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Sent Electronically to: P65Public.comments@oehha.ca.gov

SUBJECT: OEHHA's Proposed "Labor Code" Listing Mechanism Regulation

Dear Ms. Vela:

The California Chamber of Commerce and the below-listed organizations thank you for the opportunity to submit comments regarding the Office of Environmental Health Hazard Assessment's ("OEHHA") Notice of Proposed Rulemaking to clarify the procedure and criteria OEHHA uses to list and de-list chemicals via the "Labor Code" listing mechanism of Proposition 65.

On June 17, 2013, OEHHA held a public pre-regulatory workshop for the purpose of gathering input from interested parties concerning the listing of chemicals under the Proposition 65 Labor Code listing mechanism. In response to the comments received during and after the pre-regulatory workshop, on

January 27, 2014, OEHHA released for public review the text of its proposed Labor Code listing regulation as well as its associated Initial Statement of Reasons. According to the Initial Statement of Reasons, the purpose of OEHHA's proposed regulation is to "ensure transparency, certainty and clarity for the general public, non-governmental organizations, and the business and enforcement communities" and to "clarify and explain to interested parties the way OEHHA identifies chemicals and substances that must be added to the Proposition 65 list based on their identification by reference via the Labor Code provisions in Proposition 65 and explain the process for reconsidering chemicals that have been listed via this mechanism."

The primary purpose of our comments is to ensure that the proposed regulation is consistent with (1) the stated purpose detailed in OEHHA's Initial Statement of Reasons; (2) published appellate case law concerning the proper interpretation of the Labor Code listing mechanism; and (3) the federal Occupational Safety and Health Administration's ("OSHA") recent changes, effective May 2012, to the federal Hazard Communication Standard ("HCS 2012") regulations found in Title 29 of the Code of Federal Regulations, section 1910.1200.

Although OEHHA's proposed regulation contains considerable improvements from the pre-proposal regulation issued last year, the proposed regulation nonetheless contains five significant flaws that demonstrate inconsistencies with published appellate law and OSHA's HCS 2012. Accordingly, OEHHA would exceed the scope of its legal authority if it were to adopt the proposed regulation in its current form.

The five flaws we have identified, which will be discussed in more detail in the balance of this letter, are briefly summarized as follows:

1. Although we appreciate OEHHA's intent to codify *Styrene Information and Research Center v. OEHHA* (2012) 210 Cal.App.4th 1082 (hereinafter "*SIRC*") in subsection (a)(1) by adding the phrase "based on sufficient animal or human evidence," subsection (a)(1) nonetheless invites an overly inclusive interpretation which, in effect, would require the listing of chemicals otherwise beyond Proposition 65's reach. Specifically, one can and indeed may interpret subsection (a)(1) to mean that sufficient evidence of carcinogenicity to animals or humans exists as a matter of law for *all* Group 2A and 2B chemicals. We trust that this is not OEHHA's intent, as OEHHA's Initial Statement of Reasons makes it abundantly clear that only those Group 2A and 2B chemicals for which sufficient evidence of human or animal carcinogenicity has been established may be listed under Proposition 65. Accordingly, below we will propose amended language, consistent with the rationale provided in OEHHA's Initial Statement of Reasons, to clarify this issue so as to accurately track the *SIRC* decision.
2. OEHHA's Initial Statement of Reasons interprets that chemicals classified as carcinogens or potential carcinogens on the International Agency for Research on Cancer ("IARC") Monograph or the National Toxicology Program's ("NTP") Report on Carcinogens are "within the scope" of the HCS 2012. OEHHA's interpretation expressly ignores the fundamental purpose of the HCS 2012, which was to (1) repeal the mandate that employers treat substances listed on IARC's Monograph or NTP's Report on Carcinogens as conclusive findings of carcinogenicity and (2) establish a "weight of the evidence" analysis which directs manufacturers and importers to evaluate their chemicals in accordance with 29 C.F.R., section 1910.1200.

Contrary to the purpose of HCS 2012, however, OEHHA's maintains that the manner in which one single individual manufacturer or employer classifies a chemical in a safety data sheet ("SDS") under HCS 2012 may constitute the basis for listing under the Labor Code Mechanism. OEHHA's position is fundamentally flawed as a factual and legal matter. As articulated in further detail below, chemicals listed as human or animal carcinogens by IARC may only now be listed pursuant to Labor Code section 6382(b)(1), which is the only reference contained in that section. Because the purpose of Labor Code section 6382(d) is to conform California law to HCS 2012, subdivision (d)'s reference to the HCS no longer incorporates the chemicals listed by NTP or IARC. Accordingly,

such chemicals may not be the basis for listing under subdivision Labor Code section 6382(d). OEHHA's proposed regulation and its Initial Statement of Reasons expressly ignore the changes mandated by HCS 2012, however, and instead identify an attenuated rationale for automatically bootstrapping chemicals identified on IARC's Monograph and NTP's Report on Carcinogens within the purview of Proposition 65 listing. Put another way, despite the significant changes resulting from the HCS 2012, OEHHA appears to define "within the scope" of the HCS in the *very same way* as it did prior to the 2012 amendments.

3. Notwithstanding the Initial Statement of Reasons' express acknowledgment that OEHHA is no longer proposing chemical listings of reproductive toxicants under subdivision (d) of the Labor Code listing mechanism, OEHHA has nonetheless included the phrase "or reproductive toxicity" in subdivision (a)(2) of its proposed regulation "so that chemicals could be listed as reproductive toxicants in the future if they are otherwise identified as 'within the scope' of the HCS." Subdivision (a)(2) of the proposed regulation must be consistent with OEHHA's Initial Statement of Reasons. In this respect, subdivision (a)(2) must expressly state that reproductive toxicants shall not be listed until such time as OSHA amends its HCS to reintroduce Threshold Limit Values or another metric as a definite source for identifying chemicals that are known to cause reproductive toxicity.
4. OEHHA limits comments on proposed listings to "whether or not the chemical has been identified by reference in either Labor Code section 6382(b)(1) or 6382(d) or both." OEHHA's proposal to list by reference, however, is not "essentially automatic" as it suggests in its Initial Statement of Reasons. In fact, the *SIRC* court expressly rejected such a rigid position, and instead held that a chemical can only be listed under section 6382(b)(1) or 6382(d) if there is sufficient evidence of carcinogenicity in humans or animals. In establishing this legal standard for listing purposes under the Labor Code listing mechanism, OEHHA is obligated to provide the public with an opportunity to comment on whether the sufficient evidence standard for a given listing proposal has been established. Limiting public comment merely to which Labor Code section applies, therefore, expressly ignores *SIRC* decision and, in doing so, precludes meaningful public comment regarding the sufficiency of the evidence standard.
5. Subsection (d) requires a chemical to remain on the list pending review by the Carcinogen Identification Committee ("CIC") or the Developmental and Reproductive Toxicant Identification Committee ("DART"), even *after* a determination by OEHHA that (1) a listed chemical no longer meets the criteria for listing under the Labor Code Mechanism and (2) a listed chemical no longer meets the criteria for listing under Health and Safety Code sections 25306 and 25902. Put another way, a chemical must remain on the list pending review by CIC and DART even if OEHHA determines that there is no basis for including the chemical on the Proposition 65 list. OEHHA's rationale for doing so is that it will "reduce potential confusion that could otherwise occur if a chemical were to be delisted pending a committee decision, and then relisted if the committee determines it causes cancer or reproductive toxicity, or both." Confusion, however, is not a legal basis for keeping chemicals on the list. Absent such a legal basis, OEHHA cannot allow a chemical which does not meet listing criteria to nonetheless remain on the list pending the formal delisting process.

Prior to discussing these five flaws in more detail, we provide a brief legal summary of the Labor Code listing mechanism, the pertinent case law interpreting the same, and OSHA's HCS, including both the pre-2012 HCS and the 2012 amendments thereto. This legal summary is important because it defines OEHHA's scope of authority and, in doing so, provides the legal limitations to which OEHHA is bound in promulgating its regulation.

LABOR CODE LISTING MECHANISM, INTERPRETIVE CASE LAW, AND OSHA'S HCS

This section provides a brief legal discussion regarding (1) the Labor Code listing mechanism under Proposition 65; (2) pertinent case law interpreting the same; (3) OSHA's pre-2012 HCS; and (4) OSHA's 2012 amendments to its HCS.

Labor Code Listing Mechanism

Proposition 65 required the Governor to establish and update a list of chemicals “known to the state to cause cancer or reproductive toxicity” (Health & Safety Code, § 25249.8(a).) Chemicals may be added to the list through one of four avenues. One such avenue, known as the Labor Code listing mechanism, provides that the list shall contain “those substances identified by reference in Labor Code Section 6382(b)(1) and . . . (d).” (Health & Safety Code, § 25249.8.) The Labor Code sections identified in the Health and Safety Code provide as follows:

Section 6382(b)(1): “Substances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC).”

Section 6382(d): “Notwithstanding Section 6381, in addition to those substances on the director’s list of hazardous substances, 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.”

Accordingly, the “reference” in subdivision (b)(1) is IARC and the chemicals identified are those listed by IARC as human or animal carcinogens in its Monographs on the Evaluation of Carcinogenic Risks to Humans. The “reference” in subdivision (d) is any substance within the scope of OSHA’s HCS.

Thus, Proposition 65’s Labor Code listing mechanism embraces two separate and distinct sources for purposes of listing: (1) substances listed as human or animal carcinogens by IARC; and (2) any substance within the scope of the HCS.

As we now discuss, notwithstanding the clear terms of subdivisions (b)(1) and (d), case law has carved out certain limitations over the years with respect to how chemicals can be listed using the Labor Code listing mechanism. Specifically, a reference substance in and of itself does not provide a basis for listing. Instead, the list shall include only those substances identified by reference in subdivisions (b)(1) and (d) for which there is sufficient animal or human evidence that the referenced substance is known to cause cancer or reproductive toxicity.

Case Law

The first significant case to address Proposition 65’s Labor Code Listing Mechanism was *AFL-CIO v. Deukmejian* (1989) 212 Cal.App.3d 425. In *Deukmejian*, the court rejected the Governor’s argument that the list was required to include only known *human* carcinogens and reproductive toxins, concluding instead that a chemical must be included on the Proposition 65 list if it is identified by reference in the Labor Code section 6382 (d) as one known to cause cancer in either humans or animals.

About 20 years later, in *California Chamber of Commerce v. Brown* (2011) 196 Cal.App.4th 233, an appellate court held that OEHHA may add chemicals to the Proposition 65 list using the methodology set forth in subdivision (a) of section 25249.8. According to the court, the Labor Code listing mechanism set forth in subdivision (a) of section 25249.8 specifies the minimum content of the Proposition 65 list as it is revised and republished.

Most recently, in *Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment* (2012) 210 Cal.App.4th 182, the court held that the ultimate test in determining whether a chemical should be listed under Proposition 65 is whether the substance is “known to the state to cause cancer or reproductive toxicity,” and further suggests that judicial review may be available to examine whether that standard is met, *regardless of which listing mechanism is employed*.

By way of factual background, OEHHA had proposed the listing of styrene and vinyl acetate under the Labor Code listing mechanism. OEHHA, citing to Health and Safety Code section 25249.8, had

contended that the list must include those substances identified “by reference” to Section 6382 subdivision (d) of the Labor Code. The HCS at that time required one to treat a chemical as “hazardous” if it was identified as a hazard by one of several possible sources, including the IARC Monographs. OEHHA noted that IARC had evaluated vinyl acetate and styrene and placed both chemicals in Group 2B (“Possibly Carcinogenic to Humans”).

OEHHA argued that the Agency was required by the Court’s previous decision in *Deukmejian* to include on the Proposition 65 list not only those chemicals known to cause cancer in humans, but also chemicals known to cause cancer in animals. By extension, OEHHA contended that *Deukmejian* required the listing of all IARC Group 2B chemicals, including those with less than adequate evidence of carcinogenicity in animals, because these chemicals were “within the scope” of the chemicals for which warnings were required under the HCS.

The court rejected OEHHA’s argument for listing Group 2B chemicals. The Court explained that *Deukmejian* arose from the Governor’s decision to include on the initial Proposition 65 list only chemicals that were known to be human carcinogens, excluding chemicals for which the only evidence of carcinogenicity was animal data. Accordingly, the only issue presented in *Deukmejian* was whether the list must include *both* human and animal carcinogens. The question is *SIRC*, however, was whether substances identified by references in an IARC Monograph *for which there is not sufficient evidence of carcinogenicity in either humans or animals* must be included on the list.

The court answered this question in the negative, noting that Proposition 65 is concerned only with those substances that are known to cause cancer or reproductive toxicity. Thus, the initial list, and subsequent lists published thereafter, need not include all substances listed under HCS but only those known carcinogens and reproductive toxins listed therein.

With the above cases in mind, we now turn to a brief summary of OSHA’s HCS, including the most recent amendments to which the proposed regulation is required to conform.

OSHA’s HCS (Pre-2012)

The federal HCS referenced in Labor Code section 6382, subdivision (d), was created in 1983 pursuant to title 29, section 655 of the United States Code. That statute authorized the Department of Labor, through OSHA, to promulgate a “final occupational safety and health standard entitled ‘Hazard Communication’ (29 C.F.R. § 1910.1200.)” (48 Fed.Reg.53280 (November 25, 1983.))

In *California Chamber of Commerce v. Brown*, the court provided an informative summary of the purpose of the HCS one year before it was amended in 2012:

The purpose of the HCS is “to ensure that the hazards of all chemicals produced or imported are evaluated, and that information concerning their hazards is transmitted to employers and employees.” This information is transmitted by “means of comprehensive hazard communication programs” which include, among other things, “container labeling and other forms of warning.”

Health “hazards” under the federal HCS include more than “chemicals known to the state to cause cancer or reproductive toxicity” included in the Proposition 65 list, but do include “carcinogens” and “reproductive toxins.” Instead of attempting to identify every hazardous chemical by creation of a single list of hazardous substances, the HCS requires manufacturers, importers and employers to evaluate chemicals they produce, import or utilize to determine if the chemicals are hazardous and the particular hazards they pose.

(*California Chamber of Commerce*, 196 Cal.App.4th at 218-219.)

Prior to 2012, the HCS required manufacturers, importers, and employees to treat three sources as establishing that a chemical is a carcinogen. (29 C.F.R. section 1910.1200(d)(4).) These sources were (1) NTP's Annual Report on Carcinogens, (2) IARC's Monographs, and (3) the chemicals determined by OSHA to be carcinogens through substance-specific rulemakings and listed in 29 C.F.R. part 1910, subpart Z.

OSHA's HCS (2012 Amendments)

OSHA's 2012 amendments to its HCS were a significant departure from the previous HCS. Specifically, the 2012 amendments to the federal HCS align the HCS with three aspects of the United Nations' Globally Harmonized System of Classification and Labeling of Chemicals ("GHS"). HCS 2012 continues to mandate that employers automatically treat substances as carcinogens if they are so-identified in an OSHA substance-specific standard (subpart Z), but, relevant and significant here, mandatory treatment as a carcinogen based on an IARC Monograph is no longer required under HCS 2012. Rather, HCS 2012 directs the domestic manufacturer or importer to self-classify each chemical based on a weight of the evidence analysis.

With the enactment of HCS 2012, OSHA no longer treats the finding of IARC and NTP as conclusive under HCS 2012 and makes reliance on them an individual option for each manufacturer or importer. Accordingly, given that OSHA no longer deems the IARC and NTP findings to be binding, they no longer fall within Labor Code section 6382 subdivision (d), and OEHHA cannot expand the scope of the statute to include chemicals that are outside its scope (even if they were previously within its scope).

With respect to reproductive toxicants, HCS 2012 deleted the previous HCS's express reference to the American Conference of Governmental Industrial Hygienists Threshold Limit Values for occupational exposures to chemical hazards. Under the previous HCS, using the Threshold Limit Values was the only source for identifying chemicals that are known to cause reproductive toxicity. Accordingly, HCS 2012 provides no basis for a Labor Code reference listing of OSHA reproductive or developmental toxicants.

OEHHA's Scope of Authority

Summarizing the above legal principles and regulatory developments, OEHHA's Labor Code listing regulation must incorporate and be limited to the following:

1. The only references and chemicals that may be considered for listing are (1) substances listed as human or animal carcinogens by IARC [Labor Code section 6382(b)(1)]; and (2) chemicals "within the scope of the HCS, *i.e.*, chemicals for which OSHA has included cancer as a health hazard in 29 C.F.R. part 1910, subpart Z [Labor Code section 6832(d)].
2. Reproductive toxicants may not be included as "within the scope" of HCS 2012. HCS 2012 does not reference subpart Z chemicals as reproductive or development toxins.
3. Substances identified by reference in Labor Code Section 6382 subsections (b)(1) and (d) may only be listed if there is sufficient animal or human evidence that the substance is known to cause cancer.

We now discuss the five significant flaws with OEHHA's proposed regulation.

OEHHA'S PROPOSED REGULATION CONTAINS FOUR SIGNIFICANT FLAWS

As noted above, OEHHA's proposed regulation contains the following five flaws: (1) subsection (a)(1) invites an overly inclusive interpretation; (2) OEHHA erroneously interprets "within the scope" of the HCS in subsection (a)(2) by treating NTP and IARC determinations as conclusive findings of carcinogenicity; (3) OEHHA's position that reproductive toxicants may be within the scope of a future HCS does not justify including reproductive toxicants in Subsection (a)(2); (4) OEHHA unjustifiably precludes public comment

on whether the sufficient evidence standard has been satisfied; and (5) “confusion” is not justifiable legal basis to require a chemical to remain on the list pending CIC or DART review. We now discuss each flaw in turn.

Subsection (a)(1) Invites and Overly Inclusive Interpretation

In its Initial Statement of Reasons, OEHHA expressly stated that it intended to incorporate the *SIRC* holding into its proposed regulation. Specifically, the Initial Statement of Reasons states the following, in relevant part:

In October, [2]012, the 3rd District Court of Appeal stated in *Styrene Information and Research Center v. Office of Environmental Health Hazard and Assessment*, (October 31, 2102, 3rd District), that chemicals listing via the Labor Code method must be based on sufficient animal or human evidence. Therefore, the phrase “based on sufficient animal or human evidence” was added to the proposed regulatory language.

(Initial Statement of Reasons, p.8)

Consistent with this statement, OEHHA’s Initial Statement of Reasons also correctly acknowledges that chemicals in Group 2A and 2B would not qualify for listing via Labor Code section 6382(b)(1) if there is less than sufficient evidence of carcinogenicity in humans or experimental animals. (Initial Statement of Reasons, pp.5-6.)

Notwithstanding OEHHA’s inclusion of the phrase “based on sufficient animal or human evidence” in subsection (a)(2) and despite its correct statement that Group 2A and 2B chemicals may only be listed if sufficient evidence of carcinogenicity in humans or experimental animals are present, subsection (a)(1) contains certain grammatical flaws that leave some uncertainty regarding how OEHHA would evaluate chemicals identified by IARC in its IARC Monographs series on the Evaluation of Carcinogenic Risks to Humans (most recent version). For example, subsection (a)(2) indicates that a chemical will be listed if it has been identified in IARC Monographs, “based on sufficient animal or human evidence as” carcinogenic to humans (Group 1), probably carcinogenic to humans (Group 2A), or possibly carcinogenic to humans (Group 2B).

Stated in this way, it remains unclear whether OEHHA’s listing authority depends on the presence of sufficient evidence of carcinogenicity or the *classification* of the chemical. As such, one could and indeed may read subsection (a)(1) to mean that all chemicals within identified by the IARC Monographs are deemed by OEHHA to have sufficient evidence and thus must be listed under Proposition 65. Such an application, however, would require the listing of chemicals ordinarily beyond Proposition 65’s reach, and would further be contrary to both OEHHA’s Initial Statement of Reasons and the *SIRC* decision. Because the *SIRC* decision clearly holds that the relevant question for purposes of listing under Proposition 65 is not simply whether the chemical is identified by the IARC Monographs, but whether the chemical is carcinogenic to humans based on sufficient animal or human evidence, we propose the following language to clarify this issue and to accurately track the *SIRC* decision and OEHHA’s Initial Statement of Reasons:

- (a) Pursuant to Section 25249.8(a), of the Act, a chemical shall be included on the list of chemicals known to the state to cause cancer or reproductive toxicity if it is a substance identified by reference in Labor Code Section 6832(b)(1) or by reference in Labor Code Section 6382(d) as causing cancer or reproductive toxicity.
 - (1) A chemical shall be included on the list if it is identified by the International Agency for Research on Cancer in its IARC Monographs series on the Evaluation of Carcinogenic Risks to Humans (most recent edition) ~~based on sufficient animal or human evidence as~~ **and if the chemical identified by the International Agency for Research on Cancer**

in its IARC Monographs series on the Evaluation of Carcinogenic Risks to Humans (most recent version) is:

- a. Carcinogenic to humans **based on sufficient evidence of carcinogenicity in humans or experimental animals** (Group 1);
- b. Probably carcinogenic to humans **based on sufficient evidence of carcinogenicity in experimental animals** (Group 2A); or
- c. Possibly carcinogenic to humans **based on sufficient evidence of carcinogenicity in experimental animals** (Group 2B)

Importantly, we emphasize that our proposed language merely enumerates with greater specificity and clarity OEHHA's true intent, as provided in its Initial Statement of Reasons. Our proposed language is also consistent with the following two-prong approach required for purposes of listing under Labor Code section 6832(b)(1):

1. Is the chemical identified by the IARC in its IARC Monographs?
2. If the chemical is identified by the IARC in its IARC Monographs, is the chemical known to cause cancer based on sufficient evidence of carcinogenicity to animals or humans?

As a final matter, we note that if OEHHA's proposed subsection (a)(1) is not modified in a way that is consistent with its Initial Statement of Reasons and the *SIRC* decision, a court will perhaps interpret the regulation literally without deference to OEHHA's true intent specified in its Initial Statement of Reasons. (See, e.g., *Department of Alcoholic Beverage Control v. Alcoholic Beverage Control Appeals Bd.* (2003) 109 Cal.App.4th 1687 [if the words of an administrative regulation, given their usual and ordinary meaning, are clear and unambiguous, the court *presumes the adopting authority meant what it said* and the plain language of the regulation applies].) Here, the terms of subsection (a)(1) of the proposed regulation appear to be clear and unambiguous. However, when giving the terms in subsection (a)(1) their usual and ordinary meaning, subsection (a)(1) does *not* mean what OEHHA actually means it to say. For this reason, subsection (a)(1) must be modified to track its Initial Statement of Reasons and the *SIRC* decision so as to avoid a judicial presumption that the plain language of subsection (a)(1) applies.

OEHHA Erroneously Interprets "Within the Scope" of HCS 2012 in subsection (a)(2) by Treating NTP and IARC Determinations as Conclusive Findings of Carcinogenicity

OEHHA's Initial Statement of Reasons states that chemicals under Appendix D of OSHA's revised changes to the HCS are "within the scope" of the HCS and thus must be listed under Proposition 65. In support of its position, OEHHA opines that because Item 11 in Appendix D of the HCS requires a safety data sheet ("SDS") to disclose whether a workplace chemical is listed in the NTP Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the IARC Monographs, such chemicals fall "within the scope" of the HCS and thus must be listed under Proposition 65. OEHHA's interpretation, however, is fundamentally flawed as a factual and legal matter, and is in direct contradiction to the very purpose of the HCS 2012.

As discussed above, until 2012, the HCS mandated that employers treat substances as carcinogens if the substances were identified as carcinogens in an OSHA substance-specific standard or classified as a carcinogen or possible carcinogen by the IARC Monograph or NTP Report on Carcinogens. In an attempt to align the HCS with three aspects of the GHS, however, HCS 2012 continues to mandate that employers automatically treat substances as carcinogens if they are so-identified in an OSHA substance-specific standard. Significantly, however, HCS 2012 repealed the requirement to treat IARC's Monograph or NTP's Report on Carcinogens as establishing that a chemical is a carcinogen. Rather, in its place, HCS 2012 directs manufacturers and importers to evaluate their chemicals in accordance with section

1910.1200 and to determine the hazard class or classes using a weight of evidence approach and consulting Appendix A for classification of health hazards.

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 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). OSHA explained the basis for the amendment as follows:

With the detailed criteria, and the weight of the evidence approach in the GHS, OSHA indicated in the NPRM that it appeared no longer necessary to have such a floor or the one study rule.

(Initial Statement of Reasons, Title 27, California Code of Regulations, Proposed section 25904, Listing by Reference to the California Labor Code at 9.)

A review of changes to the language of HCS makes it clear that HCS 2012 removed mandatory classification based on IARC or NTP classifications. Section 1910.1200(d) of the HCS governs hazard classification. The previous HCS, section 1910.1200(d)(4), referenced the NTP Report on Carcinogens and IARC Monographs as part of the hazard determination process, but all the references to the NTP Report and IARC Monographs have been stricken in HCS 2012.

Further, a review of the completely overhauled Appendix A demonstrates that the HCS now operates under a weight of evidence framework; NTP and IARC determinations are no longer treated as conclusive findings of carcinogenicity under HCS 2012.

Section 1910.1200(d) to Previous HCS	Section 1910.1200(d) to HCS 2012
(d) Hazard determination ... (d)(4) Chemical manufacturers, importers and employers evaluating chemicals shall treat the following sources as establishing that a chemical is a carcinogen or potential carcinogen for hazard communication purposes: (d)(4)(i) National Toxicology Program (NTP), "Annual Report on Carcinogens" (latest edition); (d)(4)(ii) International Agency for Research on Cancer (IARC) "Monographs" (latest editions; or (d)(4)(iii) 29 CFR part 1910, subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration.	(d) Hazard classification (d)(1) Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported to them to classify the chemicals in accordance with this section. For each chemical, the chemical manufacturer or importer shall determine the hazard classes, and where appropriate, the category of each class that apply to the chemical being classified. Employers are not required to classify chemicals unless they choose not to rely on the classification performed by the chemical manufacturer or importer for the chemical to satisfy this requirement. (d)(2) 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.
Appendix A to Previous HCS	Appendix A to HCS 2012
<p>1. "Carcinogen:" A chemical is considered to be a carcinogen if:</p> <p>(a) It has been evaluated by the International Agency for Research on Cancer (IARC), and found to be a carcinogen or potential carcinogen; or</p> <p>(b) It is listed as a carcinogen or potential carcinogen in the Annual Report on Carcinogens published by the National Toxicology Program (NTP) (latest edition); or</p> <p>(c) It is regulated by OSHA as a carcinogen.</p>	<p>A.6.4 Classification of Carcinogenicity</p> <p>A.6.4.1 Chemical manufacturers, importers and employers evaluating chemicals may treat the following sources as establishing that a substance is a carcinogen or potential carcinogen for hazard communication purposes in lieu of applying the criteria described herein:</p> <p>A.6.4.1.1 National Toxicology Program (NTP), "Report on Carcinogens" (latest edition);</p> <p>A.6.4.1.2 International Agency for Research on Cancer (IARC) "Monographs on the Evaluation of Carcinogenic Risks to Humans" (latest editions)</p> <p>A.6.4.2 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.</p>

Accordingly, whereas the previous HCS *required* manufacturers, importers and employers to treat IARC and NTP designations as carcinogens, HCS 2012 switches to a weight of the evidence analysis. As part of the weight of the evidence analysis, a manufacturer, importer or employer may, *but is not required to*, treat chemicals designated on IARC and NTP as carcinogens. The only similarity between the previous HCS and HCS 2012 in this respect is that manufacturers, importers and employers continue to be required to classify chemicals as a carcinogen 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.

In this respect, the only chemicals that are deemed carcinogens under HCS 2012, such that a self-implemented assessment need not be completed, are those chemicals identified as potential carcinogens by OSHA through a substance-specific rulemaking and listed under 29 CFR part 1910, Subpart Z. (See A.6.4.1 [NTP and IARC classifications "may" be treated as establishing that a substance is a carcinogen]' but see A.6.4.2 [Subpart Z chemicals "shall" be treated as a carcinogen].) Accordingly, OEHA can reference subpart Z for purposes of listing a chemical under Proposition 65, but as discussed below, this is not true for reproductive toxicants.

As further evidence that IARC and NTP classifications as are not conclusive of a hazard classification, OSHA repeatedly made statements throughout its Final Rule that the requirement to list NTP and IARC classifications on SDSs is merely informational:

OSHA finds that requiring . . . IARC and NTP classification listings on the SDS will provide employers and employees with **useful information** to help them assess the hazards presented by their workplaces.

...

Another change to the final rule is the inclusion of the IARC and NTP **as resources** for determining carcinogenicity. Commenters generally supported this modification, and OSHA believes the inclusion of this information will **assist evaluators with the classification process**. Therefore, descriptions of both the IARC and NTP classification criteria have been added to Appendix F, and IARC and NTP classifications **may be used** to determine whether a chemical should be classified as a carcinogen.

...

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 F to allow classifiers to use these 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 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.

(77 Fed. Reg., at 17574, 17735 [emphasis added].)

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. OEHHA's position that chemicals classified as a potential carcinogen or potential carcinogen on the IARC Monograph or NTP Report on Carcinogens are "within the scope" of the HCS, therefore, expressly ignores the purpose of HCS 2012 and the shift toward the weight of evidence analysis that HCS 2012 now requires. Instead, OEHHA's interpretation that a mere question regarding IARC and NTP classification on an SDS necessitates a listing under Proposition 65 is akin to proceeding as if the previous HCS was still in effect. Put another way, notwithstanding the significant changes to the HCS in 2012, namely, that IARC and NTP classifications are no longer conclusive of a hazard classification, OEHHA maintains that it may continue to list in the very same way as it did under the previous HCS.

Contrary to the views expressed by OEHHA, how an individual manufacturer or employer classifies a chemical under HCS 2012 is not relevant and cannot be the basis for a chemical classification under the Labor Code mechanism. Fundamentally, a manufacturer's SDS classification does not demonstrate known carcinogenic or reproductive toxicity status. Consider that HCS 2012 states what when the weight of the evidence for carcinogenicity of a substance does not meet the Appendix A criteria, any positive study that reports statistically significant findings must be noted on the SDS. The SDS, however, is not required to detail the basis for the manufacturer's classification and certainly not whether a single positive study supports a known finding of carcinogenicity or reproductive toxicity.

As a legal matter, OEHHA's interpretation of "within the scope" of the HCS cannot be legally sustained because, as discussed above, its interpretation flies in the face of the very purpose of the proposed regulation, which, in part, is to accurately reflect changes to the federal HCS regulations. (*County of Sacramento v. State Water Resources Control Bd.* (2007) 153 Cal.App.4th 1579, 1586-1587 [a lead agency's interpretation of a regulation involving its area of expertise will be given deference "unless the interpretation flies in the face of the . . . purpose of the interpretive provision."] Here, OEHHA has disregarded the very purpose of the HCS 2012's shift from conclusive findings of carcinogenicity to a weight of the evidence analysis, and thus its faulty interpretation would likely be disregarded in a court of law.

OEHHA's Position that Reproductive Toxicants May be Within the Scope of a Future HCS Does not Justify Including Reproductive Toxicants in Subsection (a)(2)

OEHHA's Initial Statement of Reasons correctly states that the basis for including chemical listings for reproductive toxicants under the Labor Code mechanism is no longer available under HCS 2012. Specifically, OEHHA's Initial of Reasons states the following:

In March 2012, OSHA extensively amended the regulations contained in Title 29, C.F.R., section 1910.1200. Title 29, C.F.R. 1910.1200(d)(3)(ii), which had specifically referred to the American Conference of Governmental Industrial Hygienists Threshold Limit Values for occupational exposures to chemical hazards, was deleted in the 2012 version of the regulation. OEHHA has determined that these changes have eliminated the Threshold Limit Values as a definite source for identifying chemicals that are known to cause reproductive toxicity. Therefore, OEHHA is no longer proposing chemical listings based on the Threshold Limit Values, which have been the basis to date for the listing of reproductive toxicants under the Labor code mechanism.

(Initial Statement of Reasons, p.7.)

Notwithstanding OEHHA's express acknowledgment that HCS 2012 provides no basis for a Labor Code reference listing of OSHA reproductive or developmental toxicants, OEHHA nonetheless includes the phrase "or reproductive toxicity" in subsection (a)(2). OEHHA's rationale for doing so is as follows:

[T]he proposed regulation includes the phrase 'or reproductive toxicity' in subsection (a)(2) to track the express language in the Health and Safety Code section 25249.8(a) **so that chemicals could be listed as reproductive toxicants in the future if they are otherwise identified as 'within the scope' of the Hazard Communication Standard.**

(Initial Statement of Reasons, p. 7 [emphasis added].)

Based on the above, there is a glaring conflict between the proposed regulation and the Initial Statement of Reasons. The proposed regulation makes it quite clear that reproductive toxicants may be within the scope of the HCS, whereas the Initial Statement of Reasons expressly acknowledges that this is not the case. OEHHA cannot include the phrase "or reproductive toxicity" in subsection (d) with the understanding that the HCS may be amended in the future to encompass such chemicals. The very purpose of the proposed regulation is to ensure consistency with HCS 2012.

Accordingly, subsection (a)(2) must make clear that reproductive toxicants shall not be listed until such time as OSHA amends its HCS to reintroduce Threshold Limit Values or another metric as a definite source for identifying chemicals that are known to cause reproductive toxicity.

Based on our comments regarding subsection (a)(2), we propose the following language:

(a)(2) A chemical shall be included on the list if it within the scope of the Federal Hazard Communications Standard. **A chemical is within the scope of the Federal Hazard Communications Standard if it** ~~and~~ is identified in the most recent version of Title 29 of the Code of Federal Regulations, part 1910.1200, **subpart Z**, adopted by the federal Occupational Safety and Health Administration, as causing cancer **or reproductive toxicity** based on sufficient animal or human evidence. **Reproductive toxicants shall not be listed pursuant to this subdivision unless and until the Hazard Communication Standard contains Threshold Limit Values or another metric as a definite source for identifying chemicals that are known to cause reproductive toxicity.**

OEHHA Unjustifiably Precludes Public Comment on Whether the Sufficient Evidence Standard has Been Satisfied

In its Initial Statement of Reasons, OEHHA provides the following rationale for limiting the scope of public comments under subsection (b):

Subsection (b) of the proposed regulation provides that at least 45 days prior to adding a chemical that meets the criteria established in section (a) to the list, the lead agency shall publish a notice of intent to list the chemical and provide a 30 day public comment period on whether or not the chemical has been identified by reference in either Labor Code section 6382(b)(1) or 6382(d), or both. Although this notice process is not statutorily required for Proposition 65 listings, it will promote transparency and provide members of the public an opportunity to comment on whether they believe the chemical has been identified by reference in the Labor Code as causing cancer. ***Since the listing procedure for this mechanism is ministerial and therefore essentially automatic, OEHHA restricts comment to the identification of a chemical as causing cancer or reproductive toxicity, not the underlying scientific determinations supporting the identification.***

(Initial Statement of Reasons, p.8.)

The *SIRC* court expressly rejected OEHHA's stated position that "the listing procedure for this mechanism is ministerial and therefore essentially automatic." Similar to OEHHA's position in its Initial Statement of Reasons, in *SIRC*, OEHHA argued that the Labor Code listing mechanism "must be read to mean any chemical that meets the criteria set forth in section 25249.8 is, by definition, 'known to the state to cause cancer or reproductive toxicity within the meaning of this chapter.'" (*Id.* at 787.) The *SIRC* court expressly rejected OEHHA's position, stating the following:

As for OEHHA's interpretation of Proposition 65, this too is entitled to little or no deference. As described earlier, for 15 years after enactment of Proposition 65, OEHHA did not even utilize the Labor Code method for listing chemicals solely based on their inclusion in an IARC monograph.

(*Id.* at 789.)

The court then affirmed that a chemical may be listed only if it is known to cause cancer based on sufficient animal or human evidence. In doing so, the court concluded the following:

We conclude the Proposition 65 list is limited to chemicals for which it has been determined, either by OEHHA through one of the methods described in section 25249.8, subdivision (b), or through the Labor Code method of adopting findings from authoritative sources, that the chemical is known to cause cancer or reproductive toxicity. Because the findings in the IARC monograph on which OEHHA relies to list styrene and vinyl acetate do not satisfy that standard, they cannot properly be included on the list on that basis alone. And because OEHHA does not propose any other basis for including those substances on the list, they must be excluded.

(*Id.* at 790.)

Accordingly, OEHHA's position that listing pursuant to the Labor Code listing mechanism is "essentially automatic" flies in the face of the *SIRC* decision, which expressly held that such a position is "entitled to little or no deference." In establishing a new "sufficient evidence" standard, OEHHA is obligated to provide the public with an opportunity to comment on whether the sufficient evidence standard for a given listing proposal has been established.

“Confusion” is not Justifiable Legal Basis to Require a Chemical to Remain on the List Pending CIC or DART Review

Subsection (d) requires a chemical to remain on the list pending review by the Carcinogen Identification Committee (“CIC”) or the Developmental and Reproductive Toxicant Identification Committee (“DART”), even *after* a determination by OEHHA that (1) a listed chemical no longer meets the criteria for listing under the Labor Code Mechanism and (2) a listed chemical no longer meets the criteria for listing under Health and Safety Code sections 25306 and 25902. Put another way, a chemical must remain on the list pending review by CIC and DART even if OEHHA determines that there is no basis for including the chemical on the list.

OEHHA's rationale for requiring a chemical to remain on the list pending review is as follows:

This subsection also explains that until the appropriate committee has made such a determination, the chemical remains on the list. ***This will reduce potential confusion*** that could otherwise occur if a chemical were to be delisted pending a committee decision, and then relisted if the committee determines it causes cancer or reproductive toxicity, or both.

(Initial Statement of Reasons, p.8)

“Confusion” is not a legal basis for keeping a chemical on the list after OEHHA has determined that the chemical does not, in fact, meet listing criteria. Absent such a legal basis, OEHHA cannot allow a chemical which does not meet listing criteria to nonetheless remain on the list pending the formal delisting process. Further, it is unlawful to require California businesses to be subject to Proposition 65's warning requirements for any period of time if a chemical is not known to cause cancer. Moreover, it is alarmist and poor scientific practice for the public to be warned falsely that a product causes cancer.

Accordingly, subdivision (d) must be amended to state that “[t]he chemical shall ***not*** remain on the list pending review by the Carcinogen Identification Committee or the Developmental and Reproductive Toxicant Identification Committee.”

CONCLUSION

Thank you for considering our comments. We appreciate the opportunity to participate in this very important rulemaking process.

Sincerely,



Anthony Samson
Policy Advocate
The California Chamber of Commerce

On behalf of the following organizations:

The American Chemistry Council
The American Coatings Association
The American Forest & Paper Association
The California Attractions and Parks Association
The Consumer Specialty Products Association
The California Business Properties Association
The California Construction and Industrial Materials Association

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The California Hotel & Lodging Association
The California Manufacturers & Technology Association
The California Metals Coalition
The California Restaurant Association
The International Fragrance Association of North America
The National Federation of Independent Business
The National Shooting Sports Foundation
Pactiv
The Paint Council network
The Personal Care Products Council
Western Wood Preservers Institute

cc: Cliff Rechtschaffen, Office of the Governor
Martha Guzman-Aceves, Office of the Governor

AS:cb