deemed hazardous chemicals or are deemed carcinogens under the HCS in all situations, those lists are deleted from the state program as well. To construe subdivision (d) to still refer to the NTP’s RoC and IARC’s Monographs despite OSHA’s explicit amendment of the HCS in 2012 to delete the mandatory classifications based on those documents is to ignore both the purpose of subdivision (d) and the effect of OSHA deleting those references as hazardous substances. Subdivision (d) has to be read to conform state law to the federal law. OEHHA cannot ignore OSHA’s explanation that it has removed the NTP and IARC lists as chemicals that are to be considered carcinogens and hazardous chemicals.

Consider the Prop 65’s legislative history. The Hazardous Substances Information and Training Act (HSITA), Labor Code section 6360 et seq., was initially adopted in 1980. Section 6382 contained only subdivisions (a), (b), and (c) at that time. In 1983, OSHA adopted the HCS under 29 C.F.R. section 1910.1200. To ensure that California law was at least as effective as the federal law, the Department of Industrial Relations (DIR) proposed a bill to amend section 6382 that, among other things, sought to align the HSITA with the federal HCS. Documents constituting the legislative history on the conformity bill, AB 1042 (1985), are replete with statements confirming the purpose of what is subdivision (d) today.

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<sup>8</sup> *Initial Statement of Reason* at p. 7.

DIR's Enrolled Bill Reports (EBR) states that it sponsored the bill to make HSITA as inclusive as the federal HCS by providing "that substances within the scope of the federal Hazard Communication Standard (HCS) be subject to the provisions of HSITA." The Department of Finance, in its EBR, states, "This bill would amend State law to bring it into conformity with the Federal Hazard Communication Standard." It would do so by providing that, "Any substance within the scope of the Federal Hazard Communication Standard is a hazardous substance subject to the Hazardous Substance Information and Training Act." The author, Assemblyman Bill Jones, in his letter urging Governor Deukmejian to sign AB 1042, confirmed that the purpose of AB 1042 was to conform state law to the federal HCS. The same statements are found throughout the bill analysis prepared by legislative committees and state agencies.

Having established that the federal HCS is the only relevant reference in subdivision (d), the inquiry turns to what are the chemicals identified by reference in the HCS. Pursuant to Labor Code section 6382(d), a chemical cannot be listed on the Proposition 65 List of Chemicals unless the chemical is "within the scope of the Federal hazard communication standard." For a chemical to be within the scope of the HCS" for purposes of Prop 65, the following fundamental conditions must exist:

- (1) the substance is deemed a carcinogen or reproductive toxicant by the federal HCS;  
and
- (2) evidence of carcinogenicity and reproductive toxicology rises to the "known" level.<sup>9</sup>

As stated by the *SIRC* Court, "two provisions of the HCS require a manufacturer, importer or employer to treat a chemical as a hazardous substance if it is identified as such by certain sources."<sup>10</sup> One such provision is relevant to the present matter. Subpart (d)(4) identifies 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); or [¶] (ii) International Agency for Research on Cancer (IARC) Monographs (latest editions); or [¶] (iii) 29 C.F.R., part 1910, subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration."<sup>11</sup> OSHA no longer classifies chemicals as carcinogens under the HCS 2012 pursuant to IARC and NTP. Thus, IARC and NTP carcinogens are not substance "establish[ed] as carcinogens or potential carcinogens for hazard communication purposes."<sup>12</sup> In other words, because OSHA takes no action under the HCS 2012 to recognize IARC or NTP classified chemicals as carcinogens or reproductive toxicants, the fundamental condition for listing pursuant to Labor Code section 6382(d), cannot be met under HCS 2012. An informational reference on an SDS to an IARC Monograph or NTP RoC does not meet this condition.

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<sup>9</sup> *SIRC v. OEHHA*, 210 Cal. App. 4th 1082 (2012).

<sup>10</sup> Citing *Brown*, 196 Cal. App. 4th at 241.

<sup>11</sup> *SIRC*, 210 Cal. App. 4th at 1089.

<sup>12</sup> *Id.*

**B. Informational References to NTP and IARC on SDSs Per 29 C.F.R. section 1910.12, Appendix D Do Not Bring a Chemical “Within the Scope” of the Federal HCS**

OEHHA argues that:

Because Mandatory Appendix D of the Hazard Communication Standard *requires* a safety data sheet to disclose that a workplace chemical is listed in the NTP Report on Carcinogens or has been found to be a potential carcinogen in the IARC Monographs, such chemicals clearly fall “within the scope” of the federal Hazard Communication Standard for purposes of Labor Code Section 6382(d), and therefore must be included on the Proposition 65 list.<sup>13</sup>

To maintain this position, OEHHA must disregard the *SIRC* Court and its statement that “the initial list, and subsequent lists, published thereafter, need not include all substances listed under HCS but only known carcinogens and reproductive toxins *listed* there.”<sup>14</sup> To require that an SDS reference the findings of IARC and NTP on an SDS in no way equates to a finding by the HCS/OSHA that the substance is a carcinogen or reproductive toxicant or that it is “listed” or identified as such by the HCS. In fact, OSHA has explicitly stated that the requirement to reference NTP and IARC classifications on SDSs is merely informational and not reflective of hazard classification.<sup>15</sup>

The purpose of Appendix D of HCS 2012 is to establish a uniform format and content for SDSs once the classification has been determined. The intent is to create consistency and promote a more worker-friendly, harmonized format. Appendix D does not control how a hazardous chemical is classified by importers or manufacturers. In fact, when discussing the requirement to include NTP and IARC classifications in the SDS, OSHA repeatedly stated that the requirement was merely informational and not a determination of carcinogenicity under the HCS.<sup>16</sup> OSHA said:

In the NPRM, OSHA did not propose to continue to require specific mention of IARC, NTP, and OSHA as sources of determinations regarding carcinogenicity. The requirement to consider these sources definitive in terms of a carcinogen determination was not included in the NPRM since it was not part of the GHS approach. However, as was discussed above, OSHA has modified [Appendix A] and Appendix F to allow classifiers to use these [NTP and IARC] sources when assessing carcinogenicity, rather than applying the criteria to the data themselves. In order to facilitate this, OSHA has provided a table in Appendix F that aligns the GHS criteria with those of IARC and NTP. In addition, OSHA has decided to

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<sup>13</sup> *Initial Statement of Reasons* at 7.

<sup>14</sup> *Deukmejian*, 212 Cal App. 3d at 438 (emphasis added).

<sup>15</sup> 77 Fed. Reg. at 17,735.

<sup>16</sup> 77 Fed. Reg. at 17,574.

retain the requirement to include this information on the SDS in Section 11. This information will be of use to classifiers, as well as to employers and employees, when ascertaining potential hazards and determining appropriate control measures.<sup>17</sup>

In contrast, OSHA amended Appendix A of the HCS to mandate that classifiers follow the cancer determinations made by OSHA in substance-specific rulemakings.<sup>18</sup> Thus, those substances are “within the scope” of the federal HCS.

The classification of chemicals under HCS 2012 is explicitly provided in the regulatory text of 29 C.F.R. section 1910.1200. First, the definition of the term “health hazard” in section 1910.1200(c) states:

“Health hazard” means a chemical which is classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard. ***The criteria for determining whether a chemical is classified as a health hazard are detailed in Appendix A to §1910.1200 -- Health Hazard Criteria*** (emphasis added).

Second, section 1910.1200(d)(2) provides:

Chemical manufacturers, importers, or employers classifying chemicals shall identify and consider the full range of available scientific literature and other evidence concerning the potential hazards. There is no requirement to test the chemical to determine how to classify its hazards. ***Appendix A to § 1910.1200 shall be consulted for classification of health hazards***, and Appendix B to § 1910.1200 shall be consulted for the classification of physical hazards . . . (emphasis added).

Thus, as the rule makes clear, the sole source to be used in identifying those health hazards is Appendix A of HCS 2012, which, again, does not provide that a substance in an IARC Monograph or NTP RoC is a carcinogen under the HCS. The only chemicals deemed to be carcinogens by the HCS/OSHA are those that are listed under 29 C.F.R. part 1910, subpart Z.

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<sup>17</sup> *Id.* at 17,735. NTP and IARC are specifically discussed under non-mandatory Appendix F to section 1910.1200, which is titled Guidance for Hazard Classification Re: Carcinogenicity (Non-Mandatory). In describing Appendix F, OSHA states: “The mandatory criteria for classification of a chemical for carcinogenicity under HCS (§ 1910.1200) are found in Appendix A.6 to this section. This non-mandatory Appendix provides additional guidance on hazard classification for carcinogenicity. Part A of Appendix F includes background guidance provided by GHS based on the Preamble of the International Agency for Research on Cancer (IARC) “Monographs on the Evaluation of Carcinogenic Risks to Humans”

<sup>18</sup> See 29 C.F.R. § 1910.1200, A. 6.4.2.

**C. The Only Chemicals that Meet the Listing Criteria *via* the Labor Code Mechanism are OSHA Carcinogens under 29 C.F.R. part 1910, subpart Z**

Prior to 2012, 29 C.F.R. section 1910.1200 (d)(4) of the federal HCS required manufacturers, importers, and employers to treat three sources as establishing that a chemical is a carcinogen. These sources were NTP's Annual RoC, IARC's Monographs, and the chemicals determined by OSHA to be carcinogens through substance-specific rulemakings and listed in 29 C.F.R. part 1910, subpart Z. This is no longer the case; the carcinogen findings of a chemical solely based on the NTP RoC and IARC Monographs have been eliminated under HCS 2012.

The only chemicals that are deemed carcinogens under HCS 2012 are those chemicals identified as potential carcinogens by OSHA through a substance-specific rulemaking. For all other substances, manufacturers and importers are required to self- "identify and consider the full range of available scientific literature and other evidence concerning the potential hazards" and then apply the applicable classification criteria in Appendix A to 29 C.F.R. section 1910.1200 under a weight of evidence analysis. In other words, under HCS 2012, there is no referenced floor of chemicals deemed to be hazardous chemicals or deemed to pose a particular hazard. Instead, Appendix A provides specific, detailed criteria for each type of health hazard to guide the evaluation of relevant data and subsequent classification of the chemical. Reliance on the detailed and comprehensive classification criteria developed through the GHS international collaborative process means that, except for chemicals identified as potential carcinogens by OSHA through a substance-specific rulemaking, there no longer is a requirement to rely on a cancer determination or any type of chemical hazard determination produced by a governmental agency (such as NTP or IARC) or a non-governmental organization (such as a chemical manufacturer).

Section A.6.4.2 of 29 C.F.R. section 1910.1200 states:

Where OSHA has included cancer as a health hazard to be considered by classifiers for a chemical covered by 29 CFR part 1910, Subpart Z, Toxic and Hazardous Substances, chemical manufacturers, importers, and employers shall classify the chemical as a carcinogen.

The list of toxic and hazardous substances under subpart Z of part 1910 of the OSHA regulations is quite limited and consists of only the following:

1910 Subpart Z - Toxic and Hazardous Substances

- 1910.1001 - Asbestos.
- 1910.1004 - alpha-Naphthylamine.
- 1910.1006 - Methyl chloromethyl ether.
- 1910.1007 - 3,4-Dichlorobenzidine (and its salts).
- 1910.1008 - bis-Chloromethyl ether.
- 1910.1009 - beta-Naphthylamine.

1910.1010 - Benzidine.  
1910.1011 - 4-Aminodiphenyl.  
1910.1012 - Ethyleneimine.  
1910.1013 - beta-Propiolactone.  
1910.1014 - 2-Acetylaminofluorene.  
1910.1015 - 4-Dimethylaminoazobenzene.  
1910.1016 - N-Nitrosodimethylamine.  
1910.1017 - Vinyl chloride.  
1910.1018 - Inorganic arsenic  
1910.1025 - Lead.  
1910.1027 - Cadmium  
1910.1028 - Benzene.  
1910.1029 - Coke oven emissions.  
1910.1044 - 1,2-dibromo-3-chloropropane.  
1910.1045 - Acrylonitrile.  
1910.1047 - Ethylene oxide.  
1910.1048 - Formaldehyde.  
1910.1050 - Methylenedianiline  
1910.1051 - 1,3-Butadiene.  
1910.1052 - Methylene Chloride.

Accordingly, OEHHA can only look to these substances for purposes of listing a chemical as a Proposition 65 carcinogen via the Labor Code Mechanism as only these chemicals meet the criteria for listing pursuant to Labor Code section 6382(d): (1) the chemical is “within the scope” of the federal HCS; and (2) the chemical is “identified in the most recent version of 29 CFR, part 1910.1200...as causing cancer or reproductive toxicity based on sufficient animal or human evidence.”

#### **IV. OEHHA Must Stop Its Attempts to Draw in the NTP RoC**

The findings of IARC, of course, are separately addressed under Labor Code section 6382(b)(1) and really do not need to be considered in the debate of how to implement section 6382(d). OEHHA’s proposed regulatory approach of listing chemicals identified as IARC Groups 1, 2A or 2B carcinogens as long as they are based on sufficient animal or human evidence of carcinogenicity is consistent with the statutory text and case law. Where OEHHA strays is in its desperate attempts to make the NTP RoC meaningful to the Proposition 65 listing process. The reality is that since the 2012 amendments to the HCS, the NTP RoC is not meaningful and rightfully so, because the NTP RoC does not necessarily represent the current state of science and the listings are often outdated. In fact, during the existence of NTP, nine NTP listings have been determined to be inappropriate and withdrawn.<sup>19</sup>

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<sup>19</sup> NTP, Report on Carcinogens, Twelfth Edition (2011), Appendix B, available at <http://ntp.niehs.nih.gov/ntp/roc/twelfth/appendices/AppendixB.pdf#search=156-10-5>.

As NTP states, “The 1st RoC was published in 1980 and contained 26 listings. Each edition of the RoC is cumulative and consists of substances newly reviewed in addition to those listed in the previous edition.”<sup>20</sup> To date, a total of 12 RoCs have been published; the most recent, the 12th RoC, was released in 2011 and includes 240 listings, but only added six substances to the 234 previously listed substances.<sup>21</sup> The 11<sup>th</sup> RoC was published over nine years ago and added only 17.

It is highly likely that additional, significant studies on many of these 240 substances have been published since these chemicals were first listed by NTP, many of them decades ago. Furthermore, many of the NTP assessments pre-date key scientific advances, and there appears to be a bias in the NTP process against recognizing those scientific advances. No one should confidently rely on these determinations made so many years ago without first thoroughly reviewing any new data produced since the listing as well as examining the analysis that led to the original listing in light of the steadily advancing science of hazard assessment since the initial listing. Similarly, risk assessment methodology and mode of action analysis have changed over time. It is for these reasons that the National Academy of Sciences (NAS) is conducting a Congressionally-mandated scientific peer review of the determinations concerning formaldehyde and styrene in the NTP’s 12th RoC to ensure that both the classification criteria used by NTP, and the application of those criteria, reflect science best practices.<sup>22</sup> The final NAS report is expected by September 2014.

## **V. Federal HCS Preempts the Proposed Rule**

In adopting HCS 2012, OSHA explicitly acknowledged that: “significant portions of the benefits of the rule . . . can only be achieved if the system used in the U.S. is consistently and uniformly applied throughout the nation and in conformance with the internationally harmonized system.”<sup>23</sup>

As discussed elsewhere in these comments, it is possible that a chemical deemed a carcinogen by NTP will not be classified a carcinogen under the HCS based on a weight of evidence evaluation. A Proposition 65 listing stating otherwise, therefore, would be contrary to the classification developed under the federal HCS. Conflicting classifications would cause employees to receive conflicting messages about the chemical and would undermine the effectiveness and credibility of the hazard communication system.

A Proposition 65 listing presumably would require workplace training, signage and container labels communicating cancer warnings; yet the OSHA-required training, container label and

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<sup>20</sup> NTP, “History of History of the RoC,” available at <http://ntp.niehs.nih.gov/?objectid=03CA7EEA-CBAA-EB17-20B4B2C329C5DDCF>.

<sup>21</sup> See <http://www.niehs.nih.gov/health/topics/agents/sya-roc/>.

<sup>22</sup> The National Research Council of NAS, at the request of the Department of Health and Human Services, has undertaken a scientific peer review of the determinations concerning formaldehyde and styrene in the NTP’s 12th Report on Carcinogens (RoC). The review will also consider whether NTP’s listing criteria are scientifically defensible.

<sup>23</sup> 77 Fed. Reg. at 17,575.

SDSs for an interstate shipment would not. OSHA's concerns for these types of multiple schemes and inconsistent characterizations were expressed when the agency promulgated HCS 2012:

The changes to the HCS will create a uniformity standard for the presentation of hazard information and, as such, will serve to improve the efficiency and effectiveness of the existing hazard communication system in the U.S., and to reduce unnecessary barriers to trade. Hazard communication is currently addressed by many different international, national, and State authorities.... [T]hese existing requirements are not always consistent and often contain different definitions of hazards and varying provisions for what information is required on labels and safety data sheets. Complying with these different rules results in increased costs for employers with hazardous chemicals in their workplace and for chemical manufacturers, distributors, and transporters involved in international trade. In addition to these effects on businesses, the different existing requirements result in workplaces receiving chemicals with varying information, with potential adverse impacts on the safety and health of employees. The revisions to the OSHA HCS will standardize the hazard communication requirements for products used in U.S. workplaces, and thus provide employees with uniform and consistent hazard communication information. Secondly, because these revisions will harmonize the U.S. system with international norms, they will facilitate international trade.<sup>24</sup>

OSHA works to eliminate conflicts between federal and state hazard communications standards consistent with Occupational Safety and Health Act (OSH Act) provisions designed to prevent those conflicts. To the extent it is applied to the workplace, a Proposition 65 listing would “stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,” and make it “impossible” for a private party to comply with both state and Federal law.<sup>25</sup>

A preemption analysis begins with the Supremacy Clause of the U.S. Constitution, which declares that the "Constitution and the Laws of the United States . . . shall be the supreme Law of the Land."<sup>26</sup> As the U.S. Supreme Court has stated, “it has been settled that state law that conflicts with federal law is without effect.”<sup>27</sup> The same holds true of state law that conflicts with federal regulation.<sup>28</sup> Courts look specifically to the intent expressed by Congress when

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<sup>24</sup> *Id.* at 17,605.

<sup>25</sup> *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000) 166 F.3d 1236, affirmed.

<sup>26</sup> Article VI, Section 2, of the U.S. Constitution; *Cipollone v. Liggett Group, Inc.*, 112 S.Ct. 2608, 2617 (1992).

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

<sup>28</sup> *Fidelity Fed. Say. & Loan Ass 'n v. De La Cuesta*, 458 U.S. 141, 153 (1982) (“Federal regulations have no less pre-emptive effect than federal statutes”).

adopting a statute as the “ultimate touchstone” of preemption analysis.<sup>29</sup> Such intent may be explicitly stated or implicitly contained in the statute's structure and purpose.<sup>30</sup>

While there are various types of preemption, at least one is relevant here—conflict preemption. Specifically, Federal law nullifies conflicting state law in at least two instances. The first type is where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress” (“obstacle preemption”).<sup>31</sup> The second type is where it is “impossible” for a private party to comply with both state and Federal law (“impossibility preemption”).<sup>32</sup>

Obstacle preemption would apply if OEHHA proceeds to finalize a listing. Under obstacle preemption, courts look specifically to the goals underlying a given regulatory scheme and ask whether the state law would frustrate the Federal agency's efforts to reach those goals. For example, the U.S. Supreme Court in *Geier* held that an injured motorist's design defect claim, which sought to hold a car manufacturer liable for failing to install a driver's side airbag, was preempted. The Court noted that Federal regulations at the time required manufacturers to install passive restraints in “some but not all” of their vehicles and provided a “range of choices among different passive restraint devices” to be “introduced gradually over time.”<sup>33</sup> Citing to comments made by the Department of Transportation (“DoT”) when issuing the regulation, the Court noted that its purpose was to “lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance—all of which would promote [the regulation's] safety objectives.”<sup>34</sup> In other words, DoT adopted a compromise between gradually forcing technological development and addressing immediate safety needs. The Court, not surprisingly, found that a state tort law which would require airbags in all vehicles “presented an obstacle to the variety and mix of devices that the federal regulation sought” and to the “gradual passive restraint phase-in that the federal regulation deliberately imposed.”<sup>35</sup>

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<sup>29</sup> *Cipollone v. Liggett Group, Inc.*, at 2617.

<sup>30</sup> *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

<sup>31</sup> *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000).

<sup>32</sup> *Cipollone v. Liggett Group, Inc.*, at 2617.

<sup>33</sup> *Geier v. Am. Honda Motor Co., Inc.* at 874-75.

<sup>34</sup> *Id.* at 875.

<sup>35</sup> *Id.* at 881. *See also In re Bextra*, No. M: 05-1699 CRB, 2006 WL 2374742, at \*9 (N.D. Cal. Aug. 16, 2006) (finding failure to warn tort claims involving an anti-inflammatory drug preempted under the Federal Food, Drug, and Cosmetic Act where class action plaintiffs argued for warnings that would have upset the policy choice made by the U.S. Food and Drug Administration to require the disclosure of known risks, but prohibit “defensive” labeling warning of unsubstantiated risks); *Blue Circle Cement, Inc. v. Bd. of Cnty. Comm'rs*, 917 F. Supp. 1514, 1519-20 (N.D. Okla. 1995) (holding local ordinance effectively prohibiting the burning of hazardous waste for energy was preempted by the Resource Conservation and Recovery Act's goal of “replac[ing] land disposal with advanced treatment, recycling, and incineration”).

OSHA expressly sought in HCS 2012 to “create a uniformity standard for the presentation of hazard information.” This uniformity will supplant “different existing requirements [that] result in workplaces receiving chemicals with varying information, with potential adverse impacts on the safety and health of employees,” and “because these revisions will harmonize the U.S. system with international norms, they will facilitate international trade.”<sup>36</sup>

All of this starts to unravel if California proceeds with the Labor Mechanism rule as proposed. Certain listings will undoubtedly create implied conflict preemption and the Proposition 65 requirements that would follow from a listing would frustrate the clear purpose of HCS 2012 to harmonize United States practices with the GHS.

## **VI. Conclusion**

With one significant exception, we support OEHHA’s revised approach. Consistent with substantial judicial precedent, the OEHHA proposal properly requires sufficient evidence of carcinogenicity for listing substances. We also agree that the Director’s List is not a basis for listing substances under Proposition 65.

Regrettably, OEHHA is attempting to establish a Labor Code listing mechanism process that is outside the realm of what the California legislature contemplated or authorized when it enacted Labor Code section 6382(d). OEHHA interpretation of HCS 2012 flatly contradicts both the regulatory text and OSHA’s intent in adopting HCS 2012. The *Initial Statement of Reasons* issued by OEHHA to support the Proposed Rule reflects an inappropriate effort by the agency to rewrite both its statutory authority and the HCS 2012. As reasoned by OEHHA, the Proposition 65 rule is inconsistent with the language, the intent and the underlying principles of the HCS 2012 and Labor Code section 6382(d).

Under HCS 2012, substances identified as human or animal carcinogens by IARC or the NTP are not carcinogens “within the scope” of the HCS by virtue of their reference on a substance’s chemical SDS. For OEHHA to list based on an information reference and ignore the cancer determination mechanism in HCS 2012 is to clash with: (1) the purpose of the Labor Code Mechanism provision, which is to conform the state law to federal law; (2) the criteria for a substance to be a carcinogen “within the scope” of the HCS, which is specific finding by OSHA that a chemical is a carcinogen; and (3) the amendments to the HCS in 2012 and OSHA’s repeal of the requirement that the HCS treat NTP’s RoC and IARC’s Monographs as establishing that a chemical is a carcinogen.

The only chemicals that meet the listing criteria of section 6382(d) are those chemicals determined to be carcinogens by OSHA and listed under 29 C.F.R. part 1910, subpart Z. This finding is consistent with the statutory language, existing case law, and the terms of the HCS 2012. Accordingly, the agency must amend the “Summary and Rational of Regulation” section of its *Initial Statement of Reasons* and delete any suggestion that because HCS requires a SDS to disclose that a workplace chemical listed in the NTP RoC or has been found to be a carcinogen

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<sup>36</sup> 77 Fed. Reg. at 17,605.

Ms. Monet Vela  
April 4, 2014  
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in the IARC Monographs, the substance is within the scope of the HCS and can be listed pursuant to Labor Code section 6382(d).

Respectively submitted,

A handwritten signature in black ink, appearing to read "John O. Snyder". The signature is fluid and cursive, with the first name "John" being the most prominent.

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