Responses to Comments from the Flavor and Extract Manufacturers Association, Consumer Healthcare Products Association, International Chewing Gum Association, International Fragrance Association, North America National Confectioners Association and the Personal Care Products Council Concerning the Notice of Intent to List Pulegone Pursuant to the Labor Code Mechanism of Proposition 65

Office of Environmental Health Hazard Assessment
California Environmental Protection Agency

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Comment: OEHHA's proposed action is based upon two unexplained conclusions that recently were announced by the International Agency for Research on Cancer (IARC): first, IARC's classification of pulegone as a "Group 2B" carcinogen; and, second, IARC's conclusion that "sufficient evidence of carcinogenicity in experimental animals" exists for pulegone. These two bare conclusions, without sufficient information on their *basis,* are not adequate grounds upon which to list a chemical such as pulegone as a matter of law. OEHHA must review the IARC monograph and determine whether there is sufficient evidence to conclude that pulegone is a ”known carcinogen”.

Response: OEHHA must list pulegone as known to cause cancer via the Labor Code mechanism. Such listing is a ministerial act that is not based on any independent review of the scientific conclusion by IARC that sufficient evidence of carcinogenicity is present in human or animal studies.

To examine the basis of IARC’s conclusions as the commenters suggest, OEHHA would have to review the final IARC monograph on pulegone, which has not yet been published. The question of whether or not OEHHA can wait for a final monograph prior to listing of a chemical via the Labor Code listing mechanism was resolved by the trial court in the *Sierra Club v Brown* (Alameda County Superior Court case# RG07356881 (Lead Case) in 2011. While the decision is persuasive if not precedential, OEHHA is following the court’s determination on this question as it represents a well-reasoned judicial interpretation of the statutory requirements to list chemicals via this mechanism. The court specifically found the following:

> “The Court agrees with Plaintiffs that Defendants' practice [*of waiting until the final monograph is published*] cannot be reconciled with the clear language of Labor Code §6382, subdivision (b)(l), which is phrased in terms of "substances listed ... by [IARC]," with no reference to monographs. Under AFL-CIO v. Deukmejian (1989) 212 CaLApp.3d 425, **OEHHA has a mandatory duty to list any chemical for which IARC has concluded there is "sufficient" evidence of cancer in humans or animals**. This includes those agents added to the IARC list, *whether or not the final monograph has been published*.” (Italicized, bracketed material added, emphasis added)

The Court of Appeal decision in *SIRC v OEHHA* (2012) 210 Cal.App.4th 1082, requires nothing more.[1] In that case the court determined that listings under Proposition 65 must be based on "sufficient" animal or human evidence in order to be "known" to cause cancer or reproductive toxicity. Here, IARC has stated there is *sufficient evidence* in animals that pulegone causes cancer. This conclusion can clearly be determined without the necessity to review the final IARC monograph because IARC states its conclusion that pulegone is a known carcinogen on its website[2] and has explained the identification is based on sufficient evidence from animal studies.[3]

Comment: Proposition 65 incorporated the IARC standard for "sufficient evidence" that existed in November 1986, and IARC has changed the "sufficient evidence" standard for carcinogenicity in animals. Because IARC has adopted new, more permissive criteria for sufficient evidence, a current sufficient evidence conclusion cannot and should not be used, by itself, as the basis for Labor Code listings. As a matter of law, OEHHA must confirm, without controversy, that IARC's conclusion under the new criteria would have been the same under the old criteria adopted by specific reference in Proposition 65. OEHHA has not done this for pulegone.

Response:
The commenter cites *Palermo v. Stockton Theaters*, (1948) 32 Cal.2d 53, as authority for the proposition that the IARC sufficiency of evidence criteria were adopted by reference into Proposition 65. This extends the *Palermo* decision far beyond the actual holding in that case. In the *California Chamber of Commerce v. Brown* (2011), 196 Cal. App. 4th 233, 257-58, 126 Cal. Rptr. 3d 214, 231 case the court interpreted the holding in *Palermo*, and applied it to the Labor Code listings under Proposition 65. In that case the court held:

> "Here, the incorporated law analogous to the federal treaty in *Palermo* is Labor Code section 6382, and specifically subdivisions (b)(1) and (d). Accordingly, if the first rule recognized in *Palermo* applies, as CalChamber contends, what

[1] It should be noted that the question presented to the court in the *SIRC v OEHHA* case was different than the question before the court in the *Sierra Club v Brown* case. In *SIRC*, OEHHA proposed to list styrene as known to cause cancer via Labor Code section 6382(d) which relies on certain provisions of the federal Hazard Communication Standard to identify hazardous chemicals. In the current action, OEHHA proposed listing pulegone as known to cause cancer via Labor Code section 6382(b)(1), which refers directly to "chemicals identified by the International Agency for Research on Cancer".
[2] International Agency for Research on Cancer (IARC, 2013). Agents Classified by the *IARC Monographs*, Volumes 1-108. Available at URL: http://monographs.iarc.fr/ENG/Classification/ClassificationsAlphaOrder.pdf [Accessed July 16, 2013].
[3] Grosse Y, Loomis D, Lauby-Secretan B, El Ghissassi F, Bouvard V, Benbrahim-Tallaa L, Guha N, Baan R, Mattock H, Straif K on behalf of the International Agency for Research on Cancer Monograph Working Group. (2013). Carcinogenicity of some drugs and herbal products. *The Lancet Oncology*. Published online July 5, 2013, doi: 10.1016/S1470-2045(13)70329-2. [URL: http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045%2813%2970329-2/fulltext.

must be deemed to have been written into Proposition 65 is the language of those subdivisions as they existed at the time the proposition was enacted. There is no issue in this regard, however, because the language of Labor Code section 6382, subdivisions (b)(1) and (d), is the same today as it was when Proposition 65 was enacted. (Stats.1980, ch. 874, p. 2737, § 1; Stats.1985, ch. 1000 § 1.) In fact, there also has been no change in the relevant language of "the federal [HCS] (29 C.F.R. Sec.1910.1200)" to which subdivision (d) of section 6382 refers.[15] (Compare 29 C.F.R. Ch. XVII C7 (1987) & 29 C.F.R. § 1910.1200(c), (d) (2010).)

Thus, what CalChamber actually urges is that *Palermo* extends beyond the expressly incorporated statutes—indeed, beyond even the regulations expressly incorporated by the expressly incorporated statutes—to reach the specific substances identified on the lists referenced by Labor Code section 6382, subdivisions (b)(1) and (d), at the time Proposition 65 was enacted. In other words, according to CalChamber, what must be deemed to have been written into Proposition 65 is not only the language of Labor Code section 6382, subdivisions (b)(1) and (d), and the language of "the federal [HCS] (29 C.F.R. § 1910.1200)," but also all lists of identified substances referenced by these statutory and regulatory provisions. *Nothing in Palermo requires such a burdensome or labyrinthine result*. Furthermore, unlike in *Palermo,* the incorporating statute here, section 25249.8, subdivision (a), anticipates change, by mandating annual revision and republication of the Proposition 65 list. (§ 25249.8, subd. (a).)" (emphasis added).

In the case of pulegone, it cannot be argued that the *Palermo* case supports a conclusion that the statute not only incorporated the Labor Code provisions, but also the non-regulatory, scientific criteria that were applied by IARC at the time Proposition 65 was enacted in 1986, any more than it could be argued in the *Chamber of Commerce* case that Proposition 65 only incorporated the base lists identified by reference in the federal OSHA regulations as they existed at the time the statute was adopted in 1986. As the court pointed out, Health and Safety Code section 25249.8(a) specifically contemplates, and indeed requires, the updating of the list based on "additional knowledge". Certainly IARC has developed "additional knowledge" that informs its current scientific criteria for identifying carcinogens. It is unreasonable to argue that the state of the science in 1986 should apply to chemical identifications in 2014.

The court in *SIRC v OEHHA* similarly held that:

> "We agree with [*Chamber of Commerce v Brown*] that the method of populating the Proposition 65 list *is not frozen in time* but may be updated as the lists identified in the HCS are updated." (Emphasis added)

Indeed, if OEHHA were to accept the commenters' argument, all the recent changes

to the Proposition 65 list based on 2012 modifications to the Hazard Communication Standard (HCS) regulations would be invalid and those chemicals would stay on the list in perpetuity, even though the HCS regulations no longer identify the chemicals as reproductive toxicants.[4]

Comment: The evidence on which OEHHA relies is not adequate to demonstrate that pulegone is a *"known"* animal carcinogen, and only "known" animal carcinogens may be listed through the Labor Code.

OEHHA has not adequately explained or substantiated its conclusion that pulegone warrants listing through the Labor Code listing mechanism. Not all IARC "Group 2B" chemicals may be added to the Proposition 65 list pursuant to the Labor Code listing mechanism. *See Styrene Information and Research Center v. OEHHA*, 210 Cal.App.4th 1082, 1088 (2012). Only "known carcinogens" can be drawn from the Labor Code sources and placed on the Proposition 65 list. *Id.* at 1094. OEHHA has not proffered sufficient evidence to conclude that pulegone has been identified by IARC as a "known carcinogen."

Response: The court in the *SIRC v OEHHA* case required that proposed listing via the Labor Code mechanism be based on "sufficient" scientific evidence of carcinogenicity in either humans, animals or both. The court specifically held that:

> "In other words, as long as there is sufficient evidence that the EPA placed a particular chemical on the TRI list based on criteria sufficient to satisfy Proposition 65's requirement that the chemical be *known* to cause reproductive toxicity, it does not matter that the federal standard may otherwise be broader and that other chemicals may have been placed on the TRI list based on a lesser showing.
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> 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).
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> 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

[4] See http://www.oehha.ca.gov/prop65/public_meetings/pdf/112113Proposition%2065%20_%20HCS.pdf for an explanation and list of chemicals affected by the changes to the HCS.

satisfy that standard, they cannot properly be included on the list on that basis alone."

In the case of pulegone, IARC has specifically found that there is *sufficient* animal evidence to support its identification of the chemical as a known carcinogen.[5] Thus, the listing of pulegone based on its 2013 IARC identification is entirely consistent with the *SIRC, Chamber of Commerce, Western Crop* and *Deukmejian*[6] cases, which all dealt with the appropriate standard for identifying chemicals as known to cause cancer or reproductive toxicity under Proposition 65.

Comment: The Director of the Department of Industrial Relations has not yet "identified" pulegone as a hazard, which is necessary for a listing to proceed under section 25249.8(a).

Response: For purposes of Labor Code subsection 6382(b)(1) no action by the Director is required in order for OEHHA to determine if IARC has identified a given chemical as a known carcinogen. Health and Safety Code Section 25249.8(a) provides that:

> "On or before March 1, 1987, the Governor shall cause to be published a list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter, 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).*" *(*Emphasis added)

Labor Code subsection 6382(b)(1) provides:

> "Substances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC)."

Labor Code section 6382(d) provides:

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[5] International Agency for Research on Cancer (IARC, 2013). Agents Classified by the *IARC Monographs*, Volumes 1-108. Available at URL: http://monographs.iarc.fr/ENG/Classification/ClassificationsAlphaOrder.pdf [Accessed July 16, 2013]. Grosse Y, Loomis D, Lauby-Secretan B, El Ghissassi F, Bouvard V, Benbrahim-Tallaa L, Guha N, Baan R, Mattock H, Straif K on behalf of the International Agency for Research on Cancer Monograph Working Group. (2013). Carcinogenicity of some drugs and herbal products. *The Lancet Oncology*. Published online July 5, 2013, doi: 10.1016/S1470-2045(13)70329-2. [URL: http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045%2813%2970329-2/fulltext.

[6] *SIRC v OEHHA* (2012) 210 Cal.App.4th 1082; *Chamber of Commerce v Brown* (2011) 196 Cal. App.4th 233; *Western Crop Protection v Davis* (2000) 80 Cal.App.4th, 741; and *AFL-CIO v Deukmejian* (1989) 212 Cal.App.3d. 425.

> "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."

Because the reference in Health and Safety Code section 25249.8(a) is only to two specific subsections of the Labor Code, rather than a full incorporation of the California Hazardous Substances Information and Training Act[7] (HSITA), it is unlikely that the drafters of the law intended to graft HSITA's requirements or limitations into Proposition 65. It would have been quite simple to refer to HSITA in its entirety if that had been the intent of the drafters of the law. A reference to all of Labor Code section 6382 or even a reference to Labor Code section 6380 *et seq*., rather than only Labor Code sub-sections 6282(b)(1) and (d), would have accomplished a full incorporation of the Department of Industrial Relations (DIR) list by reference. The fact that only certain subsections of the HSITA relating to the findings of specific scientific entities were included in Proposition 65, argues against a requirement that OEHHA adopt only those substances placed on the DIR list by its director or that OEHHA adopt the entire DIR list.

It should also be noted that Health and Safety Code section 25249.8(a) specifically states that it is "*those substances identified* by reference" in the Labor Code that are being discussed, and not those substances identified by the Director of DIR. This reading of the statute is also consistent with the court's findings in *AFL-CIO v. Deukmejian,* which did not require a wholesale adoption of the list established by the DIR Director and instead allowed a chemical-by-chemical listing process.

Comment: Proposition 65 did not and could not delegate to IARC the power to redefine what constitutes a "known carcinogen." Since IARC does not specifically identify "known" animal carcinogens, nor did it do so in 1986, the IARC standard for "sufficient evidence" at the time of the ballot measure must be used to list chemicals pursuant to section 25249.8(a). Any other result would impermissibly delegate to IARC authority to redefine what is "known to the state to cause cancer."

Response: Health and Safety Code section 25249.8 expressly states that the Proposition 65 list must contain "at a minimum" those substances identified by reference to Labor Code sections 6382 subsections (b)(1) and (d). This provision has been part of Proposition 65 since 1986. Labor Code section 6382(b)(1) specifically identifies "substances listed as human or animal carcinogens" by IARC. OEHHA is merely carrying out a ministerial act required by statute when it lists the substances identified through this provision of law.

Further, "[W]hile the legislative body cannot delegate its power to make a law, it can make a law to delegate a power to determine some fact or state of things upon which

[7] Labor Code Section 6360 *et seq*.

the law makes or intends to make its own action depend." (*Kugler v Yocum* (1968) 71 Cal. Rptr. 687, 690;*Wheeler v Gregg* (1949) 90 Cal. App. 2d. 348, 363.) In this instance, the people and the Legislature are relying on an internationally recognized scientific body to identify human and animal carcinogens. In turn, that identification triggers other provisions of the law.

OEHHA is the intermediary agency that performs the ministerial function of adding to the Proposition 65 list the substances identified as carcinogens by IARC pursuant to Health and Safety Code section 25249.8(a) and the referenced Labor Code provisions. Relying on IARC's scientific findings for purposes of listing substances known to cause cancer appears to fit the definition of a "delegation of power to determine a fact or state of things upon which the law depends" [8] (i.e. the identification of substances that are known to cause cancer that are subject to the warning requirements and discharge prohibitions of the law).

Comment: The federal Hazard Communication Standard ("HCS") makes clear in a section titled "scope and application" that it applies only to chemicals which are "known to be present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency." 29 C.F.R. § 1910.1200(b)(2) (1987); *see also* 29 C.F.R. § 1910.1200(b)(2) (2013) (same). OEHHA has presented no finding or evidence that pulegone is present in the workplace in such a manner that employees may be exposed under normal conditions or use or in a foreseeable emergency. Thus, OEHHA cannot rely on section 6382(d) of the Labor Code to support its February 7 Notice.

Response: Labor Code section 6382(d) provides:

> "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." (Emphasis added)

In March 2012, OSHA extensively amended the regulations contained in Title 29, C.F.R., section 1910.1200. New Mandatory Appendix D of the 2012 version of the federal Hazard Communication Standard provides that a "safety data sheet (SDS) *shall* include the information specified in Table D.1…"(emphasis added). Item 11 of Table D.1 is entitled "Toxicological Information" and states that the SDS *must* include a description of the various toxicological (health) effects and the available data used to identify those effects, including:

…"(e) Whether the hazardous chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs

[8] *Kugler v Yocum* (1968) 71 Cal. Rptr. 687, 690; *Wheeler v Gregg* (1949) 90 Cal. App. 2d. 348, 363

(latest edition), or by OSHA"…

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.

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 SDS 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 all Californians are informed about exposures to these same chemicals. Thus, OEHHA can base the listing of pulegone on either or both of the provisions of the Labor Code that are incorporated into Proposition 65. It is not restricted to only Labor Code section 6382(b)(1).