



April 4, 2014

Monet Vela
Office of Health Hazard Assessment
1001 I Street
Sacramento, CA 95812

Re: Comments of the American Chemistry Council on draft regulation to implement the Labor Code Listing Mechanism

Dear Ms. Vela:

The American Chemistry Council appreciates the opportunity to submit the attached comments to the Office of Environmental Health Hazard Assessment (“OEHHA”) regarding the proposed regulations for implementation of the Labor Code listing mechanism.

We offer four discrete comments, described fully in the attachment:

- First, that the provision in Proposed Section 25904 that would incorporate Labor Code Section 6382(d), which calls for the listing of chemicals within the scope of the Federal Hazard Communication Standard (“HCS”), is impermissibly vague and should be revised to avoid misinterpretation.
- Second, to conform OEHHA’s interpretation of what is “within the scope” of the HCS with federal and state law.
- Third, to revise the current proposal to provide for prompt and automatic delisting of chemicals, where appropriate, to avoid unnecessarily misleading the public about the safety of beneficial chemical products.
- Fourth, to have the Statement of Reasons clarify that Proposed Section 25904, proposed on January 27, 2014, is separate from an earlier version of this proposed regulation, proposed on May 15, 2013; and to similarly clarify that the Initial Statement of Reasons accompanying the 2013 proposal is not to be used in interpreting or applying any regulation adopted as a result of the 2014 proposal.

We appreciate the opportunity to participate in the regulatory process. Please feel free to contact me with any questions about ACC’s comments.

Very truly yours,

Tim Shestek – Senior Director, State Affairs
American Chemistry Council
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Attachment



INTRODUCTION

The American Chemistry Council¹ welcomes and appreciates this opportunity to comment on the draft regulation proposed by the Office of Environmental Health Hazard Assessment (“OEHHA”) to implement the “Labor Code Listing Mechanism” for designating chemicals as carcinogens or reproductive toxicants under the California’s Safe Drinking Water & Toxic Enforcement Act of 1986, hereinafter referred to as “Proposition 65.” The draft regulation, proposed on January 27, 2014 as Section 25904 in Title 27 of the California Code of Regulations, is referred to herein as “Proposed Section 25904.”

ACC and its members apply the science of chemistry to make innovative products and services that make people’s lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing.

For the basic chemistries of consumer products, buildings, and environments, the communication of information regarding hazards alone – without accompanying information to explain the significance of the hazard significance or the risk to human health risk, if any – does little to safeguard public health. Decisions to protect public health are properly informed by complete information and founded on the science of risk assessment – the determination and quantification of risks arising from exposure. ACC has long taken the view that presentation of chemical hazard information, by itself, can be counterproductive to public health goals by promoting precipitous and misinformed decisions to substitute or reformulate products in order to avoid a perceived hazard without regard to actual risks to safety or health, and thereby undermine public health.

For the reasons above, ACC historically has opposed Proposition 65 and many of its provisions. Nevertheless, we seek constructive engagement with OEHHA in the implementation of Proposition 65 and offer comments on Proposed Section 25904 in four key areas.

First, the provision in Proposed Section 25904 that would incorporate Labor Code Section 6382(d), which calls for the listing of chemicals within the scope of the Federal Hazard Communication Standard (“HCS”), is vague. After the 2012 amendments to the HCS by the Occupational Safety and Health Administration (“OSHA”), the HCS incorporates only those chemicals identified in subpart Z of the HCS regulation. Yet, as Proposed Section 25904 is drafted, it appears that OEHHA would interpret the HCS as requiring the listing of chemicals identified in the National Toxicology Program’s (“NTP”) Report on Carcinogens and in Monographs prepared by the International Agency for Research on Cancer (IARC). Accordingly, OEHHA should revise Proposed Section 25904 so that the regulation is not vulnerable to this misinterpretation.

¹ ACC represents the leading companies engaged in the business of chemistry. The business of chemistry is a \$770 billion enterprise and a key element of the nation’s economy. It is one of the nation’s largest exporters, accounting for twelve percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation’s critical infrastructure.

Second, to the extent that Proposed Section 25904 stands for the proposition that NTP's Report on Carcinogens and IARC's Monographs are "within the scope" of the HCS, it is in direct conflict with OSHA standards for occupational safety and thus preempted by federal law. As OEHHA is aware, OSHA recently amended to HCS to conform that standard to the Globally Harmonized System of Classification and Labeling of Chemicals ("GHS"). The OSHA rulemaking record makes clear that OSHA intended the current version of the HCS to harmonize U.S. law with modern, international standards, which require a weight-of-the-evidence review of a chemical for potential hazards before it is classified as hazardous for purposes of the HCS. By contrast, to Proposed Section 25904 would call for the automatic listing of chemicals based on NTP and IARC classifications alone.

Third, the method devised for delisting chemicals under Proposed Section 25904 would delay the process unnecessarily for months or even years, leaving Californians in the dark about new science and data when evaluations by IARC or NTP show that chemicals no longer should be listed. The proposed method for informing Californians that a chemical no longer meets Proposition 65 listing criteria works far too slowly in an age where science is progressing rapidly. OEHHA should revise the current proposal to provide for prompt and automatic delisting of chemicals, where appropriate, to avoid unnecessarily misleading the public about the safety of beneficial chemical products.

Fourth, we believe the Statement of Reasons should clarify that Proposed Section 25904, proposed on January 27, 2014, is separate from an earlier version of this proposed regulation, proposed on May 15, 2013, the text of which was similar in many ways to Proposed Section 25904. OEHHA similarly should clarify that the Initial Statement of Reasons accompanying the 2013 proposal are not to be used in interpreting or applying any regulation that is adopted as a result of the 2014 proposal.

COMMENTS

1. The Proposal Should Be Amended to Clarify that NTP and IARC Listings Are No Longer "Within the Scope" of the HCS

Proposed Section 25904(a)(2) reads as follows:

A chemical shall be included on the list if it is *within the scope* of the Federal Hazard Communications (sic)² 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.

(Emphasis added.)

With this section, OEHHA appears to propose to list a chemical if it is identified as causing cancer or reproductive toxicity in the federal HCS regulation. Although the regulation appears to straightforwardly implement the Labor Code mechanism by calling for the listing of only those chemicals identified in the federal regulation, the Initial Statement of Reasons ("ISOR") suggests an ambiguity that opens the door for possible misapplication.

² The reference to the Federal Hazard Communications Standard, in the plural, is a typographical error. The "s" in the word "Communications" should be deleted.

In the ISOR, OEHHA states 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.

Notwithstanding this statement, chemicals are only identified (*i.e.*, listed and named) in the HCS by inclusion in subpart Z. The listing of a substance in NTP’s Report on Carcinogens or IARC’s Monographs does not make it “within the scope” of the HCS standard. And such a construction of federal law would make little sense under state law, since Proposition 65’s Labor Code listing mechanism seeks to emulate federal warning standards in the first place. To require automatic Proposition 65 warnings for NTP and IARC classified chemicals, which the revised HCS does not do, decouples Proposition 65 from the federal standard with which it was designed to harmonize, directly conflicts with the state statute itself, and is beyond OEHHA’s authority under Proposition 65.

Additionally, this interpretation would contradict the very regulation it seeks to implement. Proposed Section 25904 (a)(2) would, correctly, require only the listing of those chemicals “identified” as carcinogens in the federal regulation. The federal regulation, at subpart Z, does in fact list and name certain hazardous substances that were the subject of OSHA rulemaking. Yet, OEHHA proposes to include chemicals that are not actually identified in the HCS regulation. To the extent that this incongruous reading of the regulation is possible, a clarifying amendment is required.

Accordingly, the regulation should be amended to clarify that chemicals are not “identified” in the federal regulation simply because they are the subject of NTP’s Report on Carcinogens or IARC Monographs. Rather, only those chemicals listed in subpart Z are “within the scope” of the HCS and identified as carcinogens.

2. The Proposed Rule is Preempted by Federal Law

Proposed section 25904(a)(2) will create a conflict between Proposition 65 and federal HCS requirements because the proposed regulation effectively adopts the HCS’s former policy and ignores revisions adopted by OSHA in 2012. While the revised HCS no longer deems a chemical’s inclusion on the NTP Annual Report or IARC Monographs as conclusive evidence of carcinogenicity, OEHHA departs from OSHA’s approach and proposes to continue to do so. This is in conflict with both the HCS and OEHHA’s authority to list chemicals pursuant to the Labor Code mechanism.

The HCS operates by requiring manufacturers, importers and employers to evaluate the chemicals they produce, import or utilize and determine which if any of these chemicals are hazardous. Prior to the 2012 amendments, the HCS required these groups to treat three sources as conclusively establishing that a chemical is a carcinogen. 29 C.F.R. § 1910.1200(d)(4). These sources included: (i) the NTP’s Annual Report on Carcinogens; (ii) IARC’s Monographs; and (iii) the chemicals listed by OSHA in Title 29, C.F.R. part 1910, subpart Z.

OSHA's 2012 amendments to the HCS were part of an effort to align the HCS with three aspects of the United Nations' Globally Harmonized System of Classification and Labeling of Chemicals. The amended HCS continues to require manufacturers and importers to automatically treat substances as carcinogenic if they are listed by OSHA. However, these parties are no longer required to presume that a chemical is a carcinogen based on an IARC Monograph or NTP Annual Report. Rather, 2012 amendments direct the manufacturer or importer to self-classify each chemical based on a weight of the evidence analysis.

The explanation in the ISOR for listing chemicals by reference to the IARC and NTP findings is insufficient to support the regulation as proposed. It states:

The requirement to list NTP and IARC-identified carcinogens via the Labor Code mechanism is consistent with the principal objective of Proposition 65. The mandatory disclosure on an [safety data sheet] of NTP's and IARC's determinations of a chemical's carcinogenic effects is intended to provide workers with critical information about the chemicals they are being exposed to in the workplace. By requiring that the Proposition 65 list "shall include, at a minimum, those substances...identified additionally by reference in Labor Code Section 6382(d)," Proposition 65 clearly is intended to ensure Californians are informed about exposures to these same chemicals.

Manufacturers, importers and employers are only required to distribute and maintain safety data sheets for those chemicals identified as a health hazard. 29 C.F.R. § 1910.1200(e)(1)(i). As discussed above, IARC and NTP determinations are no longer conclusive of carcinogenicity. The fact that Appendix D of the HCS requires that safety data sheets include references to the IARC or NTP determination does not support a finding that all such chemicals are known carcinogens in accordance with Proposition 65 statutory criteria. This mandate simply reflects a requirement that safety data sheets provide the data used to identify a chemical a health hazard. Such a disclosure requirement does not bring the IARC and NTP determinations within the scope of the HCS and to hold otherwise is in conflict with federal law.

3. The Process for Delisting Chemicals Under Section 25904 Should Be Streamlined So That Chemicals Are Removed Promptly from the List if the Basis for Listing No Longer Exists

Proposed Section 25904(d) reads as follows:

If the lead agency determines that a listed chemical no longer meets the criteria in this section, the lead agency shall determine if the criteria for listing established in Section 25306 or Section 25902 are met. If the criteria in those sections are not met, the lead agency shall refer the chemical to the appropriate committee established in Section 25302, namely the Carcinogen Identification Committee or the Developmental and Reproductive Toxicant Identification Committee, for a recommendation as to whether the chemical should continue to be included on the list of chemicals known to the state to cause cancer or reproductive toxicity. The chemical shall remain on the list pending review by the Carcinogen Identification Committee or the Developmental and Reproductive Toxicant Identification Committee.

The proposed section properly reflects the concern that potentially harmful chemicals should not be hastily removed from the Proposition 65 list. However, in failing to provide for a prompt evaluation of new evidence, the regulation is overly cautious in its approach, and provides for the continued listing of chemicals when the criteria for listing are not met without an affirmative determination that listing under other mechanisms is appropriate.

As OEHHA is aware, toxicological reviews of chemicals by IARC and other review panels are nearly always ongoing, even after a scientific conclusion is reached. In fact, IARC regularly reevaluates prior monographs and determinations of carcinogenicity. Accordingly, it is increasingly common for a review panel to reverse or alter a prior conclusion, especially given recent developments in the study of mechanistic data. When this occurs, the basis for listing a chemical under Proposition 65 may no longer exist.

OEHHA's procedures should reflect the rapid development of scientific data. To earn and maintain public trust in Proposition 65 and OEHHA's list, the agency should strive to publish only the most up to date and accurate information. Fortunately, the Labor Code mechanism allows for just such a process without compromising the integrity of the list or public safety.

For these reasons, we urge OEHHA to revise Proposed Section 25904(d) in two respects:

First, the proposed regulation should be revised to require OEHHA to delist a chemical immediately if the original grounds for listing under the Labor Code mechanism no longer exist and the chemical does not meet the standards for an administrative listing under either the "authoritative body" or "required to be labeled or identified" mechanisms. Where the basis for listing under the Labor Code no longer exists, but OEHHA believes that listing appears appropriate pursuant to either the authoritative body or "required-to-be labeled-or-identified mechanisms," OEHHA should initiate listing the listing process under the appropriate mechanism.

Second, if the grounds for listing under the Labor Code no longer exist, and listing would not be appropriate under either the authoritative body or "required-to-be labeled-or-identified mechanisms," then OEHHA may refer a chemical removed from the list to the appropriate Qualified Expert panel. The chemical should be restored to the list only if the appropriate panel determines that the current science meets the "clearly shown" standard.

These changes would provide that the State's Qualified Expert panels have the authority to consider and act on new scientific information. In doing so, the list may be periodically updated to reflect the latest scientific developments. In providing the most accurate information to the public, such a regulation would best serve the purpose behind the law: to inform and protect the people of California.

4. OEHHA Should Clarify That Proposed Section 25904 and the Statement of Reasons that Support the Regulation Are Separate from the Version of the Regulation and Initial Statement of Reasons Published in 2013

As noted above, Proposed Section 25904 is similar in many respects to a version of the same regulation that was proposed on May 15, 2013. The ISOR for Proposed Section 25904 does not mention this and, to our knowledge, there has been no announcement that the May 15, 2013 proposal was abandoned and that the ISOR accompanying that proposed regulation no

longer has any effect. We believe OEHHA should state this explicitly in the Final Statement of Reasons that accompanies Proposed Section 25904, in whatever form that proposed regulation may be adopted. In part, this is necessary to make clear that specific statements in the initial statement of reasons accompanying the May 15, 2013 proposal do not apply to Proposed Section 25904.

The Initial Statement of Reasons accompanying the May 15, 2013 proposal referred to chemicals identified as reproductive toxicants in Appendix A to Section 1910.1200 of the HCS, under Categories 1, 1A, 1B, and 2 as chemicals that should be listed, with the following explanation:

Thus, when a chemical is classified by a manufacturer or employer as a carcinogen or a developmental or reproductive toxin pursuant to the above mandatory criteria, the chemical is, by definition, within the scope of the Hazard Communication Standard and will be listed under Proposition 65.

Comments submitted by many parties in response to this proposal demonstrated (1) that there was no basis for including such “Appendix A” chemicals automatically on the Proposition 65 list and (2) that the voluntary and subjective “classification” of chemicals as carcinogens or developmental or reproductive toxicants by a *manufacturer or employer* were not a valid basis for any chemicals to be listed as “known to the state” to cause cancer or reproductive toxicity for purposes of Proposition 65. We are concerned, however, that strangers to this rulemaking or overzealous “private” enforcers of Proposition 65 may not understand from the ISOR accompanying Proposed Section 25904 that this is the case.

Similarly, Proposed Section 25904 (a)(2) (also discussed above) reads as follows:

A chemical shall be included on the list if it is within the scope of the Federal Hazard Communications (sic)³ 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.

(Emphasis added.)

With reference to the italicized phrase “or reproductive toxicity,” the ISOR explains at page 7 that, due to the recent amendments to the HCS, there is *no* basis “within the scope of the Federal Hazard Communication Standard” for designating any chemicals as reproductive toxicants under Proposition 65 under the Labor Code Listing Mechanism. Rather, that phrase was added to Proposed Section 25904(a)(2) “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,” in the event of future amendments to the HCS.

The passage above is clear explanation on its face that reproductive toxicants presently may not be added to the Proposition 65 list under the Labor Code Listing Mechanism. We recommend and request, however, that OEHHA include a statement in the Final Statement of Reasons to clarify that statements in the May 15, 2013 proposal and its accompanying Initial Statement of Reasons should not lead a reader to a contrary conclusion.

³ The reference to the Federal Hazard Communications Standard, in the plural, is a typographical error. The “s” in the word “Communications” should be deleted.

CONCLUSION

ACC appreciates the opportunity to provide comments on Proposed Section 25904 in its draft form. We acknowledge that changes to this proposed regulation from the May 15, 2013 proposal have improved the regulation substantially. Nevertheless, we believe the revisions we have proposed above will improve the regulation further and are necessary to conform the regulation to preemptive provisions of the federal Hazard Communication Standard as well as to keep the regulation consistent with Proposition 65 itself.

Respectfully submitted,

Tim Shestek
American Chemistry Council
Sacramento