Final Statement of Reasons
Title 27, California Code of Regulations

Proposed Repeal of Article 6 and
Adoption of New Article 6
Regulations for Clear and Reasonable Warnings

California Environmental Protection Agency
Office of Environmental Health Hazard Assessment

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General Information

Overview of the New Article 6

Proposition 65[1] requires that businesses with 10 or more employees give a clear and reasonable warning to individuals before knowingly and intentionally exposing them to a chemical listed as known to cause cancer or reproductive toxicity. The Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency that implements Proposition 65. OEHHA maintains the list of chemicals known to the state to cause cancer or reproductive toxicity and has the authority to promulgate and amend regulations to implement and further the purposes of the Act. The existing regulations adopted by OEHHA's predecessor agency in 1988 (Title 27, Cal. Code of Regs., section 25601, *et seq*.) establish general criteria for providing "clear and reasonable" warnings. These regulations also provide safe harbor, non-mandatory guidance on general message content and warning methods for providing consumer product, occupational and environmental exposure warnings. The new regulations proposed for adoption into Article 6 retain the "safe harbor" concept by giving a business the opportunity to use warning methods and content that OEHHA has deemed "clear and reasonable". Alternatively, a business may use any other warning method or content that is clear and reasonable under the Act.

Under the existing regulations, a warning is "clear" if it clearly communicates that the chemical in question is known to the State of California to cause cancer, birth defects or other reproductive harm. It is "reasonable" if the method employed to transmit the message is reasonably calculated to make the warning message available to the individual prior to exposure. However, the existing safe harbor warnings lack the specificity necessary to ensure that the public receives useful information about potential exposures.[2] Further, the existing regulations were adopted more than 25 years ago; communication technology has progressed significantly during that time, and the demographics of California have also shifted such that there is a much higher percentage of the population that speaks limited or no English. It is therefore necessary to update the regulations to take advantage of current and future approaches to providing important health-related information to the public.

The regulatory action OEHHA is proposing would repeal the current Article 6 regulations and adopt new regulations into Article 6. The new provisions in proposed Subarticle 1

[1] Safe Drinking Water and Toxic Enforcement Act of 1986, codified in Health and Safety Code section 25249.6 et seq.
[2] See discussion in Initial Statement of Reasons published on November 15, 2015 available at: http://oehha.ca.gov/media/downloads/crnr/112715warningreg20isor.pdf.

would, among other things, set forth a new, mandatory regulation addressing the relative responsibility of product manufacturers and others in the chain of distribution, versus the product retail seller. It also contains the definitions relevant throughout Article 6. These provisions are explained in detail in the Initial Statement of Reasons (ISOR) for these regulations.

The regulations in proposed Subarticle 2 provide specific guidance on methods and content for safe harbor warnings. Any express requirements under Subarticle 2 are requirements for safe harbor protection. Failure to meet the requirements of Subarticle 2 is not an automatic violation of the Act; rather, a business may provide warnings that differ from the safe harbor warnings, but that are nevertheless compliant with the Act. In that situation, the person would not have the benefit of a safe harbor defense to an enforcement action. It is the intent of OEHHA that safe harbor warnings under Subarticle 2 will provide more detailed information for the public, including a clear statement that a person “can be exposed” to a listed chemical, the names of one or more listed chemicals that are the subject of the warning, a link to a website maintained by OEHHA containing supplemental information, and information about the source of the exposure for environmental warnings.

These new regulations would further the “right-to-know” purposes of the statute and provide more specificity for the content of safe harbor warnings for a variety of specific kinds of exposures, and corresponding methods for providing those warnings. Businesses would continue to be assured that compliance with the safe harbor regulations will help them avoid litigation because the content and methods provided in the regulation are deemed “clear and reasonable” for purposes of complying with the Act.

By adopting these new regulations, OEHHA intends to address many of the issues that have surfaced since the original regulations were adopted in 1988 by clarifying the relative responsibilities of manufacturers and others in the chain of distribution for products that are eventually sold at retail, and making needed changes to the current requirements for a safe harbor warning; by integrating new technology including the internet, providing more useful information to Californians about their exposures to listed chemicals; and by providing more compliance assistance for affected businesses, thereby furthering the purposes of the Act.

Process and Timeline

On January 16, 2015, OEHHA published a Notice of Proposed Repeal of Article 6 and Adoption of New Article 6. A public hearing was held on March 25, 2015 and the comment period closed on April 8, 2015. Sixty-one written comments were received during this comment period and OEHHA met with dozens of interested stakeholders

over the course of several months. After reviewing written and oral public comments, OEHHA elected to further evaluate the potential economic impact of the regulations and the effectiveness of the existing and proposed warnings. As a result, OEHHA withdrew the January 2015 rulemaking in order to restart the regulatory process.

OEHHA published a new proposed set of regulations and ISOR for this action on November 27, 2015, and held a public hearing on January 13, 2016. The initial comment period was originally scheduled to close on January 22, 2016; however, OEHHA granted requests from the Auto Alliance, Global Automakers, and the Motor & Equipment Manufacturers Association to extend the public comment period to January 25, 2016. OEHHA received 45 written comments during this comment period, some of which incorporated by reference their comments on the previously withdrawn version of the regulation issued in January 2015.

After careful consideration of the comments received during the initial comment period, OEHHA amended the regulations to provide greater clarity and consistency on a number of details and issues in the regulations. OEHHA published the modified regulations and released the Notice of Modification to Text of Proposed Regulation on March 25, 2016. The comment period on this 1st modification to the regulatory text was originally scheduled to close on April 11, 2016; however, OEHHA granted a request from interested stakeholders to extend the public comment period to April 26, 2016. Thirty-two comments were received.

After careful consideration of the comments received on the 1st Modification, additional amendments were made, mostly for clarity. A 2nd Notice of Modification to Text of Proposed Regulation was released on May 20, 2016, with the comment period closing on June 6, 2016. Seventeen comments were received.

OEHHA's response to the comments received throughout this rulemaking process is incorporated within this Final Statement of Reasons (FSOR). Several written and oral comments submitted during the regulatory process included observations about these regulations or other laws and regulations that do not constitute an objection or recommendation directed at the proposed action or the procedures followed in this rulemaking action. Also, many parties offered their interpretation of these regulations or other laws and regulations, sometimes in connection with their support of, or decision not to object to the regulations, which again does not constitute an objection or recommendation directed at changing the proposed action or the procedures followed in this rulemaking action. Accordingly, OEHHA is not required under the Administrative Procedure Act (APA) to respond to such remarks in this FSOR. Since OEHHA is constrained by limitations upon its time and resources, and is not obligated by law to

respond to such remarks,[3] OEHHA does not provide responses to all of these remarks in this FSOR. However, the absence of responses to such remarks should not be construed to mean that OEHHA in any way agrees with them.

[3] California Government Code section 11346.9(a)(3)

Summary and response to comments on the November 2015 proposed regulations

The following organizations submitted comments on the proposed regulations to OEHHA during the comment period (November 27, 2015 to January 25, 2016):

- Advanced Medical Technology Association (AdvaMed)
- Alliance of Automobile Manufacturers, Association of Global Automakers, and Motor & Equipment Manufacturers Association (Auto Alliance et al.)
- American Beverage Association (ABA)
- American Chemistry Council (ACC)
- American Coatings Association (ACA)
- American Home Furnishings Alliance (AHFA)
- American Herbal Products Association (AHPA)
- Applied Safety and Ergonomics, Inc. (ASE)
- ARC and United Cerebral Palsy California Collaboration (ARC-UCP)
- The Art and Creative Material Institute (ACMI)
- Association of Home Appliance Manufacturers (AHAM)
- Automotive Aftermarket Suppliers Association, Auto Care Association, and California Automotive Wholesalers Association (AASA et al.)
- Lauren Ayers (LAyers)
- Battery Council International (BCI)
- California Apartment Association (CAA)
- California Attractions and Parks Association (CAPA)
- California Chamber of Commerce Coalition (CalChamber)
- California Council for Environmental and Economic Balance (CCEEB)
- California Craft Brewers Association (CCBA)
- California Dental Association (CDA)
- California Grocers Association (CGA)
- California Hotel & Lodging Association and California Association of Boutique & Breakfast Inns (CH&LA)
- California New Car Dealers Association (CNCDA)
- California Restaurant Association (CRA)
- California Rural Legal Assistance, Inc. (CRLA)
- CHANGE (and a coalition of other non-governmental organizations)
- Karen Hamilton-Roth (KHamilton-Roth)
- Claigan Environmental, Inc. (Claigan)
- Consumer Healthcare Products Association (CHPA)
- Consumer Specialty Products Association (CSPA)
- Consumer Technology Association (CTA)
- Council for Responsible Nutrition (CRN)
- Environmental Law Foundation, As You Sow, Center for Environmental Health, Center for Food Safety, Lexington Law Group and Mateel Environmental Justice Foundation (Environmental Coalition)
- Family Winemakers of California (FWC)
- Grocery Manufacturers Association (GMA)
- Illinois Tool Works (ITW)
- Independent Lubricant Manufacturers Association (ILMA)
- National Marine Manufacturers Association (NMMA)
- National Electrical Manufacturers Association (NEMA)
- Natural Products Association (NPA)
- David Roe (DRoe)
- Rubber Manufacturers Association (RMA)
- The Truck and Engine Manufacturers Association (TEMA)
- The Vision Council (TVC)
- Wine Institute, the Beer Institute and the Distilled Spirits Council of the United States (Wine et al.)

The following organizations provided only oral comments at the public hearing on January 13, 2016:

California Manufacturers & Technology Association (CMTA)

West Coast Lumber Building Material Association (WCLBMA)

These oral and written comments are summarized and responded to below.

Section 25600 General

Subsection 25600(a)

1. Comment (CH&LA): The proposed regulations "obligate businesses to engage in extremely complex, complicated, expensive, and time consuming scientific and operational analyses to determine whether any warning is required". While OEHHA may discourage businesses from providing a warning that is not necessary, it does not prohibit such action. Recommend that the proposed regulations be amended to expressly allow businesses to give warnings that might not be necessary.

Response: The regulations expressly apply where a business has decided to provide a warning (subsection 25600(a)). The regulations are intended to increase the meaningfulness of warnings, not to state criteria for when a warning is required. Those issues are addressed in other regulations[4]. The change recommended by this commenter would contribute to "over-warning" by encouraging persons to transmit unnecessary warnings to the public. This is not consistent with the purposes of the Act. OEHHA therefore declines to make the requested change.

Subsection 25600(b)

Two-year implementation period and sell-through provision

2. Comment (AHAM): The regulations should explicitly state that if a compliant safe harbor warning is provided on a product label or its labeling at the time the product was manufactured, the warning is still compliant under the new regulations.

Response: Subsection 25600(b) provides that "a warning for a consumer product *manufactured* prior to the effective date of this article is deemed to be clear and reasonable if it complies with the September 2008 revision of this article." As explained in the ISOR[5] for these regulations, OEHHA is sympathetic to the concerns expressed by some manufacturers regarding the change from the old to the new safe harbor labels on

[4] See for example Title 27, Cal. Code of Regs., sections 25501, 25701 and 25801 *et seq*.
[5] Initial Statement of Reasons published on November 15, 2015 available at: http://oehha.ca.gov/media/downloads/crnr/112715warningreg20isor.pdf

durable goods. Some of these products can remain in the stream of commerce for several years. In order to avoid the difficulties and expense involved for manufacturers and retail sellers to locate all products bearing the old warnings, the regulations allow the old safe harbor warnings to remain and be considered compliant if the product was manufactured prior to the effective date of the new regulations.

Specifically, the since-withdrawn January 2015 version of the regulations proposed a two-year period for businesses to convert to the new safe-harbor warnings. Many stakeholders expressed concern over anticipated logistical and economic costs associated with changing the warnings on products already produced and distributed to the marketplace; this was of particular concern to businesses dealing in durable goods with compliant warnings and a long shelf-life. In order to address these concerns and mitigate potential cost impact on businesses, subsection (b) provides that a warning provided on products manufactured prior to the effective date of the new Article 6 provisions is deemed to be clear and reasonable if it complies with the September 2008 version of Article 6.

3. Comment (CalChamber and AHAM): The ISOR (p. 11) appears to suggest that in between the regulation's adoption date and effective date, businesses are limited to only using either old safe harbor warnings or newly proposed safe harbor warnings. However, both the current and newly proposed regulations expressly allow businesses to provide alternative warnings other than the safe harbor warnings. The ISOR should thus be revised to clarify that businesses may continue to provide such alternative warnings during the two-year period between the adoption date and the effective date.

Subsection (b) should affirmatively state that a warning that complies with all applicable requirements of Article 6 prior to the two-year implementation date is deemed to be clear and reasonable. To further clarify, a warning for a consumer product manufactured prior to the effective date is deemed to be clear and reasonable if it complies with the current regulations when the product was manufactured.

Response: Subsection 25600(b) expressly provides that either the old safe harbor warnings or the new regulations may be used for the two-year phase-in period after the regulations are adopted. In order to increase clarity, OEHHA modified the regulatory text by adding that such a warning will be deemed to be clear and reasonable. In terms of alternate warnings, under Health and Safety Code (HSC) section 25249.6 and subsection 25600(f) of the new regulations and Section 25601 of the existing regulations, a business is allowed to provide warnings that are otherwise compliant with the Act irrespective of the timing for implementation of the proposed regulations. Therefore, during and after the two-year phase-in period of these regulations, a business will continue to be able to provide warnings that do not meet the method and content requirements for a safe harbor under Subarticle 2 but otherwise provide a clear

and reasonable warning required by HSC section 25249.6. However, OEHHA encourages businesses to transition to the new warning requirements as soon as is feasible in order to effectuate the purposes of the changes.

4. Comment (AASA et al., AdvaMed, Auto Alliance et al., CRN, and CSPA): Requests that the implementation period in subsection (b) be extended to three years because many products have long shelf lives and remain in distribution for multiple years.

Response: The two-year phase-in was retained; however, OEHHA agrees with the recommendation that a product that has a compliant warning at the time it is manufactured is still compliant. Thus, subsection 25600(b) of the regulations provides an unlimited sell-through period for these products. An extension of the phase-in period for the new safe harbor provisions is therefore unnecessary.

5. Comment (CRN): OEHHA should provide specific guidance in grandfathering dietary supplement product labeling to assure effective implementation of the proposed regulation and avoid unnecessary compliance costs on the industry.

Response: As noted above, the grandfathering provision in subsection 25600(b), which provides for unlimited sell-through of products manufactured before the effective date of the regulations, and subsection 25600(f) applies equally to dietary supplements as to any other product covered by a court order or settlement. The commenter did not indicate what kind of additional guidance was needed. OEHHA will consider issuing interpretive guidance[6] on the subject for a specific industry such as dietary supplement makers if such a request is made. No change was made based on this comment.

6. Comment (GMA): The proposed regulations should clarify that the implementation period in subsection 25600(b) includes “food, manufactured or packaged” prior to the effective date; should make clear that provision applies to consumer products that are not necessarily “manufactured” in the traditional sense, but also to those that are simply packaged for retail sale with minimal processing.

Response: A definition for the term “consumer product” was added as subsection 25600.1(d) subsequent to this comment. “Consumer product” expressly includes “food” that is “produced, distributed, or sold for the personal use, consumption or enjoyment of the consumer”. The revised definition would encompass foods being packaged for retail sale to consumers. Subsection 25600(b) applies to all consumer products including food. The term “manufactured” is not intended to exclude foods that may be minimally processed. Either the version of the regulations adopted in September 2008, or the one

[6] See Title 27, Cal. Code of Regs., sections 25203 (Interpretive Guideline Requests) and 25204 (Safe Use Determinations).

newly adopted may be used during the two-year phase-in period. However, OEHHA encourages businesses to begin using the newer warning provisions as soon as is feasible in order to effectuate the purposes of the regulatory changes.

7. Comment (ACA): Because industrial product manufacturers also use on-product warnings, the word "consumer" should be removed from the term "consumer product" in subsection 25600(b) in order to clarify that the sell-through period applies to all products and not only consumer products.

Response: Exposures to industrial chemicals are most likely to occur in the occupational setting. Warnings for these types of exposures are covered in section 25606, including subsection 25606(b), which was added in the 2nd modified version of the regulations to expressly allow for the use of consumer product warning methods and content where a given exposure is not covered by federal or California Occupational Safety and Health Act (OSHA) warning requirements. This change will ensure that the sell-through period also applies to products in the occupational setting. No further change was made to the regulations based on this comment.

8. Comment (CDA): Support the two-year implementation period in subsection 25600(b).

Response: Comment noted, no response required.

9. Comment (ACA): The 2-year effective date in subsection 25600(b) is too short. Recommend an unlimited sell through period for labeled products already in the distribution chain. Some industrial products also use on-product warnings and so the sell-through period should apply to all products and not only consumer products. Strikeout the word, "consumer" in subsection (b).

Response: Subsection 25600(b) provides that a warning for a consumer product that is manufactured prior to the two-year effective date is deemed to be clear and reasonable if it complies the September 2008 revision of Article 6. This provision was included in the regulatory text primarily to facilitate the transition to the new warnings. Consumer products in the distribution chain with a currently compliant Article 6 warning will not require relabeling and will effectively have an unlimited "sell-through" period. As noted above, warnings for exposures in the occupational setting that are not subject to federal or California OSHA requirements are covered by subsection 25606(b) which was added in the 2nd modified version of the regulations to expressly allow for the use of consumer product warning methods and content where a given exposure is not covered by federal or California OSHA warning requirements. No additional change was made to the regulations based on this comment.

10. Comment (Environmental Coalition): Does not believe there is any reason to provide a phase-in period for a regulation that establishes "safe harbor" warnings that are, by definition, optional.

Response: The two-year phase-in period was included in response to industry stakeholder comments noting the time and expense required to change their warnings to comply with the new regulations. While the safe harbor warnings are voluntary, many businesses using the current safe harbor warnings will want to change to the new safe harbor warnings to ensure protection against enforcement actions. It is reasonable to provide a clear time period for this transition to occur. OEHHA anticipates that many businesses will transition sooner than the two-year effective date of the regulations, so individuals will begin to see the newer warnings prior to the effective date of the regulations. No change to the regulations was made based on this comment.

Subsection 25600(c)

Request for specific exposure warning, interpretive guideline or safe use determination

11. Comment (AHPA, CAA, and Wine et al.): It is unclear what standard OEHHA will use to evaluate a warning method or message that is requested via the petition process in subsection (c). As proposed, the subsection pertains only when OEHHA has not already adopted a warning method or content specific warning in Section 25607, i.e., it would not pertain to alcohol beverage exposures. Also, this subsection appears to be limited to one particular company or brand of product and it should be revised to allow requests for a type or category of related products.

Response: As is explicit in subsection 25600(c), this provision applies when there is no "tailored warning" in Section 25607. The standard OEHHA will use to evaluate a warning method or content is whether it is "clear and reasonable" in accordance with the purposes of the Act and consistent with the approach OEHHA has developed for warning methods and content in these regulations. Subsection 25600(c) is not intended to be limited to one particular company or brand of product, and the language was revised in response to this comment for the purpose of clarity. Subsection 25600(c) was modified to include the phrase "specific product, chemical or area exposure warning" to correspond with the title of Section 25607 that includes the general provisions regarding the various "tailored warnings" found in Section 25607, *et seq*.

Further, even without this provision, under existing law any person may petition OEHHA for a rulemaking under the APA (Government Code section 11340.6), regardless of whether there is an existing provision covering a certain type of product or exposure. Given its limited resources, OEHHA would likely give priority to requests for new tailored

warnings; however there may be situations in which an existing provision should be changed. OEHHA will consider such requests on a case-by-case basis. No additional change to the regulations was made based on this comment.

12. Comment (BCI and RMA): BCI and RMA support the petition process in subsection (c). However, BCI requests additional clarification that the OEHHA guidance issued pursuant to this subsection would create a presumption that the activity described in the guidance is in compliance with the Act.

Response: The existing regulations in Sections 25203 (Interpretive Guidance) and 25204 (Safe Use Determinations) already provide the criteria and state the legal effect of these actions. Therefore there is no need to address these issues as part of this rulemaking. No change to the regulations was made based on this comment.

13. Comment (ACC): Under subsection (c), parties other than the regulated entities may flood OEHHA with petitions creating an impossible burden for OEHHA to respond. The right to petition for warning language should belong solely to statutory owners of an affirmative defense.

Response: While OEHHA does have limited resources available to respond to requests for rulemaking, interpretive guidance and safe use determinations, OEHHA does not anticipate a “flood” of petitions under subsection 25600(c). There is no legal or policy reason to limit the requests to only certain individuals or businesses beyond the limitations already establish by relevant laws and regulations. No change to the regulations was made based on this comment.

Subsection 25600(d) (now 25601(e))

Supplemental information within warning content

14. Comment (ACC, CCEEB, CHPA, CalChamber, CRN, and RMA): Several commenters expressed concern about the legality of restricting manufacturers from communicating with their customers and potentially violating First Amendment free speech rights. Some commenters stated, incorrectly, that OEHHA has the authority to bring action against deceptive business practices under Business and Professions Code section 17200. It was suggested that in subsection (d), the phrase, "In order to comply with this article, supplemental information may not contradict the warning" be removed. The commenters encourage OEHHA to clarify that as long as requirements are met for a Proposition 65 warning, a manufacturer is not precluded from adding any other accurate and substantiated information it chooses, consistent with existing laws.

Response: Based on these and other comments, the March 2016 amendments to the regulations (1st text modification) moved the provision regarding supplemental

information to Section 25601 in Subarticle 2, Safe Harbor Methods and Content. The provision was also rewritten and the word “contradict” is no longer used. This is discussed further in the response to the next comment.

15. Comment (AHPA, CAA, CHPA, and CalChamber): The terms, ‘supplemental information’ and ‘contradict’ lack clarity. Neither term is expressly defined. AHPA recommends that the restriction of any supplemental information should be eliminated. If any restriction is included it should be that the information be “truthful and not misleading”. CalChamber comments that OEHHA should not go beyond Proposition 65’s mandate and restrict what a business may choose to say to its customers and public. If OEHHA believes a statement is inaccurate or misleading, then it may say so and engage in a debate in a public forum. But it cannot attempt to ban the debate.

Response: As noted in the previous response, subsection (d) was revised and moved into Subarticle 2, Safe Harbor Methods and Content, specifically subsection 25601(e). In the new provision, information that is supplemental to the content required for the safe harbor warning may only explain the source of the exposure or provide information on how to avoid or reduce exposure to the chemical, and the supplemental information may not be substituted for the required warning. The term “contradict” was not included in the relocated provision.

Moving this provision into Subarticle 2 means that businesses wishing to benefit from a safe harbor warning deemed by OEHHA to be clear and reasonable are required to limit any supplemental information directly included with the warning to information explaining the source of the exposure and how exposures can be reduced or avoided. Businesses that wish to provide other types of supplemental information with a warning can certainly do so; such a warning would not be a safe harbor warning. The businesses are simply required to meet the mandatory statutory requirement (HSC section 25249.6) of Proposition 65 for providing a clear and reasonable warning.

16. Comment (CSPA): Supplemental information will be illegal if it is judged to contradict the warning. It will be difficult to describe anything related to science or assessment of the product, without being accused of trying to counter the warning. Moreover, one reading is that the provision prohibits a company from publically discussing its views on the Proposition 65 listings or warnings which seems needlessly proscriptive of a company’s ability to express an opinion. Ask for clarity about how a company can provide information on the assumptions it used in assessing product exposure or which uses of the product result in significant exposure. In addition, it is not clear if subsection (d) means that OEHHA’s interpretation of the science cannot be refuted publically once a listing or safe harbor has been developed

Response: Subsection 25600(d), now subsection 25601(e), restricts the information provided in a warning that supplements the safe harbor warning content in Subarticle 2. Subsection (e) sets forth specific information that can be included with the safe harbor warning content. Specifically the information may only identify the source of the exposure or provide information on how to avoid or reduce exposure to the identified chemical or chemicals. Subsection (e) does not prevent a business from engaging in public discourse regarding listing decisions and methodology; however, providing this information in the warning would be inconsistent with the safe harbor warning methods and content and a business that chooses to do so would not be afforded safe harbor protection under Article 6.

17. Comment (ITW): Subsection 25600(d) discourages, if not restricts, manufacturers from providing contextual information for customers. Urge OEHHA to consider a way to recognize manufacturers' affirmative decisions and to afford greater leeway for how and where warnings can be incorporated into supplemental product information to achieve OEHHA's goal of maximized consumer awareness.

Response: Subsection 25600(d) was revised and moved into Subarticle 2, Safe Harbor Methods and Content. In the new provision, information provided in the warning that is supplemental to the content required for the safe harbor warning may only explain the source of the exposure or provide information on how to avoid or reduce exposure to the chemical, but the supplemental information may not be substituted for the required warning. Moving this provision into Subarticle 2 is intended to clarify that businesses are not prohibited from providing other kinds of supplemental information. They simply may not do so within a safe harbor warning. This is discussed further in the response to the previous comments.

18. Comment (DRoe): In its present form and location, the provision would offer shelter to much mischievous additional material in all warnings. The provision should be relocated to Subarticle 2. The location and drafting of subsection 25600(d) in its current form is inadequate and would encourage deceptive warnings, by impliedly granting safe harbor to any “supplemental information” that did not actually “contradict” the safe harbor language. The regulations should closely track the discussion in the ISOR on the specific additional information that is allowed (e.g., “instructions or suggestions on how to avoid or minimize the exposure” or “more specific information about the source of the exposure”; etc.). The phrase, “to the extent it does not contradict,” could be interpreted as authorizing anything that does not actually “contradict”. If OEHHA cannot draft more specific language, it should abandon any supplemental information provision.

Response: Subsection 25600(d) was revised and moved into Subarticle 2, Safe Harbor Methods and Content. It is now in subsection 25601(e), and the text was additionally modified a second time (May 20, 2016 modification of text) since this comment was

received. The modified text increases clarity as to the information that may be provided as part of a safe harbor warning. The term “contradict” was stricken from the provision, and as currently proposed, information that is supplemental to a safe harbor warning may be provided only to the extent that it identifies the source of the exposure or provides information on how to avoid or reduce exposure to the chemical; the supplemental information may not be substituted for the required warning content. This is discussed further in the response to the previous comments.

19. Comment (Environmental Coalition): Object to the removal of language from subsection 25600(d) prohibiting warnings that “dilute” or “diminish” the regulatory warning text. Without that language, companies can provide information that severely undercuts the warning’s message without directly contradicting it. This is a serious step back from the previous draft.

Response: Subsection 25600(d) was revised for clarity and moved into Subarticle 2, Safe Harbor Methods and Content; the text was additionally modified a second time since this comment was received. The modified text increases clarity as to the information that may be provided as part of a warning. The terms “dilute” and “diminish” were in the now-withdrawn January 2015 regulatory proposal and are outside the scope of this rulemaking proposal. It is noted, however, that the underlying primary concern is that there is no limitation on supplemental information being provided with the safe harbor warning content. The text was modified to strike “contradict”, and provides that supplemental information for a safe harbor warning deemed to be clear and reasonable by OEHHA may be provided only to the extent that it identifies the source of the exposure or provides information on how to avoid or reduce exposure to the chemical; the supplemental information may not be substituted for the required warning content. Businesses may provide Proposition 65 warnings with other kinds of supplemental information as long as the warnings meet the general statutory requirement under Proposition 65 for a clear and reasonable warning. Such warnings would not be safe harbor warnings deemed clear and reasonable by OEHHA, but may nevertheless comply with HSC section 25249.6 of the Act, as provided for now in subsection 25600(f).

20. Comment (CHANGE): Support restrictions on the amount of supplemental text in a safe harbor warning.

Response: Comment noted. See responses to other comments on subsection 25600(d) above.

Subsection 25600(e) (now 25600(d))

Placement and maintenance of warning responsibility

21. Comment (CH&LA): Subsection 25600 (e) states that a separate warning to each exposed individual is not required. However, OEHHA has said that warnings might well be required in every hotel room and public space and must identify each source of exposure. How subsection (e) applies to hotels and each potential environmental exposure scenario is not clear. Without specific guidance, the provision is unworkable and fails to meet the APA clarity standard.

Response: The commenter is correct that there is no legal requirement to provide a warning to each exposed individual, however this does not mean that warnings should not be communicated in a way that is designed to reach most if not all affected individuals. Subsection 25600(e) carries over a provision from the existing regulations (Section 25601) that mirrors the language in Section 25249.11(f) of the Act which states that "a separate warning to each exposed individual is not required." In the regulations, the section has been renumbered as subsection (d). It is located in the general provisions that are applicable to all clear and reasonable warnings; the regulations would be unwieldy if an explanation of each potential exposure scenario for each affected industry was included in the regulatory text. Rather, Section 25607, *et seq*. consists of "tailored warnings" to address warnings for exposure scenarios typical in an industry. Although the recommended regulatory language for tailored warning for hotels is not being adopted by OEHHA as part of this rulemaking (see response below), OEHHA is considering an informal request for the development of a "tailored warning" pursuant to Section 25607, *et seq.* for exposures to listed chemicals in hotels. In addition to "tailored warnings", subsection 25600(c) further provides that an interested party may petition the agency for a rulemaking under the APA, request guidance through an Interpretive Guideline Request pursuant to Article 2, section 25203 or a Safe Use Determination pursuant to Article 2, section 25204. No change to the regulations was made based on this comment.

22. Comment (AHPA): In response to the now-withdrawn January 2015 regulatory proposal, AHPA supports the provision that it is not necessary to provide separate warnings to each exposed individual; however, it should also not be necessary to provide repeat warnings to the same individual in the same year.

Response: As noted above, this regulatory provision simply repeats a provision of the existing law and regulations related to Proposition 65 warnings, the general principle being that one cannot always ensure that every exposed individual will see and understand a given warning prior to every exposure. However, the regulations adopted by OEHHA are designed to ensure that most if not all persons receive a warning prior to

exposure. Extending the provision to provide that a warning need not be given more than once a year would be contrary to the purposes of the Act, which requires that a warning be provided for exposures to listed chemicals. Allowing for an annual warning to exposed persons would be inconsistent both with the intent of the law and with other provisions of the warning regulations (both this version and the earlier regulation originally adopted in 1988) that, for example, provide for quarterly newspaper warnings for environmental exposures.

Subsection 25600(f) (now 25600(e))

Court-ordered settlements or final judgments

23. Comment (AHFA, CCEEB, CalChamber, and CRN): The commenters support the addition of language acknowledging that court approved Proposition 65 warnings are "clear and reasonable".

Response: Subsection 25600(f) which was included in the rulemaking provides that parties to a court-ordered settlement or final judgment establishing warnings are deemed to be providing a "clear and reasonable" warning for that exposure. OEHHA declines to expand the reach of this provision to grandfather such warnings beyond the parties to a specific settlement or court order because such an approach would reduce the reach of the new provisions being enacted in these regulations. As explained in the ISOR for these regulations, subsection 25600(c) provides that any interested party can petition OEHHA to adopt additional regulations that are tailored to address exposures to listed chemicals in specific products or the environment that are not already sufficiently covered by the regulations. OEHHA will evaluate these requests on a case-by-case basis and develop regulatory provisions that are consistent with the purposes and intent of these regulations that also meet the needs of a given industry or product category in a similar manner to those tailored warnings already included in these regulations. OEHHA encourages businesses to continue to work with OEHHA staff to develop a tailored warning method or message where the existing regulatory provisions are not sufficient to address a particular exposure scenario. In addition, this provision encourages interested parties to use other available options under existing regulations to request guidance concerning application of the Act to specific situations or products, including whether or not a warning is required.

24. Comment (CCBA): As drafted subsection 25600 (f) (subsequently renumbered as subsection (e)) will create a two-sign conundrum for alcohol warnings where two separate Proposition 65 signs with slightly different content must be posted where alcohol is sold. Failure to post both signs could lead to litigation. CCBA understands that parties to a settlement or judgment can "re-open" the agreement to make necessary changes to comport with new regulation, but defendant parties are not likely

to freely do so due to legitimate legal and economic reasons. Request the language be revised to provide that parties that provide a sworn declaration that they are participating in an industry program developed pursuant to a court-ordered settlement or final judgment are deemed to be providing a clear and reasonable warning.

Response: The comment addresses a situation unique to alcoholic beverages. Under both the original 1988 warning regulations and these regulations, manufacturers of alcoholic beverages who wish to provide safe harbor warnings are responsible for providing Proposition 65 warning signs that are posted where alcohol is sold. Subsection 25600(e) of these regulations recognizes court-ordered settlements or final judgments establishing warning or method content as "clear and reasonable" as to parties to that settlement or judgment. The parties to the 2014 alcohol industry Consent Judgment[7] represent approximately 90 percent of all alcoholic beverage products in California,[8] and pursuant to subsection 25600(e) may use the warnings described in the Consent Judgment. It is correct that non-parties to the court-ordered settlement or final judgment (the businesses that produce the remaining 10 percent of alcoholic beverages) may use the methods and content in Sections 25607.2 and 25607.3, respectively, if they wish to take advantage of the "safe harbor" under Article 6. It is also true that these businesses can post any warning that is clear and reasonable, including the one adopted in the court settlement. There is no requirement in law or regulation that both versions of the warning must be posted where alcohol is sold. While the court-settlement warning is not considered a "safe harbor" warning under this regulation for non-parties to the settlement, the only substantive difference between the two warnings is the inclusion of the OEHHA website URL in the safe harbor warning content. There is nothing in the consent judgment that appears to prohibit non-parties from using the warning or adding the OEHHA URL. Extending the grandfathering provision in the manner requested by the commenter is unnecessary. No change was made based on this comment.

25. Comment (AHFA, CalChamber, CCEEB, and Wine et al.): The phrase, "if the warning fully complies with the order or judgment" in subsection 25600 (f) could unintentionally be interpreted as allowing third-party enforcement of court-ordered settlements or final judgments. Such an interpretation is at odds with the res judicata protection afforded by court-approved settlements. Only the court that presided over the settlement or judgment has authority to subsequently make a compliance determination. The phrase should be eliminated. In addition, alternative language was

[7] *Bonilla v Anheuser-Busch, LLC et al*. (2014) Los Angeles County Superior Court case # BC537188

[8] Based on a joint letter from Wine Institute, Beer Institute, and Distilled Spirits Council of the United States dated Jan. 25, 2016 that is included as part of this rulemaking record, at p.4

suggested that affirmatively stated that the provisions of this Article do not apply to court-approved settlements or judgments because businesses that are parties to such settlements or judgments must comply with the court order and any provision that is inconsistent with a pre-existing court-approved settlement or judgement also has no application to the parties subject to that court order.

Response: In the 2nd modification of text, the term "fully" was stricken from subsection (f) (subsequently renumbered as subsection (e)), to clarify that this regulatory provision is not intended to grant third-parties authority to enforce court-ordered settlements.

26. Comment (CalChamber and CCEEB): Subsection (f) only grandfathers in warnings for consumer products or environmental exposures. Older court-approved consent judgments also address occupational exposures. There is no legal or policy basis to exclude them from the regulations. The regulations should be revised to either add the phrase "occupational" to this subsection or eliminate the phrase "consumer product or environmental".

Response: In response to this comment, subsection (f) (subsequently renumbered as subsection (e)) was modified to remove the terms "consumer products or environmental exposures"; thus it covers all court ordered settlements that include required warning methods or content.

27. Comment (Environmental Coalition): Many court settlements allow for weaker warnings than those provided for by these proposed regulations. OEHHA should not codify those weaker warnings. At the very least, language should be added making it clear that non-parties to court settlements are not allowed to use court-approved language as a safe harbor. In addition, it should be made clear that subsection (f) only applies to the specific products covered by the court settlement.

Response: Subsection (f), subsequently renumbered as subsection (e), is expressly limited to a "party" to a court-ordered settlement or judgment. OEHHA is not sanctioning the use of court-ordered settlements or judgments by a non-party. As such, this provision is simply a statement of existing law. A party to a court order must follow its provisions and, by definition, a court has found the warnings to be clear and reasonable in the context of the particular case. OEHHA declines to modify the regulations to limit the provision to specific products; the scope of the court-ordered settlement or judgment will be dictated by the terms of the court-ordered settlement or judgment.

28. Comment (ACC): In some past court settlements, inappropriate chemical "groupings" have been deemed acceptable for safe harbor warnings. Many stakeholders have requested "grandfathering" of settlement-based safe harbor language. If OEHHA must reference such language derived from a settlement in the

regulations, OEHHA should include an explanation why such approaches are inappropriate, offer an example, and caution that OEHHA will not consider such approaches acceptable.

Response: As noted above, the "grandfathering" provision is a statement of existing law. OEHHA states no opinion concerning the propriety of particular settlements or the language used in court ordered warnings.

29. Comment (BCI and CDA): Support the inclusion of subsection (f).

Response: Comments noted, no response required.

30. Comment (ITW): Non-parties to court-ordered settlements or final judgments must petition OEHHA to be granted similar safe harbor protection. OEHHA should allow equal coverage to manufacturers of like or competing products under the provisions of subsection 25600(c) as those manufacturers and products that were direct parties of a settlement or judgment without the need of a separate petition.

Response: As stated previously, subsection 25600(f) (subsequently renumbered as subsection (e)) provides that parties to court-ordered settlements are not required to comply with the OEHHA regulations. OEHHA cannot change the terms of a court order or settlement by regulation. Most court ordered warnings are based on the existing safe harbor language in place at the time they were entered that provides less information for the public than the methods and content in the new regulations. However, over time, OEHHA anticipates that new settlements will incorporate the new provisions in the regulations. Some older settlements may be modified by the parties to conform to the new regulations. Allowing non-parties to use warning methods and content from old settlements and orders would be contrary to the intent of promulgating revised warning methods and content; namely to provide for more meaningful warnings to the public regarding exposure to listed chemicals. For these reasons, OEHHA declines to make the recommended change.

Section 25600.1 Definitions

Subsection 25600.1(a): "Affected Area"

31. Comment (Environmental Coalition): Suggest adding language regarding the "vicinity of the source of the exposure" to clarify that the affected area is limited to the area where the exposure occurs at a level requiring a warning.

Response: This provision is carried over from the existing regulations in substantially the same form. OEHHA declines to revise the definition of "affected area" by adding "vicinity of the source of the exposure". The definition currently limits the area to the location where the chemical can occur "at a level that requires a warning". The

definition of “environmental exposure” now includes an explanation of the source of exposure in subsection (f) (previously subsection c) and naming one or more sources of exposure is a required component of the environmental warning methods and content for safe harbor warning in Sections 25604 and 25605. These changes should adequately address the issues raised by the commenter.

32. Comment (CH&LA): The phrase, “is reasonably calculated to occur" in the definition for "affected area” in the now-withdrawn January 2015 regulatory proposal was removed from the November 2015 version with no rationale for why it was done. Recommend that the definition be revised to "…other reproductive harm is reasonably and feasibly calculated to occur at a level that requires a warning." A clear definition of "reasonably and feasibly calculated" should be provided with examples demonstrating how a business can 'reasonably' and 'feasibly' make a calculation.

Response: The regulations state that “affected area” means the area in which an exposure to a listed chemical can occur at a level that requires a warning. The phrase “reasonably calculated to occur” was not included in the November 2015 regulatory proposal to improve clarity and consistency. The determination of “affected area” does not necessarily require calculation. Using language similar to the existing regulatory language is more clear and consistent with the law, which requires warnings unless the business can show the exposure is below a specified level[9].

Subsection 25600.1(b): “Authorized Agent”

33. Comment (Environmental Coalition): The term “authorized agent” is unclear and could lead to confusion and strategic behavior. The retailer could avoid compliance by simply refusing to authorize an agent. The regulation contains no requirement that a retailer actually designate an agent. If the retailer does not do so, this definition will not prevent a retailer from avoiding receiving the notice from a manufacturer or distributor required by subsection 25600.2(b) and thus avoids the warning requirement. A better solution is to require the distributor or manufacturer to contact a retailer at the address to which it customarily directs correspondence.

Response: The regulations place the responsibility on the retail seller to designate a person to receive warning information from product manufacturers, distributors, packagers, importers, and suppliers. Each of the entities in the chain of commerce will likely do this through contractual language. However, where a given retail seller has not designated such an agent, the manufacturers, producers, packagers, importers, suppliers, and distributors can provide the notice and warning materials to the person

[9] Health and Safety Code section 25249.10(c), Title 27, Cal. Code of Regs., section 25701 and 25801 *et seq*.

they normally communicate with at the retail seller regarding their products. They may also wish to provide the materials with the product when it is delivered to the retail seller. In the unlikely event that it is impossible to locate an agent for a retail seller, the manufacturers, producers, packagers, importers, suppliers, and distributors may choose to label the product with a compliant warning in order to ensure the consumer receives a warning.

34. Comment (AHFA): Agree that the term authorized agent must be defined, but notes that the definition for “authorized agent” in subsection 25600.1(b) is ambiguous and could be interpreted to exclude an agent authorized to receive notices under "Proposition 65" or "Health and Safety Code Section 25249.5 et seq." or "the Safe Drinking Water and Toxic Enforcement Act," or "California law" if the authorization does not specifically mention "Article 6 of Title 27 of the California Code of Regulations." The regulations do not specifically require the retailer to designate an agent for purposes of this regulation. Without this requirement in the regulations, a retailer can unilaterally vitiate a manufacturer’s right to comply with Proposition 65 under subsection 25600.2 by simply not specially and specifically designating an authorized agent. This special designation is unnecessary. Urge OEHHA to maintain consistency by defining an authorized agent to be those persons authorized to receive summons as defined in the California Code of Civil Procedure (CCCP) section 416.10.

Response: The definition of “authorized agent” in subsection 25600.1(b) is clear on its face and refers to the person or entity designated by the retail seller to receive notices from product manufacturers, producers, packagers, importers, suppliers, and distributors “under this article”. OEHHA declines to adopt the provisions of CCCP section 416.10 because the agents for service of process are unlikely to be the persons with responsibility for ensuring that warnings are provided for exposures to listed chemicals from particular products. The agents for service of process may be private attorneys or other individuals unfamiliar with the day-to-day operations of the business and would likely not know how to handle such notices in a timely manner. Retail sellers are in the best position to know which person within their organization is the most appropriate individual to receive and act on these notices. Therefore, OEHHA has placed the responsibility on the retail seller to designate an appropriate agent for receipt of warning materials.

Subsection 25600.1(c): “Environmental exposure” (now 25600.1(f))

35. Comment (CAA): The **“**environmental exposure” definition states that all exposures that are not product or occupational exposures are environmental exposures. It is not clear what type of warning is required when there are combinations of exposures. Are multiple types of warnings required when multiple types of exposures are occurring?

Response: Proposition 65 requires warnings for exposures to listed chemicals. When the regulations were first adopted, exposures were divided into three categories: consumer products exposures, occupational exposures and environmental exposures. These categories have worked well over the years. It is true that in some circumstances warnings will need to be provided that do not fit neatly into a single category. In that case, more than one warning may be required for a listed chemical in a given location. For example, in an occupational setting where a warning is not required for a given chemical exposure under federal or California OSHA regulations, a person may still be required to provide a warning under Proposition 65. This can be accomplished by using the method and content appropriate for a consumer product or environmental exposure, whichever is appropriate. In some circumstances, this may be accomplished by posting a sign, as for an exposure to a chemical in the air. In other circumstances, it may be accomplished by providing a warning on or with a product. In the occupational exposures example, OEHHA added a provision expressly allowing this in subsection 25606(b).

Subsection 25600.1(d): "Food" (now 25600.1(g))

36. Comment (CRN): Support the definition for "food".

Response: Comment noted, no response required.

Subsection 25600.1(e): "Knowingly" (now 25600.1(h))

37. Comment (AdvaMed and Environmental Coalition): AdvaMed commented that OEHHA should further clarify the definition of "knowingly" in order to reduce the chances of a company being sued over whether they "knew" a chemical could cause exposure or not. Environmental Coalition commented that Article 1, section 25102 already applies to all of Chapter 1 of Title 27 of the California Code of Regulations and it is redundant to define "knowingly" again in subsection (e).

Response: The term "knowingly" is defined by reference to Article 1, section 25102(n) so there is no need to further define the term. The definition of the term "knowingly" applies throughout Chapter 1 of Title 27 of the California Code of Regulations. OEHHA has defined the term by reference in subsection 25600.1(h) to facilitate ease of reference. Changes to the definition are beyond the scope of this rulemaking.

Subsection 25600.1(g): "Labeling" (now 25600.1(j))

38. Comment (Environmental Coalition): The definition of "labeling" is confusing and outside of the ordinary use of the word. The phrases "accompanies the product", and "tags at the point of sale or display of a product", in the definition of "labeling" are vague.

Are only "tags" on the "display of a product" included, or is the entire display included? Object if this definition allows for warnings to be provided in a product's display. Believe that warnings should be placed on the products themselves so that end users receive the benefit of the warnings.

Response: The regulation states that "labeling" means any written, printed, graphic, or electronically provided communication that accompanies a product including tags at the point of sale or display of a product. This definition was carried over from the existing regulations and modified to allow for the possibility that a warning could be provided in an electronic format such as on a screen on a smart cart, at a scanner, at checkout or in some other manner as technology improves. In order to be clear and reasonable, the warning must always be clearly associated with the product and be provided in such a way as to be seen and understood prior to exposure. Shelf tags, such as those currently used in grocery stores to provide brand and pricing information, can be a form of labeling. Package inserts that are likely to be seen and read prior to exposure to the chemical may also be a clear and reasonable form of labeling in certain situations. Whether or not a given method of providing a warning is clear and reasonable is a question of fact that would ultimately be resolved through litigation. OEHHA has provided safe harbor warning methods in Subarticle 2 of this regulation that OEHHA deems to be clear and reasonable for purposes of the Act. These provisions are not mandatory, but provide guidance to businesses on how to provide clear and reasonable warnings for purposes of the Act.

Subsection 25600.1(i): "Consumer Product Exposure" (now 25600.1(e))

39. Comment (AHPA): In response to the previous version of the regulations released in January 2015 and later withdrawn and replaced in November 2015, AHPA commented that it supports the provisions of subsection 25600.2 (f) (now subsection (g)) but it should also encompass agreements between manufacturers, producers, packagers, and distributors to allocate responsibility. These agreements should supersede subsections (b), (c), and (d).

Response: Subsection (i) (previously subsection (h)) of the regulations allows the businesses responsible for providing warnings to opt-out of the requirements of the regulations as long as there is a written agreement that ensures a compliant warning is given. Nothing in this subsection prohibits any of these businesses from contracting amongst themselves about how to manage their warning responsibilities. The primary purpose of the provision, however, is to ensure that the process results in a clear and reasonable warning being provided to the consumer prior to exposure. The product retail seller is an essential player in the process. OEHHA encourages all businesses in the chain of commerce to work together to ensure that this process works in the most

efficient and effective manner possible that meets the needs of the businesses involved to the extent possible. As noted previously, some warning programs are managed by trade organizations or third parties contracted by those organization to manage their warning programs. This may be a good approach in some situations and would be consistent with OEHHA's intent in adopting this provision.

40. Comment (AHPA and CRN): The phrase, "any reasonably foreseeable" should be removed from the "consumer product exposure" definition and instead add after "use of a product": "in accordance with recommendations made in the product's labels or labeling or with other actual and accepted uses of the product" (AHPA) or "in accordance with the product labeling recommendations or ordinary conditions of use" (CRN).

Response: The definition of consumer product exposure was carried over from the existing regulations with minor modification. The proposed changes to the definition offered by the commenters would unnecessarily limit the potential exposure scenarios to listed chemicals. Such a limitation would not be consistent with the purposes of the Act. If a person's use of a product is "reasonably foreseeable" even if it is not entirely consistent with label recommendations, any resulting exposures to listed chemicals can properly be considered to be "knowing and intentional" on the part of the product manufacturer, and are therefore subject to Proposition 65. Limiting the scope of the definition would not be consistent with the Act.

41. Comment (AHFA): Because replacement parts and components are identical to the original parts and components being replaced, and are intended for use only with the finished furniture product, request clarification that a separate Proposition 65 warning is not required for such parts and components. Suggest amending the regulatory definition for "consumer product exposure" by adding, "A consumer product exposure excludes an exposure that results from a replacement part or component, designed and intended for use only with a finished consumer product, if the finished consumer product bears a clear and reasonable warning."

Response: Exposures to listed chemicals from replacement parts are separate and apart from exposures that may occur from use of the original product. For example, specific exposures to chemicals in replacement parts conceivably could occur when individuals handle the parts or install them in the furniture product. It is also possible that the chemical content and potential for chemical exposures from replacement parts could differ from those of the original furniture parts. Therefore, exposures from replacement parts require a warning unless the person causing the exposure can show

unless the business can show the exposure is below a specified level[10]. Furthermore, OEHHA does not have the authority to exclude entire classes of products from the warning requirements of the Act.

42. Comment (Environmental Coalition): Approve of the term, "consumer product" rather than "product" in definition of "consumer product exposure".

Response: Comment noted, no response required.

43. Comment (DRoe): Defining "consumer product exposure" as exposure to "a product" rather than to a "consumer product" opens a door to potential confusion and mischief. Each of the relevant definitions throughout the regulation should instead use the term "consumer product," and a separate definition of "consumer product" should be included, defining it as "a consumer good, including a food."

Response: OEHHA added a separate definition for "consumer product" using language derived from the federal Consumer Product Safety Act (CPSA),[11] as subsection 25600.1(d) in the May 20, 2016 modification of text. OEHHA considered using the term "consumer good" as recommended by the commenter, but decided the regulations would be clearer by defining "consumer product" similar to the definition used in the federal CPSA rather than linking the definition to a new term such as "consumer good". OEHHA added the phrase "including food," as recommended by the commenter in the definition of consumer product, and the phase "including consumption of a food" in the definition of "consumer product exposure".

44. Comment (NMMA): Not all manufacturers have requisite staff to determine if a consumer product's effects are reasonably calculated to occur at a level that requires a warning. A clear scientific definition of "exposure" is needed. OEHHA should define "consumer product exposure" in accordance with OSHA's Permissible Exposure Limits (PELs). In defining "exposure" it is important to distinguish between hazard and risk.

Response: The commenter is referring to the phrase "reasonably calculated to occur" which was included in the now-withdrawn January 2015 rulemaking but was not part of the November 2015 rulemaking proposal. The regulations use the phrase "can occur at a level that requires a warning". Further, the regulations were also modified to revise the definitions in subsection 25600.1(e) of "consumer product exposure" and in subsection 25600.1(f) of "environmental exposure"; and retains in subsection 25600.1(k) the definition for "occupational exposure" from the existing Article 6. OEHHA has determined that these definitions of exposure will address the three main

[10] Health and Safety Code section 25249.10(c), Title 27, Cal. Code of Regs., section 25701 and 25801 *et seq*.
[11] Consumer Product Safety Act, 15 U.S.C. 2052(a)(5), available at http://uscode.house.gov/view.xhtml?req=(title:15%20section:2052%20edition:prelim)

exposure categories contemplated under the Act and in these regulations; therefore, OEHHA declines to separately define the term “exposure”. Regarding the request for OEHHA to define “consumer product exposure” in accordance with the OSHA PELs, Proposition 65 applies to a variety of exposure scenarios, including many non-occupational exposures that are not covered by OSHA, and therefore tying any definition of “consumer product exposure” to OSHA standards would be inappropriate. Occupational exposures are covered under Section 25606 of the regulations.

Subsection 25600.1(j): “Retail seller” (now 25600.1(l))

45. Comment (Environmental Coalition): In the definition for “retail seller”, the term, “purchasers” should be changed to “consumers,” both for consistency and to avoid inadvertently including wholesale distributors. Often, the consumer of the product, and thus the individual who is exposed, is not the purchaser.

Response: OEHHA agrees with the commenter and has modified the regulatory text by striking the term “purchasers” and replacing the term with “consumers”.

46. Comment (Auto Alliance et al.): To increase clarification suggest changing the word “purchasers” to “end users” in the definition of “retail seller”.

Response: The term “end users” would introduce a new term of art that is not used elsewhere in the regulation. This would make the regulations less clear and more subject to interpretation. OEHHA has modified the regulatory text by striking the term “purchasers” and replacing the term with “consumers” for consistency within the regulations. OEHHA therefore declines to make the requested change.

Subsection 25600.1(k): “Sign” (now 25600.1(m))

47. Comment (CAA and AHPA): It is unclear what a "physical presentation of … electronically provided communication" is. On page 17 of the ISOR, it states that “signs… can be presented electronically.” What does this mean in relation to the posting requirement? The definition also states that the sign should be “clearly visible under all lighting conditions normally encountered during business hours.” What does this mean for warning signs on residential property when residents, guests, and invitees arrive at all hours?

Response: The regulations states that:

> “Sign” means a physical presentation of written, printed, graphic or electronically provided communication, including shelf signs, other than a label or labeling, posted in a conspicuous manner that is associated with the exposure requiring a warning under the Act, is clearly visible under all lighting conditions normally

encountered during business hours and under such conditions as to make it likely to be seen, read, and understood by an ordinary person."

As stated in the ISOR for these regulations, the minor changes to the definition of "sign" in subsection 25600.1(k) (now subsection m) are similar to those made in the label and labeling definitions. Signs can include graphics and other content and can be presented electronically. This reflects the technology that has developed in the 28 years since the original regulations were adopted. In order to maximize the effectiveness of the warning message, this subsection requires that a sign be posted in a conspicuous manner that is associated with the exposure. For example, if people can be exposed to the listed chemical at night, such as on a residential property, then the sign must be in a location that is already lit at night, or must itself be lit in such a way that it can be read at night. Providing a warning in an electronic format may not be appropriate for all situations. However, OEHHA is aware that current technology allows for messages to be provided to shoppers electronically as they walk through a store, make purchases over the internet, or stand in line at a check-out counter. Depending on the particular exposure scenario, providing the warning electronically may be a good option.

OEHHA is currently considering an informal request for the development of a "tailored warning" pursuant to Section 25607, *et seq.* for exposures to listed chemicals in apartments.

48. Comment (AHPA): Suggest removing the phrase "understood by an ordinary person," because the phrase is impractically vague, and implies that firms who rely on signs to provide Proposition 65 warnings must conduct consumer research to ensure the signs will be understood.

Response: The phrase "understood by an ordinary person" was used in the existing regulations and is used here in order to ensure that the warning signs are provided in a clear and reasonable manner. Nothing in the regulations requires that businesses conduct research concerning the effectiveness of their warnings. Other sections of the regulations provide warning messages that are deemed "clear and reasonable" by OEHHA that may be used for products without the need to do any research regarding whether the warning will be understood by an ordinary person. OEHHA declines to make the change requested.

Section 25600.2 Responsibility to Provide Consumer Product Exposure Warnings

Subsection 25600.2(a)

Minimize burden on retail sellers

49. Comment (CHANGE): While manufacturers and distributors should bear primary responsibility for providing warnings, retailers must share in responsibility especially when manufacturers may be distant.

Response: As noted in subsection 25600.2(a), the Act requires the lead agency to minimize the burden on retail sellers of consumer goods to the extent practicable. As stated in the ISOR for these regulations, Section 25600.2 is based on the premises that (1) the consumer must receive the warnings mandated by Section 25249.6 of the Act before being exposed to a chemical known to cause cancer or reproductive toxicity; and (2) the primary responsibility for providing the warning for products, including foods, is with the manufacturer, producer, packager, importer, or distributor of those products. The regulations therefore recognize that those parties are primarily responsible for providing warnings. This is reasonable, as manufacturers usually will have greater knowledge than retailers of a product's chemical content and whether it causes chemical exposures that require a warning.

The regulations place retail sellers in a separate category and imposes the responsibility for providing the warning on them under specific circumstances. Specifically, where the retailer has failed to display warnings received from the manufacturer, producer, packager, importer, or distributor; or has actual knowledge of an exposure under circumstances where there is no manufacturer, producer, packager, importer, or distributor who can be readily compelled to provide the warning. See subsections 25600.2(e)(1)-(5) of the regulation (May 20, 2016 2nd modified text).

Under subsection (b) the manufacturer, producer, packager, importer or distributor of a product must affix a warning to the product; or provide specific written notice to the retail seller that contains a clear description of the product and includes warning materials. Under subsection (c), the manufacturer, producer, packager, importer or distributor must obtain confirmation of receipt of this notice from the retail seller within six months during the first year after the effective date of the regulation; thereafter, confirmation of receipt need be obtained only once per year. Such confirmation of receipt can be given via e-mail or other electronic method to the entity that provides the notice. It need not be provided in hard-copy form. Also, an additional notice is required within 90 days if a different or additional listed chemical or endpoint is included in the warning.

The manufacturer, producer, packager, importer and distributor do not need to obtain the retail seller's agreement to post the warning materials that are provided under subsection (b)(3). As discussed below in connection with subsections (d) and (e)(4) (May 20, 2016 2nd modified text), once the retail seller receives a notice that complies with subsections (b)(1) through (3), the retail seller must, when selling the product, properly display those warning materials or give a warning of its own that complies with the Act.

Under subsection (d) (May 20, 2016 2nd modified text), it is the retail seller's responsibility to place and maintain any warning materials it receives from the manufacturer under subsection (b). With respect to labels affixed to the product, this means that the retail seller must ensure that it does not remove or obscure the warning label in some way, thereby thwarting the efforts of the product manufacturer, distributor, producer or packager that is providing the warning. Simply placing a product on a shelf in a manner that results in a printed warning on the product not being immediately visible is not "obscuring" the warning if the consumer will be able to see it upon picking up the product. With respect to shelf signs or tags that are not affixed to the product, the retail seller is required to post and maintain these materials in compliance with the requirements of Section 25600.2. If a manufacturer provides a shelf sign or tag to the retail seller and the retail seller covers it, fails to conspicuously post it, or intentionally removes it, the retail seller has not complied with Section 25600.2. If the retail seller loses or destroys the manufacturer's warning materials, the retail seller should request duplicate material from the manufacturer or other person in the chain of distribution. In the meantime the retail seller must still provide a warning that fully complies with the Act.

Subsection (e) (May 20, 2016 2nd modified text) sets forth the situations in which the retail seller is responsible for providing the warning. Under subsections (e)(1) through (3), the retail seller is also responsible for providing a warning if it is selling the product under its own brand name, if it has introduced the listed chemical or has caused the chemical to be created in the product (and is therefore directly responsible for the exposure), or if it has covered, altered, or obscured the warning label that has been affixed by the manufacturer, producer, packager, importer or distributor. Under subsection (e)(4), the retail seller is responsible for providing a warning if it has received the notice described in subsection (b), whether or not it has provided a confirmation of receipt pursuant to subsection (b)(4) or (c)(1) (May 20, 2016 2nd modified text). If the retail seller has received such a notice from the manufacturer, producer, packager, importer or distributor, then the retail seller has the responsibility to either pass on the warning or to provide a legally adequate warning of its own.

Under subsection (e)(5) (May 20, 2016 2nd modified text) the retail seller has the duty to provide a warning if it has actual knowledge of the potential exposure (discussed in detail below) and either of the following two circumstances is present:

(A) There is no product manufacturer, producer, packager, importer or distributor of the product that is subject to Section 25249.6 of the Act. This will most often occur when the manufacturer, producer, packager, importer or distributor has fewer than 10 employees.

(B) Where the manufacturer, producer, packager, importer or distributor are foreign persons with no agent for service of process in California. Such foreign persons will usually have an obligation under the Act to provide a warning, and the regulation does not relieve any such foreign persons of this obligation, but enforcing this obligation may be impractical because it would require the enforcing party to proceed in a foreign jurisdiction, for example, under the Hague Convention. Thus, the retail seller must provide the required warning in this situation.

The intent of subsections (e)(5)(A) and (B) is to require the retail seller to provide a warning when it has actual knowledge of the exposure and the manufacturer, producer, packager, importer or distributor cannot readily be compelled to provide it. This will ensure that the consumer will receive a warning as required by the Act. For example, if the product requiring a warning is produced and packaged by a company with no agent for service of process in California, and it is distributed by an importer with fewer than ten employees, then it will be the responsibility of the retail seller to provide the warning.

There may be situations when the retail seller is unsure whether the manufacturer, producer, packager, importer and/or distributor are subject to the Act or are foreign corporations without agents for service of process in the United States. However, the retail seller will have a duty to inquire into these facts whenever the retail seller (1) has actual knowledge of the potential product exposure requiring the warning, and (2) has not received a notice from the manufacturer, producer, packager, importer or distributor pursuant to subsection (b).

Thus, the regulation is intended to ensure that, although a product manufacturer has primary responsibility for providing a warning, a retail seller must provide the warning and, in some circumstances, must provide the warning even though a manufacturer or other business in the chain of commerce has not provided it to the retail seller.

No changes to the regulations were made based on this comment.

50. Comment (NMMA): The burden is placed on manufacturers to minimize the burden on retailers. Manufacturers are often unaware of where their goods are ultimately sold, making it difficult to comply without significant time and resource expense. OEHHA

should include language to clarify the burden on manufacturers as it did for retailers, and form a working group to develop consensus language that balances concerns of industry, the state and the public.

Response: Proposition 65 applies to all businesses with 10 or more employees that cause exposures to listed chemicals in their products. The regulations are intended to ensure that each business, beginning with the product manufacturer, passes along information concerning the need for a warning to the businesses to which it sells the product so that ultimately, the consumer receives a compliant warning. OEHHA believes that Section 25600.2 of the regulations clearly state the relative responsibilities of product manufacturer, producer, packager, importer, supplier, distributor and retail seller in terms of providing warnings that comply with the Act. A product manufacturer always has the option to directly label a product, thus discharging its responsibility under the law. No additional notice is required for labeled products, except where they may be sold over the internet. In that situation, a manufacturer should ensure that the warning message is provided to the product retail seller for use on the internet. The regulations represent a multi-year effort involving the engagement of a variety of stakeholders. OEHHA believes these regulations strike a balance between the public interest of ensuring that meaningful, informative warnings are provided to the people of California before exposure to a listed chemical, and the diverse concerns that have been clearly articulated by industry representatives and evaluated by OEHHA. No additional changes to the regulations were made based on this comment.

51. Comment (Environmental Coalition): The regulatory language gives too much discretion to manufacturers and distributors to shift the warning responsibility to retailers. The regulations should specify that upstream companies should provide the warning unless it is unfeasible to do so. Without this language, those companies will simply shift the burden downstream to retailers, which would contradict the intent of HSC section 25249.11. Where retailers are not themselves introducing a listed chemical into a product, they should only be required to provide a warning if it is unfeasible for another party higher up in the stream of commerce to do so.

Response: Section 25600.2 is intended to better align the Article 6 regulations with Section 25249.11 of the Act by minimizing the burden on retail sellers of consumer products, *to the extent practicable*. Absent a requirement that all warnings be provided directly on a product, which is not consistent with the express terms of the statute[12], all

[12] Health and Safety Code Section 25249.11(f) "Warning" within the meaning of Section 25249.6 need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that

businesses (with 10 or more employees) in the chain of commerce are subject to the warning requirements of the Act and must work together to ensure that a compliant warning is provided to consumers for exposures to chemicals listed under Proposition 65. Under Section 25600.2, retail sellers essentially would pass through the warning materials they are provided by the upstream businesses. This process would help ensure that those parties that are most likely to know that a warning is required bear the cost of providing warning materials for those products. Retail sellers are essential to the process, however, since they are in direct contact with consumers and are the most likely to be targeted for enforcement actions when a warning is not provided. OEHHA has determined that the division of responsibility in the regulations is a reasonable and consistent means of implementing the statute.

52. Comment (ACMI): The regulations should be revised to allow manufacturers and distributors to discharge their warning obligations by providing warning materials to their direct customers, rather than the ultimate retailer of the product.

Response: It is true that in some circumstances a manufacturer or other business in the chain of commerce does not have actual knowledge concerning who the ultimate retail seller of its product may be and therefore may not be able to provide a notice to all the retail sellers of its products. Given that Proposition 65 applies to all businesses in the chain of commerce, including the manufacturer, producer, packager, importer, supplier, or distributor of a product, the regulations provides that each party may provide notice to its direct customer that a warning is required, provide the necessary warning materials, and contractually require that these materials be passed along to the next business in the chain of commerce. Subsection (i) (previously 25600.2(h)) of the regulations state that "provided that the consumer receives a warning that meets the requirements of Section 25249.6 of the Act prior to exposure, the manufacturer, producer, packager, importer, supplier, or distributor of a product that may cause a consumer product exposure may enter into a written agreement with the retail seller of the product to allocate legal responsibility among themselves for providing a warning for the product, which shall bind the parties to that agreement and which shall supersede the requirements of subsections (b), (c), (d), and (e). This subsection allows for such an allocation of responsibility. Nothing in this subsection prohibits the manufacturer, producer, packager, importer, supplier, or distributor of a product from contracting amongst themselves about how to manage their warning responsibilities, so long as the

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the warning accomplished is clear and reasonable. In order to minimize the burden on retail sellers of consumer products including foods, regulations implementing Section 25249.6 shall to the extent practicable place the obligation to provide any warning materials such as labels on the producer or packager rather than on the retail seller, except where the retail seller itself is responsible for introducing a chemical known to the state to cause cancer or reproductive toxicity into the consumer product in question.

consumer receives the required warning. If a contractual agreement exists among the parties in a supply chain, and a consumer fails to receive the required warning, then the entity within the supply chain that failed in their contractual obligation to transmit the warning would be responsible under these regulations. No change to the regulations was made based on this comment.

Subsection 25600.2(b)

53. Comment (CGA): Section 25600.2 is fundamentally flawed. It directly contradicts HSC section 25249.11(f) by shifting the actual and legal burden for providing warnings from product manufacturers to retailers. Pursuant to (b), a manufacturer could simply include a notice letter and shelf tag/flyer/stickers containing specific warning label in a product shipment and thereby absolve itself of any additional burden. It would then be up to the retail entity to effectuate and maintain consumer warnings – and the retail entity would bear all liability if that were not done or done properly. This deficiency persists throughout the subsequent proposed regulation on warnings.
Response: OEHHA disagrees. As stated in the ISOR for the regulations, "for purposes of litigation to enforce the requirements of Proposition 65, when a product is sold without a warning, the enforcing party should generally proceed against the manufacturer, producer, packager, importer and/or distributor. An enforcement action against the retail seller will be appropriate only when one or more of the circumstances in subsection (d) (now 25600.2(e)) defining when a retailer would have primary responsibility for providing a warning] exist." OEHHA cannot exempt an entire business sector from compliance with Proposition 65 via a regulation. The regulations are designed to ensure that except in the specified circumstances, the product manufacturer, producer, packager, importer or distributor bears the primary burden for providing a warning. The product retailer would only be responsible for independently providing a warning in the circumstances described in the regulations. OEHHA believes this provision is consistent with HSC section 25249.11(f) because it places the primary burden on the product manufacturer, producer, packager, importer or distributor "to the extent practicable". No change to the regulations was made based on this comment.

54. Comment (CAA): The regulations address the responsibility of various parties in the chain of commerce, but it does not address responsibility of the purchaser business to provide a warning to the ultimate user.

Response: Exposures from products purchased for others' use would still be consumer product exposures as defined, "exposure that results from…any reasonably foreseeable use of product…" (subsection 25600.1(e)). Therefore, the provision of the regulations addressing the responsibility to provide warnings for consumer products would apply to these exposures. As stated in the ISOR for these regulations, Section 25600.2 is based

on the premise that the consumer must receive the warnings mandated by Section 25249.6 of the Act before being exposed to a chemical known to cause cancer or reproductive toxicity. Although the primary responsibility for providing the warning for products, including foods, is with the manufacturer, producer, packager, importer, or distributor of those products, any entity within the chain of distribution shares in the responsibility for providing a warning. The regulations do not relieve any party from its obligation to provide a warning. Each party has the responsibility to either pass on the warning it receives or to provide a legally adequate warning of its own.

55. Comment (Environmental Coalition): There needs to be a mechanism to address a situation in which an upstream entity provides warning materials to a retail seller, but materials are not clear and reasonable.

Response: If an upstream entity chooses to satisfy its obligation to provide a warning under the Act by providing a notice and warning materials to a downstream entity under the Act, subsection 25600.2(b)(3) requires that the notice include all necessary warning materials that satisfy Section 25249.6 of the Act. In other words, the warning materials provided must be “clear and reasonable” under the Act for the upstream entity to satisfy its obligation to provide a warning under the Act. If the upstream entity has not affixed a label to the product which meets the requirements of the Act, and has not provided “clear and reasonable” warning materials as part of the notice to downstream entities, it may be liable under the Act for failing to provide a “clear and reasonable” warning.

Label or written notice provision

56. Comment (ACMI): The first sentence of proposed subsection (b) contains a circular reference to “this section” and should be revised to clarify that the supplier “may comply with this Article” by undertaking the described actions. In the absence of this clarification, there will be ambiguity about whether compliance with this subsection discharges a supplier’s obligation to warn, leading to unnecessary litigation over the question.

Response: Subsequent to this comment, the regulatory text was modified by replacing “section” with “article”.

57. Comment (CGA) Pursuant to subsection 25600.2(b), a manufacturer can simply provide a notice letter containing a specific warning label and thus absolve itself of any additional burden. The retailer then bears all liability if providing the warning is not done properly, and the burden of "actual knowledge" which presumably is triggered when the retailer receives notice from the manufacturer; yet the manufacturer is not required to provide warning materials at the same time as the notice given. The manufacturer only has to “offer to provide” the warning materials. The retailer would be forced to create its own warning materials or hold the product off the sales floor until the warning materials

are received from manufacturer. This creates a situation for manufacturers to unduly delay transmission of warnings given there is no timeline noted for their response should a retailer take them up on the offer to provide warning materials. One could envision a scenario where a retailer would be forced, in an effort to manage their own legal risk, to create warning materials at their own expense.

Response: Based on this and other comments, the phrase "or offers to provide such materials at no charge to the retail seller" was deleted from the regulatory text (subsection 25600.2(b)(3)), so that manufacturers must actually provide warning materials to retail sellers along with the notice to fulfill their responsibilities under the regulations. This should ensure that there is no time-lag between receipt of the notice that a warning is required, and receipt of the warning materials themselves. Therefore, the other concerns noted in this comment are addressed through this change. No further changes to the regulations were made based on this comment.

58. Comment (AHPA): The term, "importer" is unclear and should be deleted in subsection 25600.2(b) and elsewhere in the regulations. Alternatively, OEHHA should provide a definition for "importer".

Response: OEHHA disagrees with the characterization of the term "importer" as ambiguous. "Importer" is not a term of art specific to Proposition 65 and need not be defined in the regulations. For example, in one generally available dictionary, "importer" is defined as "a person, country or company that buys products from another country in order to sell them." [13] The term is used in the regulations in this manner to refer to businesses that import products that are sold in California.

59. Comment (Environmental Coalition): Suggest providing language to allow a retail seller to return products to manufacturers, packagers, producers or distributors if that party does not comply with requirements contained in subparagraphs (b)(1)-(5). This will prevent retail sellers from being saddled with unmarketable products that do not contain the required warnings.

Response: The comment suggests provisions that are outside the scope of the regulations. Given that changes have been made to require that the manufacturer, producer, packager, importer, supplier, or distributor of a product actually provide (rather than offer to provide) the warnings, the concern about unmarketable products should be addressed by this change. However, the individual businesses in the chain of commerce could address the issue contractually. Under subsection 25600(i) a retail seller may enter into a written agreement with the manufacturer, producer, packager, importer, supplier, or distributor of a product to allocate legal responsibility among themselves for providing a warning. Similarly, the retail seller could specify in its

[13] http://dictionary.cambridge.org/dictionary/english/importer

contracts that it does not wish to sell products that require a warning and will return any that it receives. No change to the regulations was made based on this comment.

60. Comment (AHFA and ACMI): The 180-day renewal in subsection 25600.2(b)(5) (now 25600.2(c)) is unnecessary in the absence of any product changes that would alter the terms of the prior notice. There is no rationale for a frequency of notification of 180 days in the first year (ACMI). If OEHHA retains this requirement, the renewal notice should be annual and tied to the period in which the product is sold into California by the manufacturer (AHFA).

Response: Subsection 25600.2(c) (previously numbered 25600.2(b)(5)) was modified and now requires that notice renewal occurs within six months during the first year after the effective date of the regulation, and then annually thereafter. The requirement is expressly limited to the time in which the product is sold in California by the retail seller. Given that the new regulations may represent a significant change from existing practices between businesses in the chain of commerce, it is reasonable to require a second notice that a warning must be provided within the first year after the new regulations are effective to ensure that the process works smoothly and retail sellers receive all the necessary warning materials in a timely manner.

61. Comment (ACMI): Subparagraph (b)(5) (now subsection (c)(2)) could be interpreted to mean that warnings must identify all chemicals being warned for, recommend that “new chemical name” be revised to “different chemical name”.

Response: Based on this and other comments**,** the phrase “new chemical name…is required to be included” was replaced with “different or additional chemical name is included”.

62. Comment (NMMA): The cost of doing business in California is already high. Placing additional cost burdens on a manufacturer will negatively impact the economic prospects of businesses. Suggest amending subsection 25600.2(b)(3) to remove "at no charge".

Response: Consistent with the language in the statute stating, “In order to minimize the burden on retail sellers of consumer products including foods, regulations implementing Section 25249.6 shall to the extent practicable, place the obligation to provide any warning materials such as labels on the producer or packager rather than on the retail seller . . . .”, the regulations require product manufacturers, producers, packagers, importers, suppliers, or distributors to provide a compliant warning either on the product, or by providing warning materials to the retail seller of the product. This can be accomplished in many ways. Some trade associations, for example, provide

warning materials to retail sellers on behalf of product manufacturers or distributors[14], thus ensuring compliance and lowering the overall cost of providing the warnings. Similarly, under subsection 25600.2(i) (previously subsection 25600.2(h)), a retail seller may enter into a written agreement with the manufacturer, producer, packager, importer, supplier, or distributor of a product to allocate legal responsibility (and, presumably, costs) among themselves for providing a warning. No change to the regulations was made based on this comment.

63. Comment (CGA): Subsection 25600.2(b)(3) is problematic because it allows the manufacturer to dictate the manner in which warning materials are provided regardless of the specific needs of the retailer.

Response: Subsection 25600.2(b)(3) was modified to remove the manufacturer's option to "offer to provide" the materials as part of a written notice. As modified, subsection 25600.2(b)(3) requires a manufacturer producer, packager, importer, supplier, or distributor of a product to meet its obligation by either labeling the product or by providing notice along with necessary warning materials to the retail seller so they are able to pass along the warning to consumers. Under subsection 25600(i) (previously subsection 25600.2(h)) a retail seller may enter into a written agreement with the manufacturer, producer, packager, importer, supplier, or distributor of a product to allocate legal responsibility among themselves for providing a warning, which could include a different manner of providing warning materials that would meet the specific needs of the retailer. Under subsection 25600.2(e), the retailer may also choose not to provide the warnings received from the manufacturer, producer, packager, importer, supplier, or distributor of a product, in which case the retailer is responsible for providing a warning of its own that is in full compliance with Section 25249.6 of the Act.

As explained in the ISOR for these regulations, over the years, many manufacturers and retail sellers have requested that OEHHA provide more clarity concerning the relative responsibility between manufacturers and retail sellers for providing warnings under Section 25249.11(f) of the Act.

Generally two concerns have been raised. First, many stakeholders have stated that the manufacturer, distributor, producer and packager are usually in a much better position than the retail seller to determine whether and for what a warning is required. Therefore, the manufacturer, distributor, producer and packager should have the primary responsibility for identifying products that require a warning. OEHHA agrees with that premise.

[14] See for example warnings for alcoholic beverages and BPA are available free of charge for retail sellers at: http://www.kellydigital.com/q-store/prop65/ This program is managed by the alcohol distributors http://www.beerinstitute.org/policy-issues/proposition-65

Second, some stakeholders have stated that the burden of complying with Proposition 65 and the commensurate burden of defending against enforcement of the law is disproportionately focused on relatively small retail facilities that may be accused of failing to warn even though they have no actual knowledge that a product can cause an exposure that requires a warning. When a business owner receives a 60-day notice of intent to sue, he or she may choose to quickly settle with the person serving the notice to avoid paying potentially greater sums to litigate the matter, even though the violation was not knowing or intentional on the part of the retail seller. OEHHA believes that the regulation strikes a balance between the various businesses by requiring those most likely to know a warning is required (manufacturer, producer, packager, importer, supplier, or distributor) to take primary responsibility for providing the warning, while requiring retail sellers to cooperate by passing through the warnings to their customers. No further changes to the regulations were made based on this comment.

64. Comment (TVC): Requests that the phrase, "has obtained confirmation of receipt of the notice" in subsection 25600.2 (b)(4) be clarified to confirm that the retail seller has no right to reject warning materials or the offer to provide them, and that confirmation of the retail seller's receipt can be established via any means, including return receipt for USPS; proof of delivery by courier service; admission of receipt by retail seller such as by email, regular mail, or other means; affidavit of service.

Response: Subsequent to this comment, subsection (b)(4) was modified to clarify that confirmation of receipt of the notice and warning materials may be obtained electronically or in writing. Although electronic or written confirmation is not as expansive as “via any means”, use of any of these methods will serve as evidence that the retail seller has received the materials and therefore provide sufficient notice. OEHHA declines to adopt the recommended modification prohibiting a retail seller from rejecting warning materials. In the event the retail seller rejects the materials, however, the retail seller would have actual knowledge of chemical exposures that require a warning. The retailer would, therefore, be responsible for selling the products without a warning under Subsection 25600.2(e)(4) (previously subsection (d)(4)) of the regulations unless the retail seller provides a compliant warning prior to exposure.

65. Comment (TVC): Subparagraph (b)(4) should be revised to state that if a manufacturer complies with subsection 25600.2(b), then this is an affirmative defense against any notice of action filed alleging a violation of Proposition 65. Also the regulation should be amended to state that a notice of action against a manufacturer cannot proceed beyond the filing stage against the manufacturer if it produces the confirmation receipt set out in subsection 25600.2(b)(4).

Response: The regulations provide an affirmative defense for each manufacturer, producer, packager, importer, supplier, or distributor that provides a compliant notice

and warning materials and receives confirmation of receipt of those materials unless it has provided its own fully compliant warning.

OEHHA declines to go further by prohibiting enforcement actions against those parties entirely since there may be questions of fact that must be addressed by a court regarding the adequacy of the notice or warning materials provided by the manufacturer, producer, packager, importer, supplier, or distributor, or other issues such as their contractual relationships under subsection (i) (previously subsection (h)) that are beyond the scope of this regulatory action.

66. Comment (Environmental Coalition): The Coalition suggests making the requirement that retailers provide acknowledgement of receipt of the warning materials a separate requirement. This would clarify the retailer's responsibility to provide such acknowledgement.

Response: The commenter may be referring to the language in the now-withdrawn January 2015 version of these regulations which required "acknowledgement" from the retail seller. Subsection 25600.2(b)(4) as modified in the regulations requires electronic or written confirmation of receipt of the notice from the retail seller. This clearly states the responsibility of a retail seller to confirm the receipt of the notice and accompanying warning materials. There is no need for the regulations to separately require retail sellers to provide an acknowledgement that this has occurred. OEHHA declines to make the change requested.

67. Comment (Wine et al.): The practical effect of requiring manufacturers to obtain confirmation of receipt of the notice with renewed confirmation of receipt at least every 180 days is that OEHHA is making it effectively impossible for manufacturers, producers, packagers, importers, and distributors of beverage alcohol products to comply. There are over 83,000 licensees with almost 1,000 new licensees each month and the US Mail services would be cost prohibitive. The proposed subsections 25600.2(b)(4) and (5) (the latter is now subsection (c)) are unnecessary, inappropriate and unduly burdensome upon California businesses with no commensurate purpose and should be stricken. OEHHA should make amendments that would allow a sworn declaration from a manufacturer, producer, packager, importer, or distributor of beverage alcohol products to demonstrate compliance. The California Alcoholic Beverage Control currently does not require email addresses from licensees, so it is wrong to assume that email is automatically an option. Whether the notice is mailed or emailed, it would be reasonable to provide that warning materials may be included or instructions provided on where and how a warning sign may be downloaded from the Internet or ordered free of charge.

Response: The vast majority of warnings that are currently being provided for alcoholic beverages are subject to a consent decree. The parties to that action are expressly excluded from the requirements of these regulations under subsection 25600(e), which state that a person that is a party to a court-ordered settlement or final judgment establishing a warning method or content is deemed to be providing a "clear and reasonable" warning for that exposure for purposes of this article, if the warning complies with the order or judgment.[15] Therefore, these regulations only apply to warnings being provided by manufacturers or distributors who are not part of the agreement. According to the industry, businesses who are not part of the agreement are small wineries and specialty brewers, who presumably have knowledge of the businesses that sell their products. Thus, these wineries and specialty breweries can provide the appropriate warning materials to the retail sellers in the same manner as other California businesses, in either written or electronic form. Further, these businesses may wish to take advantage of the opt-out provisions in subsection(i) and enter into a written agreement to allocate responsibility for providing the notices and warnings differently. OEHHA therefore declines to make the requested changes to the regulations.

68. Comment (AHFA): Under subsections 25600.2(b)(4) and (b)(5) (the latter is now subsection (c)) written proof of receipt in any form should suffice.

Response: OEHHA has determined that written confirmation in electronic or written form is consistent with the purposes of the Act and will help alleviate burdens on the retail seller while incorporating modern technologies and electronic means of communication as an option. OEHHA declines to make the recommended change to expand the options to written proof of receipt in "any form" since that could include methods that are less reliable and harder to prove.

69. Comment (AHPA): In response to the previous version of the regulations released in January 2015 and later withdrawn and replaced in November 2015, AHPA commented that subsection (b) states that a manufacturer, producer, packager, importer or distributor *may* comply, but believes that OEHHA intends to state that compliance is *required* but may be achieved by any of the named entities in any of the enumerated manners. Also concerned that the inclusion of "importers" in the regulation implies that even products imported through California ports that may not cause an

[15] *Bonilla v Anheuser-Busch, LLC et al*. (2014) Los Angeles County Superior Court case # BC537188, see also the joint letter from Wine Institute, Beer Institute, and Distilled Spirits Council of the United States, dated Jan. 25, 2016 that is included as part of this rulemaking record, at p.4

exposure in California, are subject to Proposition 65. Alleges that OEHHA lacks the authority to apply the regulation to product importers.

Response: The commenter correctly noted that subsection 25600.2(b) is a mandatory provision of the regulation. It is located in the mandatory general provisions of Subarticle 1. The term "may", however, in this provision is intended to connote that there are alternatives for compliance, namely, affixing a label to the product or providing a written notice and warning materials to the authorized agent for the retail seller.

The commenter's statement that including "importers" in the list of businesses covered by the regulations is beyond the scope of OEHHA's authority is incorrect. These regulations do not determine when a warning is required or who is subject to the warning requirement. Proposition 65 applies to all businesses with 10 or more employees who cause exposures to listed chemicals in California.[16] The regulations simply apply to businesses that import products into the state to the extent the law applies to them. Therefore, OEHHA declines to remove the references to importers.

70. Comment (AHPA): In response to the earlier version of the regulations, released in January 2015 and later withdrawn and replaced in November 2015, commented that, because there is no connection between parties in the supply chain before the retailer, it will frequently be impossible to obtain written acknowledgment from the retailer even once. Requiring a retailer to renew acknowledgment every 180 days or more than once every few years is onerous as manufacturers, producers, distributors, etc., have hundreds and thousands of customers.

Response: It is true that in some circumstances a manufacturer or other business in the chain of commerce does not have actual knowledge concerning who the ultimate retail seller of its product may be and therefore may not be able to provide a notice to all the retail sellers of its products. Given that Proposition 65 applies to all businesses in the chain of commerce, including the manufacturer, producer, packager, importer, supplier, or distributor of a product, the regulations provide that each party may provide notice to its direct customer that a warning is required, provide the necessary warning materials, and contractually require that these materials be passed along to the next business in the chain of commerce. Subsection (i) (previously 25600.2(h)) of the regulation states that:

> "Provided that the consumer receives a warning that meets the requirements of Section 25249.6 of the Act prior to exposure, the manufacturer, producer, packager, importer, supplier, or distributor of a product that may cause a consumer product exposure may enter into a written agreement with the retail seller of the product to allocate legal responsibility among themselves for

[16] Health and Safety Code sections 25249.6, 25249.10(c) and 25249.11 (a) and (b)

providing a warning for the product, which shall bind the parties to that agreement and which shall supersede the requirements of subsections (b), (c), (d), and (e)."

This subsection allows for such an allocation of responsibility along the supply chain.

71. Comment (NMMA): Subparagraph (b)(5) (now subsection (c)) should be amended to reflect actual retailer-supplier relationships by eliminating the 180-day requirement. Suggest that the manufacturer be required to include in the product packaging sent to the retailer clear instructions that outline warning requirements pursuant to Section 25249.6 of the Act. An additional notice would be required immediately if a new chemical name or endpoint is required to be included in the warning.

Response: Subsection 25600.2(c) (previously subsection 25600.2(b)(5)) was modified and now requires that notice renewal occurs within six months during the first year after the effective date of the regulation, and then annually thereafter. The requirement is expressly limited to the time in which the product is sold in California by the retail seller. Given that the new regulations may represent a significant change from existing practices between businesses in the chain of commerce, it is reasonable to require a second notice that a warning must be provided within the first year after the new regulations are effective to ensure that the process works smoothly and retail sellers receive all the necessary warning materials in a timely manner.

No change to the regulations was made based on this comment.

72. Comment (CCBA): Concerned about compliance costs for small businesses to provide the required Notice and warning materials. The only reliable compliance strategy is the US Postal Service certified return-receipt mail which would cause significant economic impact. Request subparagraph (b)(5) strikeout "and receipt confirmed by the retail seller".

Response: Subsequent to this comment, subsection (b)(4) was modified to clarify that confirmation of receipt of the notice and warning materials may be obtained electronically or in writing at the option of the sender. The confirmation will serve as evidence that the retail seller has received the materials. The notice renewal in subsection 25600.2(c) (previously subsection (b)(5)) is required within 180 days after the effective date of the regulation, and then annually thereafter. Given that the new regulations may represent a significant change from existing practices between businesses in the chain of commerce, it is reasonable to require a second notice that a warning must be provided within the first year after the new regulations are adopted to ensure that the process works smoothly and retail sellers receive all the necessary warning materials in a timely manner. Further, the manufacturers and retail sellers can opt-out of this requirement under subsection (i) (previously subsection (h)) through a

written agreement so long as a compliant warning is in fact provided to the consumer. Therefore, OEHHA declines to make the change requested by commenter.

73. Comment (Environmental Coalition): Supports a requirement to send an additional notice and warning materials if a new chemical or endpoint is required to be included.

Response: Comment noted, no response required.

74. Comment (ITW): At the public hearing, ITW commented that when it comes to choosing the chemicals to name in the warning, to the extent a manufacturer changes a chemical, OEHHA should clarify the elements that would be required or justified for the change such that the spirit and letter of the law and intent of compliance is maintained by the manufacturer.

Response: Subsection 25602(c)(2) (previously subsection (b)(5)) of the regulations requires the product manufacturer to notify the retail seller within 90 days when the content of a warning needs to be changed to include a different or additional chemical or endpoint. This ensures that the manufacturer keeps the retail seller up to date concerning the content of a warning being provided for a given product. These regulations do not determine when a warning is required. To the extent the commenter is requesting guidance concerning that decision, the comment is beyond the scope of the rulemaking. Existing regulations in Title 27, Cal Code of Reg., sections 26701 and 25801 et seq. provide guidance concerning whether a warning is required for a given chemical exposure. No change to the regulations was made based on this comment.

75. Comment (ITW): In the case of foreign importers, ITW requests clarification regarding the duty to provide warnings between importers and other businesses in the chain of commerce. Also request guidance on who is responsible for maintaining administrative records of providing warnings.

Response: This comment is actually a question about the scope of the law. Foreign companies are subject to the Act to the extent they do business in California. All businesses with 10 or more employees who cause exposures to listed chemicals in California are covered by the Act. To the extent that a foreign supplier has no agent for service of process in California, enforcement actions will likely be taken against the importer or distributor of the product. There are no requirements in the regulations regarding maintenance of records related to the provision of warnings.

Subsection 25600.2(c) (now 25600.2(d))

Responsibility for placement and maintenance of warning materials

76. Comment (CGA): Subsection (c) absolves product manufacturers of all legal responsibility and places it on retail sellers, which is in conflict with HSC section 25249.11(f).

Response: OEHHA disagrees with the commenter. Subsection (c) (now subsection (d)) provides as follows:

> "(d) The retail seller is responsible for the placement and maintenance of warning materials, including warnings for products sold over the Internet, that the retail seller receives pursuant to subsections (b) and (c)."

Nothing in this subsection absolves manufacturers of the responsibility to provide a warning. In fact, subsection 25600.2(b) *requires* a manufacturer, producer, packager, importer, supplier, or distributor of a product to provide a warning either on the product, or by providing a notice and warning materials to the retail seller of the product. The retail seller is simply required to pass through the warning to the consumer. This ensures that the business most likely to know a warning is needed adequately communicates the necessary information to the retail seller of the product if that business does not directly label the product. As noted in responses to earlier comments, OEHHA is attempting to bring more certainty to the relationship between manufacturers and retail sellers while still ensuring that warnings are being provided to consumers for exposures to listed chemicals.

77. Comment (CCBA and TVC): Support subsection (c) that makes it the affirmative responsibility of the retailer to place and maintain warning materials that it receives.

Response: Comment noted, no response required.

78. Comment (AHPA): In response to the previous version of the regulations released in January 2015 and later withdrawn and replaced in November 2015, commented that, where a retailer has decided to use languages in addition to that provided for by the manufacturer, producer, etc., the retailer should bear responsibility to provide the warning in other languages.

Response: OEHHA agrees that where a product manufacturer or other business in the chain of commerce is not aware that a retail seller provides consumer information in other languages, the retail seller should be responsible for providing the warnings in those languages to the extent they are required. To the extent resources are available to do so, OEHHA also plans to provide compliant Proposition 65 warnings in multiple languages on its website for use by businesses, including retail sellers of consumer products.

Subsection 25600.2(d) (now 25600.2(e))

Specific circumstances for retail seller responsibility

79. Comment (CGA): Subsection (d) creates a new obligation for retailers particularly if a product is manufactured by a company with fewer than 10 employees or is an overseas manufacturer. It is inappropriate to punish retailers by forcing them to take on burdens that should appropriately be borne by manufacturers.

Response: The regulations cannot extend the scope of Proposition 65, which is limited by its terms to businesses that have 10 or more employees. As is currently the case, if a retail seller purchases a product from a manufacturer who has fewer than 10 employees, or from a foreign manufacturer, the retailer would remain responsible for providing warnings for exposures to listed chemicals from those products. Thus, the regulations does not create a new obligation. OEHHA encourages all businesses to work together to ensure compliance with the Act.

80. Comment (AHPA): In response to the previous version of the regulations released in January 2015 and later withdrawn and replaced in November 2015, AHPA commented that OEHHA assumes incorrectly that these regulations will not impact small businesses because Proposition 65 exempts businesses with less than 10 employees. In practical terms plaintiffs' attorneys circumvent the exception by naming the wholesaler and retailer as parties to the suit in addition to the manufacturer, producer or packager. The proposed regulations do not address situations where there are parties in the supply chain other than the retailer with less than 10 employees.

Response: This comment is beyond the scope of the regulations. OEHHA cannot change the fact that, as expressly written in the law, Proposition 65 does not apply to businesses with fewer than 10 employees and that all entities in the chain of distribution are potentially liable under Proposition 65.

81. Comment (CGA): If OEHHA moves forward with the proposal to allow manufacturers to shift the burden to retailers, the regulations should include: (1) A requirement that the manufacturer provide retailers with 30 days' notice that it intends to provide information regarding a required Proposition 65 warning for a given product; (2) A provision shielding retailers from liability while they await receipt of any requested warning materials offered by a manufacturer; (3) A provision allowing retail entities at least 30 days to make any adjustments to display areas, shelf tag configurations, product displays, etc.… to accommodate warnings once received from a manufacturer; (4) A provision allowing retail entities to sell through existing product when on-package warnings are employed and (5) A provision allowing retail entities a 14-day opportunity to cure any violations associated with maintenance of required warnings once received from the manufacturer and installed at the retail setting.

Response: In response to these and other comments, OEHHA modified the regulations to eliminate the provision allowing the manufacturer or other business in the chain of commerce to simply offer to provide warning materials. These businesses will be required to provide the warning materials along with the notice. The regulations were further modified to allow five days for retail sellers to provide warnings under specified circumstances where a compliant warning is not provided (subsection 25600.2(f), previously 25600.2(e)). OEHHA believes it would be inconsistent with the purposes of the statute to provide 30 days for the retail sellers to "adjust" to the requirement for a warning. Further, the regulations already provide a sell-through period by providing that products manufactured up to two years of the regulation's adoption may use warnings that are deemed to be clear and reasonable under the existing (2008) regulations.

The request for a 14-day opportunity to cure is outside the scope of this rulemaking, which concerns the format and content of warnings, and the relative responsibilities of manufacturers and retailers in providing warnings. The issue of a retailer's liability for missing warning signs is not covered in this rulemaking.

No further changes to the regulations were made based on these comments.

82. Comment (CGA): In subsection (d) (now subsection (e)), CGA suggests OEHHA revise the proposal to address "inappropriate violations" of the statute and "other deficiencies". The proposal could include provisions that allow the shift of "the actual and legal burden of warning to the retailer only if the retailer consents in writing to posting and maintenance of required warnings, and the format of the warning (shelf tag, on package, signage, etc.…)".

Response: As discussed in response to similar comments, the regulations are intended to bring clarity to an issue that has been the subject of some confusion for many years. OEHHA proposed this part of the regulations based on primary concerns which are described in the ISOR for the regulations as follows:

> "First, many stakeholders have stated that the manufacturer, distributor, producer and packager are usually in a much better position than the retail seller to determine whether and for what a warning is required. Therefore, the manufacturer, distributor, producer and packager should have the primary responsibility for identifying products that require a warning. OEHHA agrees with that premise.
>
> Second, some stakeholders have stated that the burden of complying with Proposition 65 and the commensurate burden of defending against enforcement of the law is disproportionately focused on relatively small retail facilities that may be accused of failing to warn even though they have no actual knowledge that a

product can cause an exposure that requires a warning. When a retail seller receives a 60-day notice of intent to sue, he or she may choose to quickly settle with the person serving the notice to avoid paying potentially greater sums to litigate the matter, even though the violation was not knowing or intentional on the part of the retail seller."

OEHHA believes that the regulations strike a balance between the various businesses by requiring those most likely to know a warning is required (manufacturer, producer, packager, importer, supplier, or distributor) to take primary responsibility for providing the warning, while requiring retailers to cooperate by passing through the warnings to their customers. Allowing a retailer to absolve itself of all responsibility for a warning simply by withholding its consent would be inconsistent with the Act, which seeks to minimize but not eliminate this responsibility for retailers.

OEHHA believes that clarifying the relative responsibilities of the various businesses in the stream of commerce will further the purposes of the statute by making it easier for each business to comply with the law by following a prescribed process, while allowing the various parties to opt-out of the process through a written agreement with other businesses in the distribution chain where they choose to do so as long as a clear and reasonable warning is provided.

OEHHA believes the regulations address the need for clarity regarding the relative responsibility for providing warnings for exposures to listed chemicals in consumer products. To the extent that a retailer wishes to opt-out of the provision, it can do so by written agreement with the product manufacturer, producer, packager, importer, supplier, or distributor.

No changes to the regulations were made based on this comment.

83. Comment (Environmental Coalition): The Coalition opposes subsections 25600.2(d)-(e). In creating a new exception to the statute's warning requirement, the regulations exceed OEHHA's statutory authority. The language rewards passivity: it allows a retailer to sit back and wait for a notice letter before providing a warning, even if it has "actual knowledge" that it is selling a product that is causing an exposure to a listed chemical. Such a broad exception does not comport with the purpose of Proposition 65, which is to ensure that someone in the distribution chain provides warnings for exposures to listed chemicals. Suggest subsections (d) and (e) be removed.

Response: Under subsection (e)(5) the retail seller has the duty to provide a warning if it has actual knowledge of the potential exposure (discussed in detail below) and either of the following two circumstances is present: (A) There is no product manufacturer, producer, packager, importer or distributor of the product that is subject to Section

25249.6 of the Act. This will most often occur when the manufacturer, producer, packager, importer or distributor has fewer than 10 employees. (B) Where the manufacturer, producer, packager, importer or distributor are foreign persons with no agent for service of process in the United States. Such foreign persons will usually have an obligation under the Act to provide a warning, but enforcing this obligation may be impractical because it would require the enforcing party to proceed in a foreign jurisdiction, for example, under the Hague Convention. Thus, the retail seller must provide the required warning in this situation.

The intent of subsections (e)(5)(A) and (B) is to require the retail seller to provide a warning when it has actual knowledge of the exposure and the manufacturer, producer, packager, importer or distributor cannot readily be compelled to provide it. This will ensure that the consumer will receive a warning as required by the Act. For example, if the product requiring a warning is produced and packaged by a foreign company with no agent for service of process in the United States, and it is distributed by an importer with fewer than ten employees, then it will be the responsibility of the retail seller to provide the warning.

There may be situations when the retail seller is unsure whether the manufacturer, producer, packager, importer and/or distributor are subject to the Act or are foreign corporations without agents for service of process in the United States. However, the retail seller will have a duty to inquire into these facts whenever the retail seller (1) has actual knowledge of the potential product exposure requiring the warning, and (2) has not received a notice from the manufacturer, producer, packager, importer or distributor pursuant to subsection (b).

Subsection (f) defines “actual knowledge” of the exposure to include knowledge from “any reliable source”. For example, a retail seller may acquire knowledge of an exposure that requires a warning through news media, its customers or a trade association. However, if the retail seller’s only source of this knowledge is a 60-day notice that is served on the retail seller pursuant to Section 25249.7(d)(1) of the Act, then subsection (f) provides:

> “The retail seller shall not be deemed to have actual knowledge of any product exposure that is alleged in the notice until five business days after the retail seller receives the notice.”

This provision focuses on those retail sellers who have no actual knowledge of a potential exposure prior to receiving a 60-day notice, and it provides them with a five business-day period after receipt of the notice in which to either post a warning or pull the product to avoid causing a knowing and intentional exposure. The five business-day period was selected as it is similar to policies for recalls by the federal Food and

Drug Administration and Consumer Product Safety Commission. A retail seller whose only source of actual knowledge is from the 60-day notice, and who either provides the necessary warning or stops selling the product within the five business-day time period, is deemed to have complied with the Act.

For purposes of litigation to enforce the requirements of Proposition 65, when a product is sold without a warning, the enforcing party should generally proceed against the manufacturer, producer, packager, importer and/or distributor. An enforcement action against the retail seller will be appropriate only when one or more of the circumstances in subsection (e) exist.

Thus, the regulations appropriately allocate the burden of providing the warning as between the various businesses in the chain of commerce. Retailers are not absolved of all liability for providing warnings.

For further elaboration please see response to the previous comment.

No further changes to the regulations were made based on this comment.

84. Comment (AHPA): In response to the previous version of the regulations released in January 2015 and later withdrawn and replaced in November 2015, AHPA commented that, even if an agent for service of process exists, it will be difficult or impossible to force foreign entities to comply with Proposition 65.

Response: This comment is beyond the scope of the regulations to the extent that it requests OEHHA to adopt a regulation that would require foreign companies to comply with the law. These companies are already subject to the Act to the extent they do business in California. All businesses with 10 or more employees who cause exposures to listed chemicals in California are covered by the Act. While OEHHA is sympathetic to the fact that it may not always be feasible to hold foreign companies accountable for violations of the law, it cannot change the fact that domestic businesses are still required to comply with the law.

85. Comment (RMA): RMA supports OEHHA's provisions that make retailers responsible for placement and maintenance of warning materials, but has continued concern about labeling requirements for products, like tires, where only a small number of actual tires available for sale in the store are on display. Recommend that labeling requirements for retailers only apply to products that come into contact with consumers.

Response: Comment noted. OEHHA encourages the commenters to work with their retail sellers concerning the placement of any required warnings. It may be appropriate to simply post signs in the sales area rather than attempt to directly label products in certain situations. The regulations allow for such an approach. To the extent it is

needed, OEHHA will consider developing a specific tailored warning regulation for these types of products if requested.

86. Comment (CHANGE): At the public hearing, CHANGE expressed general concerns that OEHHA should ensure that retailers do their part to comply with Proposition 65 warning requirements.

Response: Comment noted. Retail sellers continue to retain obligations for providing warnings for exposures to listed chemicals under the regulations. As discussed in response to similar comments, the regulations are intended to set forth the allocation of responsibilities amongst the entities in the distribution chain. OEHHA is aware that retail sellers are critical players in the process for providing consumer product warnings.

Subsection 25600.2(e) (now 25600.2(f))

Actual knowledge of consumer product exposure

87. Comment (AHPA): In response to the previous version of the regulations released in January 2015 and withdrawn and replaced in November 2015, AHPA commented that "actual knowledge" should require detailed information to support the allegation, including the number of samples tested, and the dates, times, and locations from which samples were obtained. Also AHPA stated that two business days is too short a timeframe to conduct investigations to determine accuracy and validity of allegations in notice. They requested that the time to cure be extended until test results are obtained to verify that a warning is actually required.

Response: The regulatory provision at issue applies to the retail seller's "actual knowledge" that a warning is required for a given product. It sets out several ways in which a retail seller could obtain such knowledge in addition to being advised by the product manufacturer that a warning must be given. The regulations state that "actual knowledge" means specific knowledge of the consumer product exposure received by the retail seller from any reliable source. If the source of this knowledge is a notice served pursuant to Section 25249.7 (d)(1) of the Act, the retail seller shall not be deemed to have actual knowledge of any consumer product exposure that is alleged in the notice until five business days after the retail seller receives a notice that provides a description of the product with sufficient specificity for the retail seller to readily identify the product in accordance with Article 9, section 25903(b)(2)(D). In response to comments from various parties that two business days after receiving a notice was not adequate time to identify products and take appropriate follow-up actions, OEHHA modified the provision to allow for five business days for these steps to occur.

There is no requirement in law or statute that a retail seller must independently test products to determine whether or not a warning is required. To the contrary, in most

circumstances, the manufacturer, producer, packager, importer, supplier, or distributor of the product is in a much better position to know whether a warning is required for a particular product than the product retail seller. Therefore, the regulations put primary responsibility on these parties to provide notice to the retail seller that a warning must be provided. Where that does not occur, the retail seller only has the responsibility for providing a warning where it has "actual knowledge," as defined, that a warning is required. Even then, the retail seller is given up to five days to provide a compliant warning. This should allow sufficient time for the retail seller to contact its supplier to determine how to proceed and obtain warning materials as necessary. Delaying the warning requirement long enough for a retail seller to determine through product testing whether or not a warning is required would not further the purposes of the statute and would place an unnecessary and costly burden on the retail seller. OEHHA declines to make the changes requested by the commenter.

88. Comment (CalChamber): The two business day time frame for taking action in response to a notice as stated in subsection (e) is unworkable for most retailers. OEHHA justified limiting the actual knowledge requirement to two business days because it is claimed to be consistent with policies for recalls by the Food and Drug Administration and Consumer Product Safety Commission; however, it is not consistent. Other federal agencies either require immediate reporting but allow a company to investigate and determine that there is an issue before being obligated to report, or they require action only upon the company's determination that there is some issue that requires action. The absolute minimum time frame for a retailer to take corrective action in response to a pre-suit notice should be 10 business days. OEHHA should clarify in the FSOR that a pre-suit notice to a retailer does not provide actual knowledge of an exposure for any consumer product not specifically identified by the manufacturer and model number or other product identifying information. OEHHA may also wish to consider additional amendments to other sections of the regulations, i.e., Section 25903.

Response: Based on this comment and others, OEHHA modified the period when a retailer is deemed to have actual knowledge to five business days after receipt of a 60-day notice. This should be sufficient time for a retail seller to contact a manufacturer to determine whether a warning is required, provide its own warning, or pull the product from the shelves to avoid liability. OEHHA agrees that actual knowledge based on a Notice of Violation would only extend to those products identified in the Notice. OEHHA added language to the regulation specifying that the notice must describe the product with sufficient specificity for the retail seller to readily identify the product, in the same manner required in Article 9, section 25903(b)(2)(D) for Notices of Violation. No further changes were made to the regulations based on this comment.

Subsection 25600.2(f) (now 25600.2(g))

Name and contact information for Retail Seller

89. Comment (ACMI): The commenter mistakenly referred to subsection (e) instead of subsection (f) of the regulation (that subsection is now numbered subsection 25600.2(g)). The regulations require a retailer to provide the identity of its suppliers upon request by a public enforcer or a private enforcer who has served a 60-day notice and argue that it is critical that the information provided be protectable as trade secret/confidential business information. Request that the regulations include a subsection stating, "Nothing herein shall limit any party from asserting its rights to protect the requested information from disclosure to third parties under applicable laws, including the California Public Records Act."

Response: The requested addition to the regulations would not provide businesses with any ability to protect sensitive information beyond what current law already provides. To the extent that existing law protects the retail seller from disclosure of supplier information, the retail seller can claim that protection. To the extent that information obtained by law enforcement, including the Attorney General's Office, is requested under the Public Records Act, existing law provides for non-disclosure of certain enforcement-related information. No change to the regulations was made based on this comment.

90. Comment (Environmental Coalition): Oppose subsection (f) (now subsection (g)) because it is only necessary if OEHHA adopts subsections (d) and (e), which the Coalition opposes.

Response: OEHHA determined that subsections (d), (e) and (f) were needed for the reasons discussed above in response to other comments and previously explained in the ISOR.

Subsection (f) (now subsection (g)) is necessary because the retail seller may have important information regarding the identity of the manufacturer, producer, packager, importer and/or distributor who have the duty to warn under subsection (a), and it may be impossible for prosecutors to enforce the Act without obtaining this information. Subsection (f) therefore requires the retail seller to provide the name and contact information for such entities, upon written request to the Lead Agency, Attorney General, a District Attorney, a City Attorney who has authority to proceed under Proposition 65, and to a person who has served a 60-day notice under Section 25249.7(d)(1) of the Act.

OEHHA declines to delete these provisions because they are necessary to the overall function of the regulations and further the purposes of the Act by ensuring there is an entity that is responsible for providing a warning in all circumstances.

91. Comment (Environmental Coalition): In subsection (f) (now subsection (g)), any interested person should be able to request manufacturer information from retailers. That information is in the public interest and should be available to any interested party. There also needs to be an enforcement mechanism otherwise there is no remedy for a person requesting this information if the retailer refuses to comply with the request. Additionally, suggests that OEHHA insert language making it clear that the manufacturer information covered by this subsection is not a trade secret.

Response: The ability to request information in subsection (f) (now subsection (g)) is reasonably limited to public entities with authority to enforce Proposition 65, and those private individuals who have served a 60-day Notice of Violation. This will limit the volume of requests to the retailers for information about product manufacturers to those entities most likely to take an enforcement action. It is beyond the scope of this rulemaking to require retailers to provide information on their suppliers to anyone for any purpose, particularly for purposes that are not related to Proposition 65. Abrogating all applicable trade secret laws through this regulatory process is also beyond the scope of the rulemaking.

Subsection 25600.2(h) (now 25600.2(i))

Written or contractual agreement between parties

92. Comment (AHFA): In response to the previous version of the regulations released in January 2015 and withdrawn and replaced in November 2015, AHFA commented that any burden sharing agreed to between a manufacturer and retailer should be effective so long as the warning to be provided to the purchaser under the parties' agreement meets the requirements of the Act. As currently drafted, the burden sharing agreement would only be effective if the retailer in fact provided the Proposition 65 compliant warning; the retailer could unilaterally nullify an otherwise valid contract by simply failing to perform. This would unnecessarily interfere with the parties' freedom of contract, and can be avoided by inserting the phrase "to be" into the last clause of subsection (f) [renumbered as subsection (i) in the November 2015 version of the regulation] as follows: "to the extent that the warning to be provided to the purchaser of the product meets the requirements of Section 25249.6 of the Act." The regulations should recognize valid, oral agreements also.

Response: In response to this and other comments, the regulations were modified to read:

> **"**Provided that the consumer receives a warning that meets the requirements of Section 25249.6 of the Act prior to exposure, the manufacturer, producer, packager, importer, supplier, or distributor of a product that may cause a consumer product exposure may enter into a written agreement with the retail seller of the product to allocate legal responsibility among themselves for providing a warning for the product, which shall bind the parties to that agreement and which shall supersede the requirements of subsections (b), (c), (d), and (e)."

After considering this comment, OEHHA decided to retain the condition that the "consumer receives a warning that meets the requirements of Section 25249.6 of the Act prior to exposure" because this is a mandatory requirement under Proposition 65. In all cases, an adequate warning must be provided. The regulations do not exempt a party from its duty to provide a warning, where a private contract does not result in an adequate warning being provided to the exposed individual. Where a party to a contract fails to comply with the terms of the contract, that party would be responsible for the failure to warn. OEHHA also declines to allow oral agreements to be binding in this situation. A written agreement would likely be the best evidence that the parties had agreed in advance to opt-out of the provisions of the regulation.

93. Comment (ARC-UCP): Distributors should be required to annually notify retailers of warning requirements and to offer retailers, at no cost, signs that retailers can use to meet the requirements. Alcoholic beverage warnings should not be subject to the provisions of the proposed Section 25600.2 that allow agreements to shift responsibility from retailers to distributors. Almost every alcohol retailer has many distributors. Allowing them to shift responsibility to some or all of their distributors would put an enormous burden on concerned citizens who want to complain about noncompliance.

Response: The regulations already require annual notification to retail sellers, the provision of warning materials at no charge, and the posting by retailers of warnings for alcoholic beverages. For the reasons stated previously, OEHHA believes the primary burden of providing warnings should rest on the product manufacturer. However, most warnings for alcoholic beverages are provided through a third party set up by the beverage distributors under a consent decree. This process is not affected by the regulation pursuant to subsection 25600.2(e) or (i). No changes were made based on this comment.

Section 25601 Safe Harbor Clear and Reasonable Warnings - Methods and Content

Subsection 25601(a)

General Provisions

94. Comment (CRN): OEHHA again fails to provide necessary guidance to businesses as to what is considered a “clear and reasonable warning” for the purposes of compliance with Proposition 65.

Response: The safe harbor methods and content in Article 6 provide guidance on how to provide a warning that is consistent with the lead agency’s interpretation of a “clear and reasonable” warning under the Act. A business may provide its own warnings that are otherwise compliant with the Act and may use the safe harbor regulations as guidance in developing its own warnings. OEHHA has determined that providing a separate definition of “clear and reasonable” for a warning that does not use the methods and content described in Subarticle 2 would compete with the safe harbor warning methods and content. In the event a particular industry feels a specific tailored warning method or content should be adopted into the regulations for a particular type of exposure or product, OEHHA will consider such a request (see Article 1, subsection 25600(c)).

95. Comment (AHFA): The definition for "clear and reasonable" was not carried over into the proposed rulemaking. Subsection 25601(b) expressly permits any clear and reasonable warning, other than the safe harbor warning, that complies with the statute. However, the statute does not define "clear and reasonable". Subsection 25601(a) would define a clear and reasonable warning under the statute to mean "the warning complies with all applicable requirements of this article [the Proposed Rulemaking]." This results in a circular definition which could imply that the only clear and reasonable warning is the safe harbor warning. Request clarification and that OEHHA maintain the existing regulatory definition of a clear and reasonable warning.

Response: OEHHA disagrees with the comment that the regulations imply a safe harbor is the only “clear and reasonable” warning. To further clarify, the previous subsection 25601(b) has been moved from Subarticle 2 on safe harbors into the general guidance in Subarticle 1, subsection 25600(f) - that expressly states:

> “Nothing in Subarticle 2 shall be construed to preclude a person from providing a warning using content or methods other than those specified in Subarticle 2 that nevertheless complies with Section 25249.6 of the Act.”

Subsection 25601(a) simply states that the safe harbor warnings set out in Subarticle 2 are deemed to be “clear and reasonable” for purposes of the Act. A business that provides a warning that uses a method or content for the warning that is different from the safe harbor methods and content of Subarticle 2 may have to defend its warning as “clear and reasonable”. Using the warning methods and content set out in Subarticle 2 provides a defense against enforcement actions for failure to provide a clear and reasonable warning.

Subsection 25601(b) (now 25600(f))

Alternative non-safe harbor warnings

96. Comment (CalChamber and CCEEB): “Clear and reasonable” continues to be used in the regulatory proposal without any interpretive guidance. Current regulatory language explaining what it means for a warning to be "clear and reasonable" was not retained. If the proposed regulations are intended only to form a new safe harbor and continue to permit businesses to provide alternative warnings then restore the existing regulatory explanation of what "clear and reasonable" means.

Response: The safe harbor methods and content in Article 6 provide guidance on how to provide a warning that is consistent with the lead agency’s interpretation of a “clear and reasonable” warning under the Act. A business may provide its own warnings that are otherwise compliant with the Act, as subsection 25600(f) (May 20, 2016 modification) makes clear, and in doing so may use the safe harbor regulations as guidance in developing their own warnings. OEHHA has determined that providing a separate general definition of “clear and reasonable” for a warning that does not use the methods and content described in Subarticle 2 would compete with the use of the safe harbor warning methods and content. OEHHA does not see a reason to provide options for what it deems to be clear and reasonable warnings in Subarticle 2 while simultaneously offering separate, unrelated guidance. In the event a particular industry feels a specific warning method or content should be adopted into the regulations for a particular type of exposure or product, OEHHA will consider such a request (see Subarticle 1, subsection 25600(c)).

Subsection 25601(c) (now 25601(b))

Requirements for all safe harbor warnings

97. Comment (Auto Alliance et al.): The law ‘requires’ warnings if exposures are above the warning level for the chemical and the law 'permits' warnings if exposures, if any, are below the warning level for the chemical. OEHHA should clarify that they do not expect those covered by the regulations to undertake an exposure assessment.

Response: Nothing in the regulations requires a business to conduct an exposure assessment to determine the exact level of exposure to listed chemicals from a given product. As stated in Subarticle 1, subsection 25600(a) states that "nothing in Article 6 or Subarticles 1 and 2 shall be interpreted to determine whether a warning is required for a given exposure under Section 25249.6 of the Act." As stated in the ISOR for these regulations, "Subsection (a) describes the general applicability of Subarticle 1 throughout Article 6 and briefly describes the contents of Subarticles 1 and 2. This subsection also explains that the proposed regulations do not address the determination by a business whether a warning is required under the Act. This determination is addressed by other provisions of the law and regulations. The proposed regulations only become relevant after a business determines that the exposure to a listed chemical knowingly and intentionally caused by the business requires a warning." Other sections of the regulations (Articles 7 and 8) provide guidance concerning which exposures require a warning under the Act. No changes to the regulations were made based on this comment.

98. Comment (ACA, ACC, CalChamber, CRN, NPA, AHAM, CAPA, CHPA, and NMMA): Proposition 65 only requires defendants to prove that no warning is required; it has never been interpreted to require defendants to justify a decision to warn. This subsection shifts the burden on businesses to demonstrate that a warning is required. In subsection (c) (now subsection (b)), remove "to the extent that an exposure to that chemical or chemicals is at a level that requires a warning." The phrase suggests that there must be an actual exposure to the chemical selected for the warning, and that exposure must be at a level not exempt from the warning under HSC section 25249.10. Recommend using language such as "chemicals…for which the warning is being provided" for a way to refer to chemicals being specified for warning.

Response: Based on this and other comments, the language in subsection 25601(b) was amended to state: "(b) Except as provided in Section 25603(c), a warning meets the requirements of this article if the name of one or more of the listed chemicals in the consumer product or affected area *for which the warning is being provided* is included in the text of the warning. Where a warning is being provided for more than one endpoint (cancer and reproductive toxicity) the warning must include the name of one or more chemicals for each endpoint, unless the named chemical is listed as known to cause both cancer and reproductive toxicity and has been so identified in the warning."(Emphasis added) This change should address concerns that this provision required companies to affirmatively determine a warning is required for a given exposure. However, by making this change, OEHHA does not intend to encourage businesses to provide a warning where none is required. Other regulations adopted by OEHHA in Articles 7 and 8 can assist businesses in determining whether or not a warning is required for a given exposure.

99. Comment (Environmental Coalition): The Coalition suggests amending the subsection to discourage including a laundry list of chemicals for which there is no evidence that a warning is required. Such a warning would not be clear and reasonable. Additionally, this section removes the language in the currently enacted Section 25601 that requires any warning to "be reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure." It is critical to retain language which would require that any warning, no matter the method used, be reasonably calculated to be read and understood.

Response: The regulation was modified in response to this and other comments. The regulation currently requires the name of one or more chemicals for which the warning is being provided. OEHHA believes it is unlikely that a business will provide a "laundry list" of chemical names in the warning. In the event this occurs as the regulations are implemented, OEHHA will consider additional changes to the regulations.

In regard to the request to retain the language, "be reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure," OEHHA believes that the additional specificity provided in the new regulations renders this provision unnecessary. OEHHA has defined in some detail the method or methods most likely to make the warning message available to the individual prior to exposure in the safe harbor regulations. If a business is challenged for using a non-safe harbor method for providing a warning, it would have to defend the use of that method as "clear and reasonable" under the circumstances.

Naming chemicals for which warning is being provided

100. Comment (CHPA): The proposal for specifying the name of the chemical may result in consumer confusion when the potential exposure involves both a listed carcinogen and a reproductive toxicant.

Response: Based on this and other comments, the language in subsection 25601(b) was amended to state: "(b) Except as provided in Section 25603(c), a warning meets the requirements of this article if the name of one or more of the listed chemicals in the consumer product or affected area for which the warning is being provided is included in the text of the warning. *Where a warning is being provided for more than one endpoint (cancer and reproductive toxicity) the warning must include the name of one or more chemicals for each endpoint, unless the named chemical is listed as known to cause both cancer and reproductive toxicity and has been so identified in the warning*."(Emphasis added) The italicized provision was added to clarify when a warning must name more than one chemical.

101. Comment (CHPA): Simplify the safe harbor language throughout the proposal by following what was previously embodied in several consent judgments reviewed by the Attorney General and approved by state courts: "This product contains chemicals, including [name of one or more chemicals], known to the State of California to cause cancer and/or birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/product."

Response: Under subsection 25600(f), a party to a court ordered settlement or final judgment can continue to use the warning methods and content required under that settlement or judgment and that warning will be deemed to "clear and reasonable" for purposes of this Article. Many of the existing settlements and judgments use warning content that is based at least in part on the existing regulations. As the lead agency statutorily tasked with interpreting the Act and implementing regulations to carry out the purposes of the Act, OEHHA has determined that the existing regulations require updating to improve the effectiveness of warnings provided to a person prior to being exposed to a listed chemical. Most existing court approved language is not in alignment with the proposed warning methods and content and it would be contrary to OEHHA's expressed intent in repealing and replacing Article 6.

The example given by the commenter uses the term "contains". As noted in the ISOR for this rulemaking, in the 25 years since the existing regulations were adopted, it has become evident that the word "contains" in a warning does not communicate the fact that individuals can actually be exposed to a chemical if they use a given product or enter an affected area. The statute clearly states that warnings are required for *knowing and intentional exposures* to listed chemicals. Warnings are not required where a product simply "contains" a listed chemical but may not actually have the potential to cause an exposure. Using the word "contains" in the warning is confusing for both businesses and the individuals receiving the warning. For example, under the existing regulation it is not clear to many businesses that a warning is not required for a chemical that is contained in a product in such a way that it cannot foreseeably cause an exposure (e.g. where the chemical is bound in a matrix or sealed inside the product but is inaccessible to the average user of the product). On the other hand, individuals who see a warning for the content of a product often will not know if they actually can be exposed to a listed chemical and might not take such a warning as seriously. OEHHA has therefore determined that the phrase "can expose you to" is more clear and consistent with the requirements of the Act than the "contains" language in the existing regulations.

OEHHA declines to make the change requested by the commenter.

102. Comment (CalChamber and RMA): The commenters suggest simplifying the safe harbor language throughout the proposal to follow that which is used in several consent

judgments reviewed by the Attorney General and approved by state courts - "This product can expose you to chemicals, including [name of one or more chemicals], known to the State of California to cause cancer and/or birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/product."

Response: The language in the regulations was revised to address this and other comments. OEHHA determined that it is clearer to state the endpoint for which the chemical is listed on the Proposition 65 list. Using the term “and/or” is ambiguous since it is not clear whether or not the chemical is known to cause any or all of these health effects. The regulations provided separate content depending on the endpoint for which the chemical is listed. This furthers the purposes of the Act by providing exposed individuals with more specific information about the type of effect (cancer, birth defects and reproductive harm) caused by the chemicals in the product.

103. Comment (CRLA): At the public hearing, CRLA expressed support for the inclusion of the chemical name in the warning and that warnings be provided in languages other than English where appropriate.

Response: Comment noted, no response required.

104. Comment (NEMA): Subsection (c) [now subsection b] remains ambiguous and problematic. It creates new opportunities for private enforcement. NEMA urges OEHHA to give serious consideration to CalChamber's recommended amendments to this subsection.

Response: The subsection was modified to add clarity regarding the naming of one or more chemicals in the warning. The regulations require that the warning contain the name of at least one chemical for which the warning is being provided. OEHHA agrees with the statement in the Chamber of Commerce’s June 6, 2016 letter stating:

> “The phrase “one or more” is intended to mean that if a warning is being provided for more than one carcinogen or more than one reproductive toxicant, then the person providing the warning may satisfy the safe harbor warning requirements by specifying one carcinogen or one reproductive toxicant in the warning. The business may, but is not required to, specify more than one carcinogen or reproductive toxicant in the warning. Further, the business may elect to specify any listed carcinogen or any listed reproductive toxin for which it is providing a warning. For example, if a warning is being provided for Proposition 65-listed carcinogens A and B, the warning may specify chemical A only, chemical B only, or both chemicals A and B.”

105. Comment (CalChamber and NPA): The proposal for specifying the name of a chemical may result in confusion when an exposure involves both listed carcinogens and reproductive toxicants. For example, if an exposure involves both Chemical A (a

carcinogen) and Chemical B (a reproductive toxicant) and the business elects to identify only Chemical A in the warning, the warning could falsely suggest to the consumer that Chemical A also causes birth defects or other reproductive harm when it does not. If only one chemical must be identified, it can lead to a false and misleading warning; e.g., if only a reproductive toxicant is identified, yet the statement says "cause cancer and birth defects and other reproductive harm", the consumer is lead to believe the chemical also causes cancer.

Response: Based on this and other comments, the language in subsection 25601(b) was amended to state: "(b) Except as provided in Section 25603(c), a warning meets the requirements of this article if the name of one or more of the listed chemicals in the consumer product or affected area for which the warning is being provided is included in the text of the warning. *Where a warning is being provided for more than one endpoint (cancer and reproductive toxicity) the warning must include the name of one or more chemicals for each endpoint, unless the named chemical is listed as known to cause both cancer and reproductive toxicity and has been so identified in the warning*." Emphasis added) The italicized provision was added to clarify when a warning must name more than one chemical.

106. Comment (CAA): The regulations give a choice of text depending on the health effect associated with the chemical that is named in the warning. However, other unnamed chemicals that are present may have other effects. The misleading nature of this warning language and the inability to provide additional clarifying information for fear of "contradiction" does not provide a clear and reliable way to comply with the law.

Response: The Proposition 65 warning requirement only applies to chemicals that are listed as known to cause cancer or reproductive toxicity. OEHHA cannot expand the reach of the statute through a regulation. The provision of the regulations prohibiting contradictory information was moved to subsection 25601(e) and revised based on this and other comments. As stated in the previous responses, OEHHA has amended the regulatory language to allow for clearer identification of chemicals named in the warning as carcinogens and reproductive toxicants. Nothing in the regulations precludes a business from naming more than two listed chemicals for which the warning is being provided.

107. Comment (Auto Alliance et al., AASA et al., CHPA, AdvaMed, ACC, CalChamber, CAPA, CRN, CCEEB, and NPA): Subsection (c) (now subsection (b)) is vague and lacks clarity regarding how a business should select the "one or more of the listed chemicals". The subsection can be problematic by creating potentially misleading or unfair market advantages if only certain chemicals are warned about and not others. The phrase "one or more of the listed chemicals" lacks clarity as to whether a business is required to list more than one chemical or if one chemical is sufficient to meet the

safe harbor requirement. It could be interpreted to suggest that a warning must include all chemicals for which warning is being provided.

Response: Proposition 65 requires a warning for significant exposures to listed chemicals. The law does not further differentiate among listed chemicals. Where feasible, a business may include the names of all the listed chemicals covered by the warning. This may not always be feasible since some products may cause exposures to several chemicals with long, complicated names that could make naming all of them in the warning impractical due to space considerations. In this situation, a business may decide to name only one chemical in the text of the warning. If the business decides to name only one chemical, the choice of which chemical to name is up to the business, and the safe harbor protection will apply, even if there are other chemicals that affect the same endpoint that can result in exposures. OEHHA does not believe that warning for certain chemicals and not others is likely to cause unfair market advantages, and has not been presented with any example scenarios to realistically illustrate this possibility. This concern is speculative. No changes to the regulations were made based on this comment.

108. Comment (Auto Alliance et al., AASA et al., CHPA, AdvaMed, ACC, CalChamber, CAPA, CRN, CCEEB, and NPA): This subsection also lacks clarity as to whether the chemical must be the one present with the greater risk of exposure or quantity or if it could be one with the least because there are no selection criteria. It is virtually impossible to identify a chemical to include in a warning without first performing an exposure assessment which is not required in the statute. A potential approach would be to revert to the traditional safe harbor warning in which a manufacturer has the option of including the chemical name in the warning based on the premise that the chemical should actually be present in the product. The regulations should specify that businesses have the sole discretion to determine which chemical and how many chemicals to list in the warning to avoid unnecessary litigation. OEHHA should consider providing detailed guidance as to the criteria for selecting one or more chemicals and seek public comment on the criteria. The selection criteria should be based on sound scientific reasoning and labeling considerations, as well as consumer safety.

Response: OEHHA considered providing criteria for selecting a chemical such as the potency of the chemical, the chemical(s) with the highest concentration, or the chemical(s) most likely to be of interest to the person being warned. However, none of these criteria lend themselves to general application in a regulation of this type. Given that Proposition 65 does not establish any clear hierarchy of concern for listed chemicals, OEHHA determined that the decision concerning which chemical(s) to name on the warning should be left to the business causing the exposure. Under the regulations, a business can claim safe harbor protection by naming any one or more of

the chemicals for which the warning is being provided. If a warning is provided for one endpoint, then one chemical is the minimum that must be named. If a warning is provided for more than one endpoint (e.g., cancer and reproductive harm), then one chemical name must be included for each endpoint covered by the warning, unless the same chemical is listed for both endpoints, in which case it would be acceptable to just name that one chemical.

109. Comment (CHANGE): Support including at least one chemical name in the safe harbor warning language.

Response: Comment noted, no response required.

110. Comment (ACC): Disagree with the single chemical proposal and encourage OEHHA to withdraw it in full and maintain the language in the current safe harbor warning. To the extent any particular chemical name is required in a warning label it is essential that OEHHA be as clear as possible about what is required and who in the supply chain has primary responsibility for making the chemical selection. The regulations should be clear that the product manufacturer has primary responsibility and full discretion to select any chemical contained in the product for a product label and cannot be challenged by other parties.

Response: For the reasons discussed in this FSOR and the ISOR, OEHHA finds that this regulatory action will further the purposes of the Act by making warnings more informative. OEHHA is adopting Section 25600.2 to provide guidance concerning the provision of warnings between the various businesses in the chain of commerce. In most situations, the product manufacturer will determine the name of the chemical that will be used in the warning, however, Section 25600.2 anticipates situations where a business other than the manufacturer will need to provide the warning -- for example, the manufacturer may have fewer than 10 employees or a product retailer may be responsible for adding a listed chemical to a product. In these and other situations, the business responsible for providing the warning would have discretion over which chemical(s) to name in the warning. Subsection 25600.2(i) also provides the ability for businesses in the chain of commerce to contractually opt-out of the responsibility provisions. This may be the more appropriate route for a given business to pursue in the event there is a conflict over which chemical(s) to name in the warning. No changes to the regulations were made based on this comment.

111. Comment (ACC): OEHHA has not produced any consumer research, focus data or empirical evidence that warnings naming a specific listed chemical will be informative or meaningful to consumers. Inclusion of a single chemical is not supported by the UC Davis study. ACC commissioned an expert review and found the study could not be relied on.

Response: As stated in the ISOR, OEHHA contracted with the UC Davis Extension Collaboration Center to conduct a study to better assess the effectiveness of the existing and proposed new warnings. The purpose of the study was to assess whether the existing or proposed safe harbor warnings more clearly communicate that the chemical in question is known to the State of California to cause cancer, birth defects or other reproductive harm. The effectiveness of the warnings was assessed in terms of helpfulness. The results showed that over 75 percent of the participants selected the warnings based on the proposed regulations as being more helpful than the current warnings. More specifically, 66 percent of the respondents said the warnings that named chemicals were more helpful than warnings that did not name chemicals. The Proposition 65 Clear and Reasonable Warnings Regulations Study ("Warnings Regulations Study") is included as Appendix A to the ISOR. The ACC critique of the UC Davis Study was responded to by the researchers. Their response is attached to the FSOR as Attachment "A" and is incorporated here by reference.[17]

OEHHA's experience over the past 25 years in responding to thousands of phone calls, emails and letters from the public on Proposition 65 warnings supports the findings of the UC Davis Study. Members of the public who contact OEHHA after seeing a warning frequently ask which chemical prompted the warning. One of the most common complaints OEHHA hears about Proposition 65 is that individuals do not know which chemical or chemicals they are being warned about. This rulemaking action stems from a May 2013 statement by Governor Brown calling for reforms to Proposition 65, including changes to "require more useful information to the public on what they are being exposed to and how they can protect themselves." The UC Davis findings are consistent with longstanding public perceptions of the inadequacies of Proposition 65 warnings that OEHHA has observed in its interactions with the public, and that Governor Brown attempted to address in his 2013 statement.

112. Comment (ACC and AdvaMed): Clarify that it is adequate to use the same chemical name as on the Proposition 65 list itself and that use of 'chemical groupings' is inappropriate and introduces inaccuracies. OEHHA offers no evidentiary basis that using simplified chemical names would increase understandability. The use of chemical categories is inappropriate and arbitrary. The listing of phthalates is not warranted by studies or reports relied on by OEHHA.

Response: OEHHA agrees with the commenters that the warning should name the chemical in the same way it is identified on the Proposition 65 list. However, in some of the tailored warnings set out in Section 25607 OEHHA used more generic references to

[17] The letter response was not relied on in the development of the regulation but is included here for reference.

chemical groupings such as “phthalates” to cover a number of listed chemicals in a manner that the public can more easily understand.

113. Comment (Environmental Coalition): The Coalition approves of the new subsection (c) requiring identification of at least one chemical known to cause cancer or reproductive toxicity, indicating it will promote informed consumer choice. However, the first clause of subsection (c) should be removed, the one allowing for the “short-form” on-product warning that does not require naming of a chemical in the warning pursuant to subsection 25603(c). There is no reason to restrict the requirement to name a chemical to off-product warnings.

Response: The requirement to name one or more chemicals covers all warnings except the “short-form” warnings that may be included on a product label. The short-form warning referred to in subsection 25603(c) is provided as an option where an abbreviated warning message is needed, such as on very small containers. The warning would appear as follows for a product that causes an exposure to a listed carcinogen:

⚠ **WARNING**: Cancer - www.P65Warnings.ca.gov

As stated in the ISOR, subsection 25603(b), which provides the content of the warning for subsection 25603(c), “sets out a specific short version of the warning that may only be used for on-product warnings. This provision proposes a very limited level of content to be included in an on-product warning to accommodate some product manufacturers’ stated concern that a longer warning message will simply not fit on the label of some small products. OEHHA is proposing a label that strikes a balance between this concern and the requirement in the statute that a person receive a warning prior to exposure. OEHHA believes that this approach will provide useful information to individuals while avoiding unwieldy on-product warnings. Further, the warning is clearer and more direct than the existing safe harbor warnings being used by many businesses. Recognizing the potentially limited space available for a warning, under subsection (c) the name of the listed chemical being warned for is not required.”

Where a product manufacturer does not choose to use the short-form warning, the safe harbor warning would look like this:

⚠ **WARNING:** This product can expose you to chemicals including formaldehyde (gas), which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Based on its discussions with business groups during the development of these regulations, OEHHA believes a relatively limited number of products will carry the short-form warning and that the vast majority of on-product warnings will conform with or at least be based on the longer safe harbor warning. However, there likely will be

situations in which the longer warning will not fit on a product's label. To the extent that certain classes of products commonly carry the "short-form warning", OEHHA can identify chemical exposures related to those products on its website. For these reasons, OEHHA declines to add the requirement to name a chemical in the short-form version of the warning.

Section 25602 Consumer Product Exposure Warnings – Methods of Transmission

114. Comment (Environmental Coalition): A warning should always enable consumers to differentiate the products to which it applies. This will enable consumers to make informed choices and minimize over-warning. Suggest adding a new subsection (f) stating, "To the extent any consumer product warning is provided by any method other than a warning on the product's label, the warning must be provided in a method that enables consumers to differentiate products to which the warning applies from those to which it does not apply."

Response: OEHHA declines to make the change requested in the comment. The regulations provide several methods by which a business can provide the warning. All of them are deemed 'clear and reasonable" for purposes of the Act. There is sufficient specificity in the requirements to ensure that the warnings are closely associated with the product causing the exposure.

Subsection 25602(a)

115. Comment (Environmental Coalition): The Coalition suggests adding a new definition for "consumer information." Without a definition tying the term to specific elements on the label, such as nutrition facts, there is nothing preventing a manufacturer from providing one very small item of "consumer information" and then placing a warning in the same tiny type.

Response: In response to this and other comments, OEHHA has added a definition of "consumer information" to the regulations as subsection 25600.1(c) for clarity.

Methods and responsibilities

116. Comment (CalChamber): Subsection (a) should be revised to reflect that pamphlets, public advertisements, and other systems of providing Proposition 65 warnings are appropriate warning methods.

Response: OEHHA will consider adopting regulations incorporating these alternative warning methods on a case-by-case basis where a particular warning method and content meets the "clear and reasonable" standard in the law. For example, OEHHA

does include newspaper advertisements as an appropriate warning method for environmental exposures, and a pamphlet could satisfy the requirement in subsection 25607.8(a)(2) for dental warnings. However, OEHHA does not believe that pamphlets and advertisements under most circumstances can provide consumer product warnings that are as clear and reasonable as on-product warnings, shelf signs and other methods cited in the regulations. OEHHA declines to provide general safe harbor protection for the alternative methods suggested by the commenter in these regulations.

117. Comment (AdvaMed, AHAM, CalChamber, CRN, ITW, NEMA, NPA, and RMA): To ensure that the regulations continues to allow for warning methods such as in a package insert, pamphlet or owner's manual, OEHHA should revise the regulations to include "other labeling".

Response: Proposition 65 requires that a warning be provided "prior to exposure"[18] to the listed chemical. The statute defines a warning as follows:

> "(f) "Warning" within the meaning of Section 25249.6 need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable…." [19]

The existing definition of "labeling" in Title 27, Cal. Code of Regs subsection 25602(e) states as follows:

> "Labeling" means any label or other written, printed or graphic matter affixed to or accompanying a product or its container or wrapper.

Proposed subsection 25600.1(j) in the new regulations states:

> (j) "Labeling" means any written, printed, graphic, or electronically provided communication that accompanies a product including tags at the point of sale or display of a product.

Neither of these definitions expressly refers to an owner's manual as an example of "labeling" that might "accompany a product" that would be sufficient for purposes of providing a safe-harbor Proposition 65 warning. OEHHA is aware that some businesses currently provide Proposition 65 warnings in the owner's manual for their products. This method of providing a warning has never been sanctioned as a safe harbor method by OEHHA.

[18] Health and Safety Code section 25249.(6)
[19] Health and Safety Code section 25249.(11)(f)

While an owner's manual may indeed "accompany a product" in a broad sense, it is unlikely a consumer will read the manual prior to most types of exposures that commonly occur via consumer products. For example, if a person is being exposed via touching a product, the exposure will begin as soon as the person opens the package or touches the product. Similarly, if an exposure occurs through inhalation of vapors from a product, the exposure would likely occur as soon as the person comes into contact with the product, well before he or she has time to review the accompanying material. Therefore, a more visible and immediate warning is needed for most types of exposures to chemicals from consumer products.

OEHHA requested data on the percentage of the consumer population that reads owner's manuals, but failed to receive data supporting any contention that typical consumers actually do read these documents prior to using most consumer products. If scientifically valid data is received showing that most consumers read the owner's manual for a given category of products prior to using those products, OEHHA would consider adopting a "tailored" warning for that product category that incorporates the owner's manual as a valid warning method.

OEHHA believes that providing a warning in an owner's manual is a very good adjunct to providing a warning in a more immediate location on the product or its packaging. As mentioned above, OEHHA has incorporated a "tailored" warning for exposures to listed chemicals from automobiles that requires the placement of the warning in an owner's manual as an adjunct to a warning label that is placed on the driver's side window of the automobile. Placing the primary warning where it will be seen prior to the consumer entering the vehicle ensures that the warning is seen and understood prior to exposure to chemicals that can occur upon entering or using the vehicle. Similarly, the tailored safe harbor warning for recreational vessels and diesel engines includes an owner's manual warning as an adjunct to an on-product warning because it is likely to be kept with the product longer than the label and would therefore be available to other users of the product.

Package inserts are also not expressly adopted as a safe harbor warning method in these regulations. Though, as noted in response to previous comments, the general definition of "labeling" can include warnings provided via this method. Providing a warning via a package insert that is seen and understood prior to exposure may be a clear and reasonable warning method in certain situations. It is up to the business providing the warning via this method to show that it is clear and reasonable under the circumstances of a given exposure

As stated in the response to the previous comment, OEHHA similarly does not believe that pamphlets under most circumstances can provide consumer product warnings that

are as clear and reasonable as on-product warnings, shelf signs and other methods cited in the regulations.

For these reasons, OEHHA declines to adopt a provision in the safe harbor warning regulations allowing for the use of an owner's manual, package inserts and pamphlets as stand-alone methods for providing a Proposition 65 warning.

118. Comment (CTA): Owner's manuals are commonly the place consumers look to readily find product information. Thus, it is important that the proposal incorporate the term "labeling" so that companies can provide Proposition 65 warnings in product owner's manuals.

Response: OEHHA is aware that some businesses currently provide Proposition 65 warnings in the owner's manual for their products. This method of providing a warning has never been sanctioned as a safe harbor method by OEHHA.

It is unlikely a consumer will read the manual prior to most types of exposures that commonly occur via consumer products. For example, if a person is being exposed via touching a product, the exposure will begin as soon as the person opens the package or touches the product. Similarly, if an exposure occurs through inhalation of vapors from a product, the exposure would likely occur as soon as the person comes into contact with the product, well before he or she has time to review the accompanying material. Therefore, a more visible and immediate warning is needed for most types of exposures to chemicals from consumer products.

OEHHA believes that providing a warning in an owner's manual is a very good adjunct to providing a warning in a more immediate location on the product or its packaging. In fact, OEHHA has proposed a "tailored" warning for exposures to listed chemicals from automobiles that requires the placement of the warning in an owner's manual as an adjunct to a warning label that is placed on the driver's side window of the automobile. Placing the primary warning where it will be seen prior to the consumer entering the vehicle ensures that the warning is seen and understood prior to exposure to chemicals that can occur upon entering or using the vehicle, and a secondary warning in the owner's manual helps to increase the likelihood that future owners of the vehicle are also reasonably likely to receive a warning after the window warning label has been removed by the first owner. Similarly, the tailored safe harbor warning for recreational vessels and diesel engines includes an owner's manual warning as an adjunct to an on-product label for the reasons stated in response to related comments (e.g., it is likely to be kept with the product longer than the label and would therefore be available to other users of the product).

For these reasons, OEHHA declines to adopt a provision in the safe harbor warning regulations to incorporate the term, “labeling” which would allow for the use of an owner’s manual as a stand-alone method for providing a Proposition 65 warning.

119. Comment (CHANGE): Product manuals are not an appropriate location for safe harbor warnings. Most manuals are not available to consumers until after purchase, so the warnings would present the same issues as warnings on receipts. In addition, many consumers do not read manuals, especially the sections that contain multiple warnings.

Response: The regulations does not allow a stand-alone warning in an owner’s manual as a safe harbor method for providing a warning; rather in some circumstances an owner’s manual serves as an adjunct to another safe harbor warning method.

120. Comment (CHANGE): Warnings must be provided before purchase. Warnings received otherwise require the customer to go through a return process to avoid exposure. Product manuals are not appropriate for safe harbor warnings. Most manuals are not available until after purchase and many customers don't read manuals.

Response: The Act requires a warning prior to exposure to a listed chemical. OEHHA is sympathetic to concerns about the difficulty of receiving warnings post-purchase and recognizes that the circumstances of some transactions such as internet and catalog sales are particularly challenging to a consumer who has made a purchase online and has received the item. In this situation, a person may be faced with the difficulty of returning an item through the mail if they do not wish to keep it. For these reasons, OEHHA has established safe harbor warning methods for internet and catalog sales wherein a warning must be provided on the webpage or in the catalog as well as on the product. OEHHA agrees that product manuals alone are an insufficient method of providing a safe harbor warning to a person prior to exposure to a listed chemical. OEHHA also recognizes that owner’s manuals may serve as an adjunct and has expressly incorporated the use of owner’s manuals in conjunction with another method. Examples are found in the tailored warnings for vehicles in Section 25607.16 and for recreational vessels in Section 25607.18.

121. Comment (CRN): Suggest that if the content requirement “is provided using at least one of the following methods” that businesses have sole discretion when determining which warning method to use.

Response: The regulations allow a business to use “one or more” of the methods set out in the regulations. This means they can choose the method to use, and have the option to use more than one method. The choice of the method is at the discretion of the business providing the warning, subject to the provisions in Subarticle 1, section 25600.2 which allows a manufacturer, producer, packager, importer, supplier, or

distributor of a product to either affix a label to the product or comply with the regulations regarding the provision of warning materials to retailers.

122. Comment (AHPA): Subsection (a) should specify who has the authority to determine which warning method is to be used. Referencing the previous version of the regulations released in January 2015 that was withdrawn and replaced in November 2015, AHPA states that it is fundamentally illogical and unfair for warnings on consumer products to be provided differently in one retail circumstance versus another. It is inherently misleading, because placement of warnings in direct association with particular products inevitably implies that those products pose a greater risk of exposure than products for which the warning occurs only via general, non-product-specific signage.

Response: Article 1, Section 25600.2 sets out the relative responsibilities for providing warnings between product manufacturers, producers, packagers, importers, suppliers, distributors and retailers. The various businesses in the chain of commerce can work out among themselves the best way to provide warnings. Section 25600.2 provides a general framework for the division of responsibility for providing warnings, but subsection 25600.2 (i) allows the businesses to establish a different structure so long as a clear and reasonable warning is provided. OEHHA believes this allows maximum flexibility for businesses to address their own unique supply chain issues.

Article 2, Section 25601 provides safe harbor methods that can be used to provide the warnings. There is no one size fits all method for providing Proposition 65 warnings. The regulations provide safe harbor methods and content for warnings that are intended to provide a level of consistency and clarity that is not currently being provided. Businesses can choose one or more warning method that work best for their business needs. No change to this section of the regulations was made based on this comment.

Minimum type size requirements

123. Comment (AHPA, TVC, and CGA): In response to the previous version of the regulations released in January 2015 and later withdrawn and replaced in November 2015, AHPA commented that the type size requirements for shelf tag or shelf sign warnings are unreasonable and impractical (subsection 25603(a)(1) in the January 2015 draft). Shelf signs are commonly oversized or exaggerated to draw attention to a product. The provision is also incompatible with requirements of subsection 25600.2(b)(3) such that a manufacturer, producer, packager, or distributor would not know in advance the type sizes used by retailers for their own promotional signs or tags. If OEHHA maintains a type size requirement then it should exclude prominent promotional text designed to attract consumer's attention. Commenting on the November 2015 regulatory proposal, TVC notes that subsection 25602(a)(1) regarding

signs and shelf tags and signs and subsection 25602(a)(3) regarding labels, by making a quantifiable test by incorporating font size restrictions, increases the risk of frivolous lawsuits. CGA added that "largest font size" is problematic when more than one shelf tag exists for the product, and during promotions font size of tags can temporarily increase. Any font size comparisons should be limited to tags for the specific product, not “similar” ones, and only to shelf tags offered for sale at its usual and customary price not temporary promotional periods.

Response: Based on this and other comments, the shelf tag or sign type size requirements were changed in the November 2015 rulemaking to revert back to language from the existing regulations. Font size requirements are no longer specified in subsection 25602(a)(1). Type sizes are specified for some of the specific tailored warnings for signs and shelf tags and signs in Subarticle 2, and on-product warnings (subsection 25602(a)(4)) carry a type size requirement. In place of a specific type size requirement, under subsection 25601(c) OEHHA carried over language from the existing regulations to establish a general readability standard.

> “Consumer product exposure warnings must be prominently displayed on a label, labeling, or sign, and must be displayed with such conspicuousness as compared with other words, statements, designs or devices on the label, labeling, or sign, as to render the warning likely to be read and understood by an ordinary individual under customary conditions of purchase or use.”

As was explained in the original FSOR for the existing regulations adopted in 1988, the precise type size, type style and format are not specified in several instances throughout the regulations so that warnings will be easier to incorporate into the warning method chosen by the business. If a sign is used, it must be placed in a location and be of suitable size to attract attention, and must have print of sufficient size and clarity to be understood by those persons who will foreseeably be exposed. The word “conspicuous” for purposes of a safe harbor warning means “easy to notice”. The safe harbor provision requires warnings be likely to be read and "understood by an ordinary individual", thus there is no requirement that a warning be understood by an exceptional or extraordinary individual in a given situation.[20] OEHHA declines to specify a minimum type size or font for all warnings as this unnecessarily restricts the ability of businesses to provide the warning in a clear and reasonable manner that is, at the same time, not out of proportion or significantly different from the size and fonts used for other information being provided to the consumer about the product.

[20] The FSOR for the original regulations is available here: http://oehha.ca.gov/media/downloads/crnr/12601fsornov1988.pdf

124. Comment (CalChamber, Environmental Coalition, ASE, and CHPA): Numerous subsections state that the warning must be in a type size no smaller than one half the largest type size or no smaller than the largest type size used for other "consumer information." "Consumer information" is extraordinarily broad. Recommend OEHHA carefully consider a requirement that is clear and can be reasonably applied to all consumer products. The regulations and/or ISOR should specifically identify what constitutes "other consumer information" in this subsection and throughout the regulations. OEHHA's minimum 6- or 8-point type size requirement could result in OEHHA-required warnings being larger than other important warnings about immediate hazards that are required by the Federal Hazardous Substance Act. Recommend OEHHA clarify how it intends type size to be measured. If typefaces are not identical, it is not clear what constitutes "smaller" or "larger" type. One alternative used in other consumer products warning regulations would be under the Federal Hazardous Substance Act which sets out type size requirements as capital letter heights in inches (see Title 16, Code of Federal Regulations, section 1500.121).

Response: Based on this and other comments, a definition of "consumer information" was added in subsection 25600.1(c) of the regulations and most references to a specific font size have been replaced with the general readability and understandability standard for consumer products of subsection 25601(c). For the general safe harbor warning for the on-product option, the requirement remains to have the type size no smaller than the largest type size used for other consumer information on the product, with the proviso that in no case should the type size be smaller than 6-point type. Further, since these regulations apply to consumer product exposures, OEHHA declines to adopt the provisions of the Federal Hazardous Substance Act, which governs, among other things, warnings for occupational exposures.

125. Comment (Environmental Coalition): The Coalition supports many of the changes made to this subsection. OEHHA has appropriately clarified that the regulations apply to "consumer products." Approve of the specification of a minimum font size in subsection (a)(1). However, 10-point should be the minimum size, 8-point is unreasonably small and will be illegible to some consumers.

Response: OEHHA declines to make the change requested. For short-form on-product warnings provided pursuant to Section 25603(b), the type size is to be no smaller than the largest type size used for other consumer information on the product, with a minimum font size of 6-point. For all consumer products, the general readability and understandability standard of subsection 25601(c) must be met. This balances the need to ensure that type sizes on warnings are sufficiently large for most readers with the needs of product manufacturers to fit the warning on small products or labels that

already may contain other required information, and also to ensure that posted signs, shelf tags and shelf signs with warnings are readable and understandable.

Subsequent to receiving this comment, OEHHA removed the 8-point minimum font size from subsection (a)(1). OEHHA expects that the general readability and understandability standard of subsection 25601(c) should result in very few warnings in small font sizes. In order for a warning to be likely to be read and understood by an ordinary individual under customary conditions of purchase or use, that warning would need to be large enough to be seen by most people. OEHHA generally agrees with the commenter that font sizes below 10-point will likely be difficult for many people to read. Most product labels will have space for larger warnings, and therefore could not justify 6-point font based on the readability and understandability provision. However, some products might come in packaging too small to accommodate 10-point type. For those packages, type as small as 6-point that is the same size as other consumer information could still be considered clear and reasonable. Shelf signs and tags would need to be easily read and understood under the lighting conditions in most stores at distances representative of those from where a person is standing to a sign on a lower shelf. In addition, OEHHA is aware of situations where information is printed without sufficient visual contrast to facilitate readability. For example, some products contain consumer information in white type against a clear glass background. A warning on such a product could be presented in the same font size as other consumer information, but would not meet the readability and understandability requirements in the regulations if it were not in a visually distinct color against the background of the label or sign.

126. Comment (ACA, ACMI, CSPA, and CHPA): OEHHA is arbitrarily imposing a minimum font size requirement without regard to the products and packages involved and other mandated text requirements. The commenters recommend that OEHHA require the font size to be no smaller than the font being used for the precautionary statements or other health and safety related information provided on the warning rather than prescribing specific font sizes that may not work for certain products. They also recommend that OEHHA adopt a more flexible approach for font size to accommodate smaller container sizes. Currently OEHHA is determining font size based on the font size used for “other consumer information” on the shelf tag, shelf sign or label and the term “other consumer information” is vague. There is concern that if OEHHA requires a font size larger than the federally mandated language, there may be confusion by the multitude of signal words that may appear on a label.

Response: As noted in the previous response, OEHHA removed the minimum font-size requirement from subsection (a)(1) and believes the general readability and understandability requirement in subsection 25601(c) is adequate. Also, as noted in responses to previous comments, OEHHA adopted a definition for “consumer

information" in subsection 25600.1(c) to address this and other comments requesting more specificity. It should also be noted that warnings are not required to be placed on product labels. This is just one method for providing a warning under these regulations. No further change to the regulations was made based on this comment.

Electronic or automatic warnings prior to or during purchase

127. Comment (CalChamber, CGA, GMA, and RMA): Subsection 25602(a)(2) does not provide detail as to the level of actions a purchaser must take in order to be considered to be "seeking out" a warning. The commenters recommend that OEHHA provide additional clarification about what level of actions a purchaser must take to be considered "seeking out" a warning. They urge OEHHA to revise subsection (a)(2) to, "…electronic device or process that makes the warning available to the purchaser, without considerable effort on the part of the purchaser, prior to or during the purchase of the consumer product" and remove,"…without requiring the purchaser to seek out the warning." The limitations on electronic information should be eliminated. A requirement for complete passivity on the part of the consumer eliminates the electronic options entirely.

Response: The regulations state that an acceptable method for providing a warning includes "a product-specific warning provided via any electronic device or process that automatically provides the warning to the purchaser prior to or during the purchase of the consumer product, without requiring the purchaser to seek out the warning." As stated in the ISOR, "OEHHA does not intend for this provision to be read in such a way that a business may rely exclusively on a website or other device to provide a warning where the individual must seek out the warning. For example, a general reference to a website would not comply with this provision or the Act. Similarly, an invitation to go to a website (or to a customer service desk) to determine which products within a given facility require a warning would not comply with the Act."

The term "seek out" a warning was used in the regulations because the court in *Ingredient Communication Council, Inc. v. Lungren* (1992), 2 Cal. App. 4th 1480.(1992) expressly determined that a person must not be required to "seek out a warning". In that case, the Grocery Manufacturers Association developed a 1-800 telephone warning system. Consumers were not given any warning information until they called the number and asked about a specific product. The court in that case found that the warning system did not provide clear and reasonable warnings. The court instead found that the system, as applied, delivered less than 500 warnings to consumers over the course of a year, even though over 7,000 products were registered with the service. The Court of Appeal stated:

> "Any meaningful definition of 'availability' prior to exposure must similarly consider the probability of the prospective consumer seeing or hearing the warning message. Availability of the warning message, to be consistent with the Act, must mean more than the possibility a consumer would be apprised of the specific warning message only through considerable effort. An invitation to inquire about possible warnings on products is not equivalent to providing the consumer a warning about a specific product." (2 Cal.App.4th 1480, 1494).

Thus, a warning may be provided through electronic means such as clicking a link, scanning a bar code, reading a QR code or viewing a display as long as the consumer has reasonable notice and instructions on how to locate the warning. However, any warning method that requires a consumer to go through "considerable effort" to find the warning is not clear and reasonable for purposes of the Act. "Considerable effort" could include searching for a warning that is buried within a "disclaimer" section in the legal notices portion of a website, rather than being easily accessible through a clickable and clearly labeled link on the product display page. OEHHA used the phrase "without requiring the purchaser to seek out the warning" in order to comply with existing case law on the subject. OEHHA declines to make the wording changes suggested by the commenters because the regulations are sufficiently clear without them.

128. Comment (Environmental Coalition): The Coalition opposes any warnings being given at the point of sale. Subsection (a)(2) allows such warnings and therefore should be removed. This subverts the purposes of Proposition 65, one of which is to allow informed purchasing decisions by consumers. The Coalition strongly requests that any language allowing point of sale warnings be removed because such warnings are contrary to the purpose of the law.

Response: The current safe harbor regulations are silent on the use of point of sale warnings and OEHHA has generally discouraged their use because other methods of warning generally make it easier for the consumer to identify the specific product for which the warning is being provided. Proposition 65 does not prohibit the use of point of sale methods. Newer technologies could facilitate point of sale warnings by displaying a prominent warning on a screen when a product is scanned, or by displaying a warning prior to payment confirmation. Such warning methods would provide consumers with information to make purchasing decisions and would allow consumers to decline to purchase a specific product and avoid exposure, thereby fulfilling the core purpose of the law.

129. Comment (CalChamber, CRN, ACA, and NEMA): The phrase, "prior to or during the purchase of the product" is inconsistent with statutory text and beyond the authority granted to OEHHA in enacting regulations. OEHHA failed to clearly delineate how this narrower approach is authorized by law or why it is necessary. This proposed approach

would invalidate several warning methods now used by businesses, such as user manuals, use and care guides, warnings on internal packaging, and on-product packaging for products bought over the internet. The proposal would be unduly expensive especially for small businesses. OEHHA is going outside the bounds of the statute in proposing that warnings be provided "prior to or during the purchase of the product." Absent further justification that explains the statutory basis of this change, believe it is unwarranted and urge OEHHA to revert to the prior standard of "prior to exposure."

Response: Subsection (a)(2) provides that "a product-specific warning [may be] provided via any electronic device or process that automatically provides the warning to the purchaser prior to or during the purchase of the consumer product, without requiring the purchaser to seek out the warning". Providing a warning electronically is just one of several methods for providing a warning under this regulation. The methods listed in the comment are non-electronic and would therefore not be subject to the limitations of this provision.

In adopting these safe harbor provisions, OEHHA is setting out warning methods and content that are deemed "clear and reasonable" by the lead agency for purposes of Proposition 65. It is well within OEHHA's authority to impose limitations on the methods sanctioned under these non-mandatory provisions of the regulations, as long as they further the purposes of the statute. If a business decides to take advantage of this safe harbor protection, it must follow the requirements of the regulations. OEHHA believes that when providing a warning electronically, it is reasonable and feasible to ensure that the warning is provided prior to completion of the purchase. This provides the consumer with information about a potential exposure to a Proposition 65 listed chemical at a point when it is easiest to make a decision about purchasing the product. This furthers the purposes of the statute by allowing consumers to make better informed purchasing decisions.

As noted in responses to previous comments, OEHHA believes that a warning that is only provided in an owner's manual is unlikely to be seen and understood prior to many types of consumer product exposures. Therefore, the safe harbor provisions of the regulation do not adopt this method of providing a warning as a stand-alone method. Instead, owner's manuals are used as an adjunct to on-product warnings for some of the tailored warning provisions in these regulations. In the event a business chooses to only provide a warning in an owner's manual, it may prove in any subsequent enforcement action that the warning was clear and reasonable under the circumstances; however, OEHHA declines to adopt such a method for purposes of these safe harbor regulations.

It should also be noted that this provision is included in the non-mandatory safe harbor provisions of the regulations. A business can choose to provide a warning in any manner that is clear and reasonable under the Act.

No changes to the regulations were made based on this comment.

130. Comment (DRoe): Product-specific warnings via electronic device or process, creates an enormous potential loophole, since as drafted it would give safe harbor to warnings provided to the purchaser "during the purchase . . . " . This would allow all consumer product warnings to be given on cash register receipts. Such information would likely be ignored or overlooked by purchasers and therefore would not be reasonable as a Proposition 65 warning. This loophole would swallow all other safe harbor options and would be the obvious preference of all parties wanting to hide or minimize their warnings.

Response: A receipt is provided to a consumer after a payment has already been made and a purchase is complete, rather than during the purchase, therefore a cash register receipt would not comply with this provision. While there may be circumstances where a warning provided on or with a cash register receipt may be clear and reasonable, that method of warning is not adopted as a general safe harbor method in this regulation. Such a method of warning would generally require additional notice for a consumer to look for the warning on the receipt, as it does in the "tailored" warning for furniture products in Section 25607.12, and would need to include a simple process for immediate return of the product if the consumer decides they do not wish to keep the product once they know a warning is required. Any such warning method would still need to meet the "clear and reasonable" warning requirements of the law. OEHHA may consider adopting a regulation specific to a given industry or product in the future addressing this option. As stated in the ISOR for these regulations:

> "The "catch-all" provision in subsection (a)(2) is intended to capture existing and future methods of communication, including currently available tools such as electronic shopping carts, smart phone applications, barcode scanners, self-checkout registers, pop-ups on Internet websites and any other electronic device that can immediately provide the consumer with the required warning. OEHHA does not intend for this provision to be read in such a way that a business may rely exclusively on a website or other device to provide a warning where the individual must seek out the warning. For example, a general reference to a website would not comply with this provision or the Act. Similarly, an invitation to go to a website to determine which products within a given facility require a warning would not comply with the Act."

No change to the regulations was made based on this comment.

131. Comment (CAPA): CAPA interprets the reference to "electronic device or process" in Section 25602 and the reference to "electronically provided communication," in the definitions of "labeling" and "sign" in Section 25600.1 to include a warning printed on a cash register receipt, provided customers are informed to check the receipt for a warning and the warning is printed on receipts only for products that need it, not all products. If this interpretation is consistent, OEHHA is encouraged to confirm so in FSOR.

Response: As discussed in response to previous comments on these two provisions, OEHHA's intent in adopting these provisions in the regulations is to allow businesses to use electronic means to provide warnings where such means provide a clear and reasonable warning. However, OEHHA has not adopted a cash register receipt warning as a safe harbor method in these regulations. Some businesses have screens at the check-out that display price and other product information to consumers, allow the consumer to input information (e.g., for customer loyalty rewards programs), and capture electronic signatures. Such displays could potentially alert consumers with readable and understandable warnings that would meet the criteria in Section 25602 when a bar code for a product is scanned, or prior to signature or payment. Some pharmacies already require a customer to acknowledge receipt of consumer information on prescription drugs provided on these displays prior to completing the purchase. A similar system would seem to be workable for Proposition 65 warnings. If a consumer decides, after seeing the warning, to decline to purchase the item, it could readily be removed prior to completion of the purchase.

Other Comments on subsection 25602(a)

132. Comment (ACA and CSPA): The Federal Hazardous Substances Act (FHSA) mandates use of one of three signal words (danger, warning or caution), and Hazard Communication Standard (HCS) 2012 requires the use of one of two signal words (danger or warning), while Proposition 65 requires only "WARNING." There is concern that if OEHHA requires a font size larger than the federally mandated language, there may be confusion by the multitude of signal words that may appear on a label.

Response: The signal word "Warning" has been carried over from the regulations and has been used in Proposition 65 warnings since the regulations were adopted in 1988. OEHHA has not seen any evidence that use of the word is problematic as it relates to other warnings that may be provided for a given product under other state or federal laws. OEHHA has removed specific font-size requirements from the subsection (with the exception of the "short-form" on-product warning pursuant to Section 25603(b)),

133. Comment (ASE and CalChamber): There is a definition for "label", but "on-product label" is not defined. The requirements for "label" and "on-product label" are

different, but they seem to refer to the same thing. Recommend clarifying the distinction between the two as well as when the requirements apply for each. The term, "on-product " is not defined. OEHHA should clarify that an "on-product" warning need not appear on the product itself but can instead appear on its label or other exterior packaging.

Response: As stated in the regulation, "'label' means a display of written, printed or graphic material that is *affixed to a product or its immediate container or wrapper* (emphasis added). The term "label" in subsection 25600.1(i) necessarily includes labels provided on a product. For purposes of subsection 25603(b), the short-form warning may only be provided on the product, which would include the immediate container (box, packaging) or wrapper for the product, but would not include other types of "labeling" as defined in subsection 25600.1(j).

134. Comment (NPA): It is unclear whether a warning is required on both the immediate container and the outer packaging of product.

Response: These regulations do not require a warning on both the container and the outer packaging, although some businesses may choose to provide both to ensure that the average consumer receives a warning as required by the Act. In general, a warning should be placed on the product in a manner that ensures it can be viewed by the consumer prior to purchase, which may be the box, wrapper or other immediate container or packaging. However, for products that are commonly re-sold, passed on, or used by multiple people in addition to the original purchaser, a warning on the product itself may be appropriate.

These regulations provide several methods that may be used to provide consumer product warnings. Warning labels on the product or immediate container or wrapper are just one option. The warning should be placed in such a manner as to ensure that it is seen and understood prior to exposure. For example, where a business provided the warning on a product label (as defined in subsection 25600.1(i)), if a person will be exposed to a listed chemical immediately upon opening a product's outer packaging through contact with the product, the warning should be placed on the outer container or wrapper.

135. Comment (RMA): In subsection (a)(1), define the term "at each point of display of the product".

Response: "Point of display" is not a term of art specific to Proposition 65 or these regulations. The term has the same meaning as in common usage. It simply means the location where the product is displayed for sale at a given facility such as on a shelf. OEHHA declines to adopt a specific definition for this term in the regulations.

136. Comment (RMA): For tires that are not on display in a retail store, request OEHHA specify that only products which can come in contact with the consumer require a shelf-tag, shelf-sign or label.

Response: OEHHA encourages the commenters to work with their retailers concerning the placement of any required warnings. It may be appropriate to simply post signs in the sales area rather than attempt to directly label products in certain situations, such as if all tires at a retail facility require a warning. The regulations allow for such an approach. To the extent it is needed, OEHHA will consider a specific warning regulation for these types of products if requested.

Subsection 25602(b)

Warnings for Internet Purchases

137. Comment (CalChamber, RMA, AHPA, and FWC): CalChamber noted that subsection (b) appears to require warnings to be given prior to an internet purchase, even if the product has proper labels included by a manufacturer. It is unclear how this requirement is meant to harmonize with the allocation of responsibility under subsection 25600.2(b), which purportedly seeks to minimize the burden on retail sellers. The provisions are inconsistent. RMA and AHPA characterized the requirement for warning on the manufacturer's website as burdensome. RMA recommended that OEHHA clarify that the retail seller of a product on the internet that contains an on-product warning is not required to provide the warning via a hyperlink. AHPA noted prior regulations required warnings prior to exposure not purchase. There is no public health justification for this change. It is not consistent with the Act.

Response: Subsequent to this comment, OEHHA modified subsection 25600.2(d) to clarify that the retail seller is responsible for the placement and maintenance of warning materials, including warnings for products sold over the internet that the retail seller receives pursuant to Section 25600.2(b) and (c).

It is not practicable to place the warning burden entirely on the product manufacturer, who may not even know where its products may ultimately be sold. Under Section 25602(b) and (c), where a product is sold on the internet or in a catalog, in order to take advantage of the safe harbor provided in the regulations, the warning must be provided on the product display page or be otherwise prominently displayed or be clearly associated with the product prior to the customer completing the purchase. The warning label used on the product may be reproduced or pictured on the internet website or in the catalog. Subsections 25600.2 (b) and (c) were modified to require product manufacturers, producers, packagers, importers, suppliers, and distributors to provide retail sellers with warning language to use on their websites or in their catalogs

for the product. Where the product manufacturer has included the warning on a product label or labeling, the retail seller may use the same warning language on its website or catalog or provide a picture of the label or labeling for the product to the extent that the warning is readable and legible in the picture.

The provisions of the safe harbor regulations addressing internet and catalog sales are intended to address the fact that consumers' purchasing habits have changed substantially over the 30 years since Proposition 65 was passed and the original warning regulations were adopted. It is now very common for people to purchase products over the internet or through electronic catalogs. Such "remote" purchases were not contemplated in the original regulations. (While hard-copy catalogs were common in the 1980s, the original warning regulations did not address them.) Providing warnings that are associated with the products on the internet website or in a catalog prior to the consumer completing a purchase is a reasonable way to ensure the consumer receives the warning prior to exposure. It also furthers the purposes of Proposition 65 by providing consumers with the information before they make a final purchasing decision, thus furthering the right-to-know purposes of the statute. Given that the internet website and catalogs are remote from the actual product being displayed for purchase, the consumer would not likely see the warning until after the product is delivered. This limits the ability of consumers to choose not to purchase the product and would require them to go through additional time and expense to return the product once they receive the warning. Some purchases may be deemed final by the retail seller, thus leaving the consumer with no recourse. OEHHA believes that it is reasonable, for purposes of the safe harbor provisions of these regulations, for retail sellers to provide the warning to potential purchasers prior to or during the purchase. The regulations were modified to require product manufacturers to provide warning language to retail sellers. Retail sellers of products are responsible for passing this information on to the consumers via their websites.

138. Comment (CSPA): Clarify who is responsible for providing the warning for internet or catalog sales. Subsection (b) and (c) should articulate the obligations of the website owner, catalog owner, and product manufacturer.

Response: Under subsections (b) and (c), where a product is sold on the internet or in a catalog, in order to take advantage of the safe harbor provided in the regulations, the warning must be provided on the product display page or be otherwise prominently displayed or be clearly associated with the product prior to the customer completing the purchase. The warning label used on the product may be reproduced or pictured on the internet website or in the catalog. Subsections 25600.2 (b) and (c) were modified to require product manufacturers, producers, packagers, importers, suppliers, and distributors to provide retail sellers with warning language to use on their websites or in

their catalogs for the product. Where the product manufacturer has included the warning on a product label or labeling, the retail seller may use the same warning language on its website or catalog or provide a picture of the label or labeling for the product to the extent that the warning is readable and legible in the picture.

139. Comment (NMMA, NPA, and ACA): The proposed regulation requires that a warning be included on each product on each retailer's website despite the fact that potential consumer(s) may or may not be in California. The proposal would be very time consuming and costly for a manufacturer to continuously ensure that its products, on a myriad of websites, are in compliance. Subsection (b) does not identify who carries the responsibility to warn on internet purchases. NMMA suggests that a warning not be needed for online purchases until the consumer identifies him or herself as a California resident upon entering their shipping address. Clarifying language should be included that outlines the compliance protocol for manufacturers. NPA urges OEHHA to create an exemption for out-of-state internet retailers regarding the 'prior to purchase' requirement.

Response: OEHHA agrees with the commenter that a Proposition 65 warning is not required for products that do not cause exposures in California. The regulation allows a business to comply in three ways: 1) by including the warning on the product display page, 2) by providing a clearly marked hyperlink using the word "WARNING" on the product display page, or 3) by otherwise prominently displaying the warning to the purchaser prior to completing the purchase. Therefore, a retail seller may comply with the regulation by providing the warning only to individuals who reside in California. For example, OEHHA is aware that some online retail sellers do this by providing the warning as a pop-up when the purchaser enters a California zip code. This process would comply with the requirements of the regulation to "otherwise prominently displaying the warning to the purchaser prior to completing the purchase". OEHHA notes that this issue is not unique to internet warnings. Many products that are sold outside California carry Proposition 65 warnings because the product manufacturer has determined that it is infeasible to only provide warnings to California purchasers. However, nothing in the regulations requires the manufacturers to provide warnings outside California.

140. Comment (Environmental Coalition): The Coalition supports the requirement that the word "WARNING" appear on the product page for internet purchases, but objects to the use of a hyperlink in lieu of a text warning. A hyperlink requires affirmative consumer action to view the full warning. This is undesirable because many consumers will not click on the hyperlink and thus will not receive the full text. The regulation should clearly require that the full warning text appear on the page before the consumer commits to purchasing the product. It is critical to place the warning such

that a consumer does not have to scroll down to see it. The Coalition suggested revised text.

Response: OEHHA believes it is not unreasonable to require a consumer to click on a hyperlink in order to see the full text of a Proposition 65 warning on an internet website page. As discussed in response to previous comments, the only reported case directly addressing the amount of effort a person must expend in order to receive a clear and reasonable warning is *Ingredient Communication Council v Lungren.* In that case, the Grocery Manufacturers Association developed a 1-800 telephone warning system. Consumers were not given any warning information until they called the number and asked about a specific product. The court in that case found that the warning system did not provide clear and reasonable warnings. The Court of Appeal stated:

> "Any meaningful definition of 'availability' prior to exposure must similarly consider the probability of the prospective consumer seeing or hearing the warning message. Availability of the warning message, to be consistent with the Act, must mean more than the possibility a consumer would be apprised of the specific warning message *only through considerable effort*. An invitation to inquire about possible warnings on products is not equivalent to providing the consumer a warning about a specific product." (*Ingredient Communication Council, Inc. v Lungren*, (2009) 2 Cal.App.4th, 1480 2 Cal.App.4th 1480, 1494, emphasis added).

Simply clicking on a hyperlink that is clearly identified with the word "WARNING", and that is clearly associated with an individual product, does not involve "considerable effort" on the part of the consumer. It is a very common action that a person using the internet to make a purchase would easily accomplish. Further, it is very likely a person who wishes to see the warning will click on the link. The statute does not require that a person be completely passive in order to receive a warning. Therefore, OEHHA declines to make the changes to the regulations requested in this comment.

141. Comment (RMA): Subsection (b) does not specify whether the internet retailer is responsible for posting and maintaining a warning provided via a hyperlink.

Response: Subsequent to this comment, OEHHA modified subsection 25600.2(d) to clarify that the retail seller is responsible for the placement and maintenance of warning materials, including warnings for products sold over the internet that the retail seller receives pursuant to subsections (b) and (c).

142. Comment (ACA and FWC): ACA and FWC object to mandating Proposition 65 warnings for internet and catalog sales. ACA states that requiring an additional warning for online or catalog sales contradicts Governor Brown's proposal to reduce

unnecessary litigation under Proposition 65. Manufacturers can ensure they are compliant by providing a warning on the product label but they cannot ensure compliance by downstream distributors. Inevitably, retailers and manufacturers will face lawsuits. With this proposed online and catalog requirement, OEHHA has opened a new market for Proposition 65 litigation. FWC indicates that requiring on-product and online and catalog warnings was duplicative. The consumer receives the warning prior to exposure with an on-product label.

Response: The provisions of the safe harbor regulations addressing internet and catalog sales are intended to address the fact that consumers' purchasing habits have changed substantially over the 30 years since Proposition 65 was passed and the original warning regulations were adopted. It is now very common for people to purchase products over the internet or through electronic catalogs. Such "remote" purchases were not contemplated in the original regulations. (While hard-copy catalogs were common in the 1980s, the original warning regulations did not address them.) Providing warnings that are associated with the products on the internet website or in a catalog prior to the consumer completing a purchase is a reasonable way to ensure the consumer receives the warning prior to exposure. It also furthers the purposes of Proposition 65 by providing consumers with the information before they make a final purchasing decision, thus furthering the right-to-know purposes of the statute. Given that the internet website and catalogs are remote from the actual product being displayed for purchase, the consumer would not likely see the warning until after the product is delivered. This limits the ability of consumers to choose not to purchase the product and would require them to go through additional time and expense to return the product once they receive the warning. Some purchases may be deemed final by the retail seller, thus leaving the consumer with no recourse. OEHHA believes that it is reasonable, for purposes of the safe harbor provisions of these regulations, for retail sellers to provide the warning to potential purchasers prior to or during the purchase. The regulations were modified to require product manufacturers to provide warning language to retail sellers. Retail sellers of products are responsible for passing this information on to the consumers via their websites. No further changes to the regulations were made based on this comment.

143. Comment (ACA): If in final regulation OEHHA mandates internet warnings, OEHHA is urged to clarify that if a manufacturer provides an on-product warning, they do not have to also provide the longer safe harbor warnings if the product is sold online by either the manufacturer or a downstream distributor. To interpret this provision otherwise would place a burden on companies to provide two Proposition 65 warnings for the same product, each with different requirements.

Response: Based on this and other comments, OEHHA modified the language in the regulation to allow retail sellers to use the same language on the internet site as is used on the on-product warning.

Subsection 25602(c)

Warnings for Catalog Purchases

144. Comment (AHPA): "Catalog" should be clearly defined. Subsection (c) mandates warnings be provided in catalogs, but subsection (a) does not acknowledge that the warning will meet the requirements of Article 6. AHPA recommends adding alternative warning methods including warning in a catalog, labeling or other literature accompanying the sale of the product, an audio warning (provided an audio warning is retained as proof of delivery of warning or written confirmation of receipt of warning), or an email sent to the customer.

Response: The term "catalog" is not a term of art for purposes of Proposition 65. It has the same meaning as common usage. For example the dictionary defines catalog as **"**a list or record, as of items for sale or courses at a university, systematically arranged and often including descriptive material"[21]. A catalog may be provided electronically via the internet or in hardcopy form as in a mail-order catalog. OEHHA declines to adopt a special definition of this term. Further, it is not necessary to amend subsection (a) as the commenter suggests. Subsection (a) simply provides general non-mandatory guidance for how safe-harbor warnings can be provided in general for consumer products. Subsection (c) provides more specific guidance for providing safe-harbor warnings for products sold in catalogs.

As for the additional warning methods proposed by the commenter, a warning provided only on product's labeling when it is sold via a catalog would be consistent with the regulation's safe-harbor requirements because, as discussed in the previous responses, the purchaser would only see the warning after receiving the product and would have limited options for returning it.

While the regulations do not specifically identify "audio" warnings as an option, it may be possible in some circumstances to provide a warning in an audible form. The suggestion that the warning be provided in a separate email to a customer was not adopted. Such a warning would likely be provided after the purchase and potentially would not be received or read prior to exposure. No further changes to the regulations were made based on these comments.

[21] http://www.dictionary.com/browse/catalog

145. Comment (ACA): Objects to mandating Proposition 65 warnings for catalog sales. OEHHA is urged to clarify that if a manufacturer provides an on-product warning, they do not have to also provide the longer safe harbor warnings if the product is sold online by either the manufacturer or a downstream distributor. ACA raises further issues and suggests changes to the provisions for internet and catalog purchases.

Response: These comments were responded to above in the discussion of ACA's comments on subsection 25602(b) on internet purchases.

146. Comment (Environmental Coalition): The Coalition supports the requirement for catalog purchases that the warning be clearly associated with the product. Suggest adding a font size minimum to avoid game playing with the definition of "consumer information".

Response: The comment supporting the language in subsection (c) is noted. No response is required. In regard to concerns about font sizes, references to a specific font size have been replaced with the general readability and understandability standard for consumer products now in subsection 25601(c).

OEHHA believes this approach will ensure that the warning is not minimized but that retail sellers using catalogs will have sufficient flexibility to choose a font size that will fit with the display of product information and not overshadow other information in the catalog, while still ensuring the warning is conspicuous and legible. In the event specific issues arise after the regulations are in place, OEHHA will consider modifying the regulations to include a minimum font size for catalog warnings. No further changes to the regulations were made based on this comment.

Subsection 25602(d)

Foreign Language Requirements

147. Comment (AdvaMed and CRN): CRN states the foreign language requirement is impractical and ambiguous, and AdvaMed states that OEHHA is overstepping its boundary in requiring translation of a warning that is only applicable in California.

Response: OEHHA disagrees that it lacks authority to require that safe harbor warnings be provided in alternative languages in certain situations. As stated in the ISOR for these regulations:

> "Under subsection (d) [consumer] product exposure warnings must be provided in the same language or languages used for providing consumer information such as directions or ingredient lists on a label, labeling or sign accompanying a product in order to qualify for a safe harbor. OEHHA does not intend for this provision to apply where only the name of the product is provided in a language

other than English. This was determined to be the most feasible method to ensure that a warning is likely to be understood by non-English speaking members of the public without burdening a business with language requirements beyond those already provided with a product. This provision will allow people to read and understand the warning and should not create a significant hardship for businesses, since it only applies where the business is already providing consumer information in an alternate language. Given California's linguistic diversity, OEHHA believes this safe harbor requirement in the proposed regulation will further the purposes of the statute by expanding the number of individuals who can understand the warning, thus ensuring it is "clear and reasonable". Further, more than 25 percent of those individuals who participated in the UC Davis Extension Collaboration Center Study reported speaking a language other than English at home and over 15 percent chose to complete the survey in Spanish, thus reflecting a need for the information to be provided in alternative languages in some situations. "

Therefore, OEHHA believes it is appropriate to require that in some circumstances, a clear and reasonable warning should be provided in a language other than English.

Based on these and other comments, OEHHA modified the language in the regulations to clarify that the trigger for an alternative language warning is when a business provides other "consumer information" (as defined in subsection 25600.1(c)) regarding the product in an alternative language.

OEHHA may adopt regulations that interpret Proposition 65 and further its purposes (HSC section 25249.12(a)). For the reasons noted above, OEHHA believes that warnings provided to Californians in alternative languages, in certain situations, will further the purposes of the statute by ensuring the warning is likely to be read and understood by the person prior to exposure.

148. Comment (CalChamber, ACA, NPA, and CNCDA): The foreign language requirement is vague. OEHHA should specifically identify what constitutes "consumer information" and further provide a statement that the requirement is not triggered if the product name contains non-English words. It only makes sense for the requirement to be triggered if other health-related warnings for a product are given in multiple languages, not solely on the use of multiple languages on a label related to "consumer information." OEHHA should specify precisely what warnings must say when provided in other languages and that translated warnings are subject to the "rule of reason". As an alternative, OEHHA should include translated warnings on its website in lieu of requiring businesses to do so.

Response: In response to this and other comments, OEHHA adopted a definition for "consumer information" in Subarticle 1, subsection 25600.1(c) that includes the type of material that is and is not considered consumer information for purposes of this subsection. By way of example, if other consumer information for a product such as directions for use or assembly instructions are provided in an alternative language, the Proposition 65 warning should be provided in English and that alternative language. On the other hand, use of a Spanish word in the name of the product would not trigger the requirement that the safe harbor warning be provided in Spanish. To the extent feasible, OEHHA plans to post approved translations for commonly used warnings on its website. OEHHA has already done this for warnings for BPA exposures in foods.[22]

149. Comment (AHPA): In response to the previous version of the regulations released in January 2015 that was withdrawn and replaced in November 2015), subsection (d) implies that the manufacturer, packager, producer, distributor are required to have advanced knowledge about all languages in which retailers may provide warnings for their products, and that all warnings will be provided in precisely the same printed material. As an example, a product with a warning on a label printed in English that is being sold in a store that uses signage in another language like Spanish or Korean, this would mean the label would have to be printed in these other languages.

Response: Based on this and other comments, OEHHA modified the language in the regulation to clarify that the trigger for an alternative language warning is where a consumer product sign, label or shelf tag *used to provide a warning* includes "consumer information" (now defined in subsection 25600.1(c)) in a language other than English. This amendment means that alternative language warnings will be triggered based only on information provided for that particular product. In the vast majority of situations, OEHHA believes the other consumer information will originate with the product manufacturer. In that case, the manufacturer can include the warning in the appropriate alternative language on the product label or labeling. Otherwise, the manufacturer, or other business in the chain of commerce would provide the warning in the appropriate language(s) to the retailer under Subarticle 1, subsection 25600.2(b).

150. Comment (CalChamber): Food labels should be exempt from multiple languages because of space limitations and the heightened need for importance of nuance and context.

Response: OEHHA disagrees with the commenter. First, food product labeling presents the same challenges as labeling for other consumer products. OEHHA has provided a "short-form" warning option in subsection 25603(b) which may be used for

[22] See https://www.p65warnings.ca.gov/chemicals/bisphenol-bpa for translated warning in nine commonly-used languages.

warnings where space is limited. OEHHA will consider adopting warning methods or content for food-related exposures upon request. However, there have been no specific requests for warnings that contain "nuanced" or contextual information in addition to that already provided in the regulation. OEHHA declines to make further changes to the regulations based on this comment.

151. Comment (CalChamber and ACA): CalChamber states that subsection (d) does not take space limitations into account. The requirement should, where triggered in the consumer product context (as distinct from the environmental exposure contact), be limited to only one language in addition to English with the additional language being the most likely to be understood by consumers of that product in California (i.e., Spanish in most cases, except where the product is targeted predominately for use by a different ethnic subpopulation). ACA asks for an evaluation of how the requirement impacts the limited space on labels, noting it burdens manufacturers by requiring more information in a finite section of product labels.

Response: Based on this and other comments the regulation was revised to clarify that the alternative language warning need only be provided on a product sign, label or shelf tag where consumer information in an alternative language is already being used on that sign, label or shelf tag. Given that the sign, label or shelf tag is specifically targeting persons who speak that language, it is reasonable to require that the warning also be provided in that language. There is no reasonable basis for restricting the alternative languages to only one, if several are already being used on the sign, label or shelf tag. Where space is at a premium for an on-product warning, the regulation allows for a short-form warning to be provided (subsection 25603 (b)).

152. Comment (CHANGE and Environmental Coalition): The commenters support the use of additional languages for safe harbor warnings and all attempts to provide warnings to non-English-speaking populations.

Response: Comments are noted; no response is required.

153. Comment (NPA): Section 25602(d) provides a foreign language requirement to warn consumers in both English and in whatever language where a foreign word appears on either the label or labeling. NPA recommends adoption of the federal statute in the Federal Food Drug and Cosmetic Act concerning foreign language requirements to provide clarity and guidance to businesses on how to comply with this requirement; however 21 CFR section 101.15(c) (federal requirement) suffers from the same ambiguity on how to enforce such a foreign language requirement. OEHHA's proposal states that the foreign language requirement is triggered only if 'consumer information' about a product is provided in that foreign language; however, 'consumer information' can be broadly interpreted and could encompass product names or words

understood and contained in an English dictionary. If it is the intent of OEHHA to limit the foreign language requirement to specific circumstances, it should provide examples in its proposal as to when the foreign language requirement is triggered and when it is not.

Response: The commenter incorrectly states that the regulation requires warnings to be provided in foreign languages "where a foreign word appears on either the label or labeling." This is not correct. The regulation only requires foreign language warnings in certain specified circumstances. Further, subsequent to this comment, OEHHA has made clarifying changes to the regulations which should address the commenter's concerns. Subsection 25602(d) was modified to limit the consumer information in a language other than English that would trigger an alternative language warning to that found on the consumer product sign, label or shelf tag used to provide a warning.

Additionally, a definition of "consumer information" was added which includes warnings, directions for use, ingredient lists, and nutritional information, but does not include the brand name, product name, company name, location of manufacture, or product advertising. In the ISOR, OEHHA noted that "Consumer information includes ingredients or preparation instructions, but does not include foreign words that identify the product brand or the type of food, such as "salsa, "ravioli," "chow mein," etc." The regulatory language sufficiently narrows the scope of the type and location of "consumer information" that would trigger the safe harbor requirement for a language other than English under subsection (d); there is no need to adopt provisions of federal law to define the circumstances under which a language other than English is required under the Act. OEHHA therefore declines to incorporate the provisions of the Federal Food Drug and Cosmetic Act as recommended by the commenter.

154. Comment (ACMI and CGA): The translation requirement will add a significant burden and expense out of proportion to the limited added benefit. The only solution would be to enlarge packaging to create more label space, adding a significant monetary cost to company and thwarting efforts to decrease packaging and waste. OEHHA should eliminate the requirement.

Response: As noted above, based on this and other comments the regulations were revised to clarify that the warning need only be provided on a product sign, label or shelf tag where consumer information in an alternative language already appears on that sign, label or shelf tag. Given that the sign, label or shelf tag is specifically targeting persons who speak that language, it is reasonable to require that the warning also be provided in that language. Where space is at a premium for an on-product warning, the regulation allows for a short-form warning to be provided (subsection 25603(b)).

155. Comment (ACA and NEMA): If OEHHA adopts the foreign language requirement in the final regulations, the commenters encourage OEHHA to only require one Proposition 65 pictogram per warning if both English and additional languages are required. The foreign language requirement will likely cause confusion for consumers who do not purchase the product in the United States and who are not affected by Proposition 65. Manufacturers often include a foreign language on a label because the product is being sent to a foreign country. If the final regulations retain the foreign language requirement, then these foreign consumers will see the warnings in their language and not understand what they mean since Proposition 65 does not exist in that country. The commenters argue that the alternative language warnings should just be provided on the OEHHA website.

Response: Simply providing the alternative warning language on the OEHHA website will not ensure that non-English readers will see it prior to exposure. It would also create an unacceptable situation where English readers would see the warning on the product (or an adjacent shelf sign or tag), but non-English readers would have to search for the same warning on OEHHA's website. Therefore, OEHHA declines to limit the regulation in the manner suggested by the commenters. Whether or not two pictograms should be included will depend on the circumstances. Where the English and alternative language warnings are provided together, a second warning symbol would not be necessary. However, if the alternative language warning is not co-located with the English version, it would be appropriate to include the symbol with the warning message.

The potential for Proposition 65 warnings to appear on products sold in foreign countries is not new. Since the first Proposition 65 warnings began appearing on products in 1988, there likely have been manufacturers who have chosen to produce a single label containing a Proposition 65 warning for a product sold both in California and foreign countries. To the extent that the safe harbor requirements in these regulations result in more informative and meaningful warnings, any potential for confusion and undue alarm over Proposition 65 warnings in foreign countries will be minimized. Because English is widely spoken throughout the world, many interested foreign consumers would be able to view supplemental information on the warnings on OEHHA's website. OEHHA could also translate specific fact sheets and other website materials into alternative languages. OEHHA has already posted fact sheets on BPA in Spanish on its website.

156. Comment (CalChamber, ACA, and NEMA): The foreign language requirement will likely cause confusion for consumers who do not purchase the product in the United States and who are not affected by Proposition 65. Manufacturers often include a foreign language on a label because the product is being sent to a foreign country. If

the final regulation retains the foreign language requirement, then these foreign consumers will see the warnings in their language and not understand what they mean since Proposition 65 does not exist in that country.

Response: As discussed in the previous response, the issue raised by the commenters would apply equally to warnings provided in English on the product. Nothing in the regulations require that the warning be provided on a product label or that it be provided to consumers outside California. On-product labeling is just one option among others. In the event a business decides to provide the warning on the product label, and other consumer information on the label is provided in an alternative language, in order to claim a safe harbor, the business must include the warning in that alternative language.

Other General Comments on Section 25602

157. Comment (ACC): If OEHHA wants to discourage default use of safe harbor warnings where there is no significant risk, it can adopt additional safe harbor levels and/or issue more safe use determinations (SUDs). These actions would not solve the problem of inappropriate warnings, but would help businesses make exposure determinations and assert the HSC section 25249.10 exemptions.

Response: This comment is outside the scope of the rulemaking. Regulations addressing safe harbor levels are contained in Articles 7 and 8 and Safe Use Determinations are covered in Article 2. Although no response is required, OEHHA welcomes requests for SUDs, as well as suggestions for chemicals that require safe harbor levels. OEHHA will respond to such requests as resources permit. OEHHA also strives to develop safe harbor levels as a feasible form of assistance to the public.

158. Comment (CalChamber): In response to the previous version of the regulations released in January 2015 that was withdrawn and replaced in November 2015, stated that OEHHA does not acknowledge the difficulty across an entire product supply chain in limiting, controlling, and distinguishing which products ultimately are sold in California as opposed to those sold elsewhere.

Response: This issue exists under the existing regulations as well. In adopting Subarticle 1, section 25600.2, OEHHA is attempting to bring some consistency to the division of responsibility for providing warnings for products sold at the retail level. OEHHA will consider providing further guidance through a future rulemaking.

Section 25603 Consumer Product Exposure Warnings – Content

Warning symbol

159. Comment (ACA, ACC, CalChamber, CHPA, AdvaMed and NEMA): Using the American National Standards Institute (ANSI) symbol in Proposition 65 warnings could

cause confusion to consumers since it is commonly used in other contexts unrelated to Proposition 65. OEHHA should create a Proposition 65 specific pictogram. Some commenters suggested that the symbol should only be in black and white and that OEHHA should eliminate the mandate that the symbol be in yellow, eliminate the symbol altogether, or have a “P65” designation. CHPA states that the symbol is associated with acute hazards where death or a serious potential injury is possible and the symbol may be misunderstood or not be meaningful to the recipient. OEHHA should not insist on the misuse of an existing and well recognized standard symbol. Similarly, AdvaMed stated that in ANSI standards the same symbol means 'danger, warning or caution' and states it should be "only used on hazard alerting signs. It is not used on safety notice and safety instruction signs." OEHHA should not require manufacturers to label their products with a pictogram that says the chemical is “known to the State of California to cause cancer” where elsewhere in the U.S., and throughout the world, the pictogram means something completely different.

Response: As explained in the ISOR for the regulation, subsection (a)(1) establishes a warning symbol to be used on all safe harbor Proposition 65 product warnings, except where otherwise stated in Section 25607 et seq. The first pre-regulatory draft of the proposed regulation required the use of a pictogram developed under the Globally Harmonized System (GHS) for chemical health hazard warnings[23] because it has been adopted by numerous federal, state and international governments to identify toxic chemicals, including chemicals that cause cancer or reproductive toxicity.[24] However, several stakeholders were concerned that the GHS symbol would not be recognizable to most individuals outside the occupational context and would result in confusion and unnecessary alarm. In response, OEHHA considered potential alternatives and selected a symbol in general use that is presently more familiar to the general public. The symbol is the same as or similar to warning symbols in widespread use by businesses in the United States and internationally for general warnings and notifications, that can be represented by the Unicode character or emoji of “U+26A0”. In typical applications this general warning symbol is provided with an additional indication

[23] U.S. Occupational Safety & Health Administration, Modification of the Hazard Communication Standard (HCS) to conform with the United Nations' (UN) Globally Harmonized System of Classification and Labeling of Chemicals (GHS), available at https://www.osha.gov/dsg/hazcom/hazcom-faq.html.

[24] U.S. Occupational Safety & Health Administration, “Hazard Communication Standard Pictogram” (2014) available at https://www.osha.gov/Publications/HazComm_QuickCard_Pictogram.html. As noted on the page, the symbol is required to be used for health hazard warnings including carcinogenicity, mutagenicity, reproductive toxicity, respiratory sensitizer, target organ toxicity and aspiration toxicity.

of the type of hazard. The symbol is currently in use by many businesses for existing Proposition 65 warnings. Variations of the symbol are used by the ANSI.[25] OEHHA does not agree that the symbol is a misuse of an existing symbol.

The symbol selected for use by OEHHA consists of a black exclamation point in a yellow equilateral triangle with a bold black outline. In order to minimize potential economic impact from printing costs, the regulations provide that if the relevant signage or labeling on a product does not utilize yellow, the symbol may be printed in black and white. Figure 1 is an example of the symbol. The symbol in Figure 1 is provided solely for illustration purposes and should not be considered a scale representation. As provided in the regulations, the symbol size must be no smaller than the height of the signal word "**WARNING**" as described further below and in subsection (a)(2). Using a graphic symbol that is familiar to consumers on both a domestic and international level is likely to enhance the effectiveness of the warnings, particularly for non-English speaking or low literacy populations.

Figure 1. Warning symbol

(Not to Scale)

Several commenters voiced concern during the development of the earlier regulatory proposal that the warning symbol was confusing, alarming, and/or meaningless. The UC Davis Warning Regulations Study tested participant's reaction to the proposed warning symbol both in yellow and black and white formats. The most frequent reaction was that the symbol meant "warning." Few people expressed confusion or fear when viewing the symbol.[26]

After careful review and consideration of all the comments received regarding this issue, OEHHA decided not to develop a California-specific symbol for Proposition 65 warnings. The yellow triangle is easily recognizable and is already in use in a variety of contexts so there will be no need for an education campaign to alert the public about what the symbol means. Further, since it is already in use, including on Proposition 65 warnings, it should be relatively cost effective for businesses to begin using it. If a

[25] Additional background information and FAQs can be found on the ANSI website located at http://www.ansi.org/about_ansi/faqs/faqs.aspx?menuid=1#overview.
[26] Appendix A, UC Davis Extension Collaboration Center, Proposition 65 Clear and Reasonable Warning Regulations Study: Survey results assessing the effectiveness of existing and proposed Proposition 65 warning signs, p. 36, (2015).

business decides not to use the symbol with their warning, it can do so (subsection 25600(f)). No change to the regulations was made based on this comment.

160. Comment (ACMI): ACMI acknowledges that the safe harbor regulations are voluntary and that a company may provide a warning without any symbol, or with another symbol altogether. However, a company acts at its peril if it does not implement the safe harbor warnings, opening the door to litigation.

Response: The concern stated in the comment is noted. The regulations provide businesses with the flexibility to either use the safe harbor warning or not, depending on their situation. OEHHA believes, for the reasons already stated in response to similar comments and in the ISOR, that the warning symbol is a reasonable and necessary part of the safe harbor warning. Businesses that believe they can provide a clear and reasonable warning without the symbol and are willing to incur the risk of a legal challenge are free to do so.

161. Comment (ACA, ACMI): Many ACA members must comply with the federal Hazard Communication Standard requirements and the GHS pictograms which use red and black, and would thus not be able to use the black and white color option. Members have spent thousands of dollars to purchase two-tone (red/black) printers. The commenters recommend that manufacturers using GHS pictograms be allowed to use the black and white option. ACMI also stated that the requirement for a symbol to be in color is burdensome and expensive. Even where the label already is in color, adding another color element to the label adds a significant additional cost without any perceptible additional benefit. This requirement should be eliminated.

Response: The regulations allows businesses to print the symbol in black and white if the label or sign does not already contain the color yellow. It is not clear from the comment why the same printer cannot be used to print in black with a white background. Further, the regulations allow for the provision of warnings via methods other than on-product labels. These methods include package inserts, which may be more cost-effective for some businesses. OEHHA declines to authorize the use of other colors associated with the GHS for the pictogram for safe harbor warnings. Proposition 65 covers exposures from a wide variety of sources well beyond the reach of the GHS. Using black and white or yellow and black pictograms will help avoid confusion concerning the meaning of the warning in relationship to warnings being provided for occupational exposures under the GHS. The warnings provided in this section are non-mandatory safe harbors, and a business can use other methods, content and colors for their warnings as long as the warning meets the “clear and reasonable” requirement in the statute. OEHHA declines to eliminate the color requirement as requested by ACMI.

162. Comment (ACC): The pictogram magnifies the warning component. It could heighten the concern among consumers rather than simply draw attention to the warning. OEHHA's recommendations with respect to font size and placement ensure consumers will receive the warning in a meaningful and effective manner without the need of a pictogram. The UC Davis Study did not test Proposition 65 warnings on actual consumer products or at facilities to see if people had any difficulty in real world conditions noticing warnings or whether the symbol would help them notice warnings.

Response: The purpose of including the symbol is discussed in the ISOR for the regulations. It is specifically intended to draw attention to the warning. The ACC critique of the UC Davis Study was responded to by the researchers. Their response is attached to the FSOR as Attachment "A" and is incorporated here by reference.[27] The vast majority of the study participants said the pictogram symbol meant "warning," "danger" or "caution". Few participants said the pictogram confused or scared them.

163. Comment (ACC): The same symbol is being used nationally by the food industry as part of the Grocery Manufacturers Association's (GMA) new SmartLabel™ program to signify allergens raising a distinct possibility that a food product will have the same symbol twice on a product with different meanings.

Response: The commenter is incorrect. According to information available on GMA's website, the SmartLabel™ program will provide detailed information on products through SmartLabel™ via the internet or by using a mobile device to scan a QR code on the package.[28] There is no indication that the system being developed by GMA intends to use on-product labels with warning symbols. Also, the warning symbols used by the food industry are not the same as the one required by these regulations for use in the safe harbor warning,[29] and should be easily distinguishable by a consumer. Further, the symbol is not required under the federal Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II, 21 U.S.C. §§ 301–399).[30] The regulations do not require businesses to use the warning symbol on food warnings so there is even less likelihood that a consumer will be confused.

[27] The letter response was not relied on in the development of the regulation but is included here for reference.
[28] http://www.gmaonline.org/file-manager/SmartLabel%20FAQ.pdf
[29] See for example: https://www.foodprotection.org/resources/food-allergen-icons/ which provides black and white icons using a triangle shape but with pictures of the allergens being referenced. Others use circular icons or pictures of the allergen with no symbol.
[30] A discussion of labeling requirements available at: http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm106890.htm#gener.

164. Comment (TVC and CHPA): The symbol will not provide an additional benefit to the public over a written warning. Companies will have to incur costs to reconfigure current labeling and the expenses will be passed on to purchaser.

Response: OEHHA disagrees that the symbol will not benefit the public. As noted above, the UC Davis Study found that the study participants found the warnings that included the symbol more helpful than those that did not. The symbol is intended to draw attention to the warning and appears to do so without generating undue alarm. Further, OEHHA conducted an economic impact assessment for the changes to the warnings that will occur based on the changes to the regulations. OEHHA determined the costs will not be significant and businesses will have two years to make the transition so costs that are incurred to change over to the new format can be spread out over a period of time. Lastly, the regulations are non-mandatory safe harbors. If a business determines it is too expensive to change over to the new format, it is not required to do so by these regulations.

165. Comment (ASE): ASE recommends that OEHHA clarify the shape, size and color of the symbol requirements. ANSI standards (Z535.6) permit safety alert symbols to be printed either in black and white or black and yellow, regardless of colors used elsewhere. ASE recommends that OEHHA use a similar approach allowing either black and white or black and yellow.

Response: The symbol selected by OEHHA consists of a black exclamation point in a yellow equilateral triangle with a bold black outline. In order to minimize potential economic impact from printing costs, the regulation provides that if the relevant signage or labeling on a product does not already utilize yellow, the symbol may be printed in black and white. Figure 1 is an example of the symbol using yellow. Figure 2 is an example of the symbol using black and white. The examples in Figures 1 and 2 are provided solely for illustration purposes and should not be considered a scale representation. Under the regulations, the symbol size must be no smaller than the height of the signal word “WARNING” as described in subsection (a)(2).

Figure 1. Warning symbol (Not to Scale)

Figure 2. Warning symbol (Not to Scale)

The black and white symbol is intended to have a black outline, black exclamation point and white interior for the triangle. OEHHA declines to be more prescriptive in the regulations. As long as the business makes a good-faith effort to present the symbol in the format provided in the regulations, minor differences in the shade of color used or thickness of outline for the triangle would still comply with the safe harbor provision in the regulations. Examples of both versions of the warning symbols will also be provided on the OEHHA website for download.

166. Comment (CAPA): CAPA interprets the language in subsection 25603(a)(1) authorizing a symbol to be printed in black and white on a sign, label or labeling that is not printed using the color yellow to include warnings on cash register receipts. If the interpretation is consistent, CAPA encourages OEHHA to confirm so in the FSOR.

Response: As noted in response to previous comments regarding cash register receipt warnings, while there may be circumstances where a warning provided on or with a cash register receipt may be clear and reasonable, that method of warning is not specifically adopted as a safe harbor method in these regulations. It is likely that such a method of warning would require additional notice by a consumer to look for the warning on the receipt and would need to include a simple process for immediate return of the product if the consumer decides they do not wish to keep the product once they know a warning is required. Any such warning method would still need to meet the "clear and reasonable" warning requirements of the law. OEHHA may consider adopting a regulation specific to a given industry or product in the future. As stated in the ISOR for these regulations:

> "The "catch-all" provision in subsection (a)(2) is intended to capture existing and future methods of communication, including currently available tools such as electronic shopping carts, smart phone applications, barcode scanners, self-checkout registers, pop-ups on Internet websites and any other electronic device that can immediately provide the consumer with the required warning. OEHHA does not intend for this provision to be read in such a way that a business may rely exclusively on a website or other device to provide a warning where the individual must seek out the warning. For example, a general reference to a website would not comply with this provision or the Act. Similarly, an invitation to go to a website to determine which products within a given facility require a warning would not comply with the Act."

OEHHA's intent in adopting these provisions in the regulations is to allow businesses to use electronic means to provide warnings where such means provide a clear and reasonable warning. OEHHA has not adopted a cash register receipt warning as a safe harbor method in these regulations. OEHHA may consider adopting such a provision in the future. No change to the regulations was made based on this comment.

167. Comment (CHANGE): CHANGE supports the use of the "exclamation mark/triangle" symbol to identify safe harbor warnings.

Response: Comment noted, no response required.

168. Comment (Environmental Coalition): The Coalition supports the use of the triangle symbol. The regulations should be revised to require the symbol for all warnings covered by this article.

Response: The regulations require the use of the symbol in most circumstances. Exceptions include warnings provided for foods, prescription drugs and occupational warnings where the Federal or State Hazard Communication Standard warnings cover the exposure. For foods, instead of requiring the warning symbol, the warning is required to be set off from other information on a product's label and be enclosed in a box. This is consistent with the way other important information is handled on food labeling and should be sufficient to draw the warning to the consumer's attention. Where there are mandatory federal warning requirements for warnings for prescription drugs or occupational hazards, the regulations do not require a separate Proposition 65 warning or symbol. This approach has been carried over from the existing regulations. For these reasons and those set out in the ISOR for these regulations, OEHHA believes the warning symbol should not be required in these specific circumstances.

"Warning" and toxicity endpoints

169. Comment (CSPA): Use of the word "WARNING" is problematic as this word conflicts with labeling provisions for both Consumer Product Safety Commission and Federal Insecticide Fungicide Rodenticide Act products. CSPA requests a change to the regulations to allow use of 'IMPORTANT' or 'NOTE' with a required Proposition 65 warning to prevent consumer confusion and to avoid misuse or other safety concerns. Also the Proposition 65 signal word and symbol may confuse consumers about other signal words and pictograms required under other authorities.

Response: The signal word "Warning" has been carried over from the existing regulations and has been used in Proposition 65 warnings since the regulations were adopted in 1988. OEHHA has not seen any evidence that use of the word is problematic as it relates to other warnings that may be provided for a given product under other state or federal laws. As stated in the ISOR, OEHHA contracted with the UC Davis Extension Collaboration Center to conduct a study to better assess the effectiveness of the existing and proposed new warnings. The purpose of the study was to assess whether the existing or proposed safe harbor warnings more clearly communicate that the chemical in question is known to the State of California to cause cancer, birth defects or other reproductive harm. The effectiveness of the warnings was

assessed in terms of helpfulness. The results showed that over 75 percent of the participants selected the warnings based on the proposed regulations as being more helpful than the existing regulations. The participants also overwhelmingly supported the use of specific elements of the proposed regulations, such as the use of the warning symbol and inclusion of chemical names.

170. Comment (AHPA): In response to the previous version of the regulations released in January 2015 that was withdrawn and replaced in November 2015, commented that the warning content is alarming and inflammatory. The word, "chemical" is misleading and the words, "cancer", "birth defects" and "reproductive harm" are inherently alarming to consumers. The pictogram and word, "Warning" will make warnings more alarming. The Act requires exposed individuals to be warned, not frightened. Recommend replacing "chemical" with "substance" because of the negative connotations that "chemical" suffers.

Response: The words “warning”, “cancer,” “birth defects,” and “reproductive harm” are already used in Proposition 65 warnings and have been for nearly 30 years. All these words come directly from the statute or ballot arguments (in regard to “birth defects”), as does the word “chemical”. No evidence was provided to support the contention that these words will cause undue concern among consumers who are already used to seeing them in warnings in a variety of contexts in California. To the contrary, the UC Davis Study found that most study participants did not find the words alarming at all. OEHHA therefore declines to change the generally-used terminology for Proposition 65 incorporated in this rulemaking.

171. Comment (AHPA): In response to the previous version of the regulations released in January 2015 that was withdrawn and replaced in November 2015, AHPA objects to subparagraphs (B), (C), and (D) that require listing of "birth defects" and "reproductive harm", especially when the chemical causes only one or the other effect. AHPA requests the return to pre-regulatory language that mentioned only "reproductive toxicity". If OEHHA requires both terms, then it should require only the term that fits the circumstances.

Response: The words “birth defects” and “reproductive harm” are already used in Proposition 65 warnings and have been for nearly 30 years. These words come directly from the statute or ballot arguments (in regard to “birth defects”), as does the word “chemical”. OEHHA has made changes to the safe harbor warning content to clarify what must be said about the listed chemicals in each warning. The Proposition 65 list indicates whether a chemical causes male reproductive toxicity, female reproductive toxicity, or developmental toxicity, or some combination of these endpoints, and a business may decide to provide a more specific warning, which may be preferable in certain instances such as in the case of alcoholic beverage warnings for birth defects.

However, to be covered by the safe harbor, the regulations provide for a warning that more simply states a chemical can cause “birth defects or other reproductive harm”. This phrase has been carried over from the existing regulations and has been in use since 1988. OEHHA considered using the term “reproductive toxicity” instead, but determined it would be less clear to the ordinary person seeing the warning. The regulation in subsection 25600(c) provides mechanisms for requesting the lead agency to adopt more specific alternative safe harbors in regulation or guidance on warnings through Interpretive Guideline Request or Safe Use Determinations.

“Can expose”

172. Comment (CHPA): The phrase “can expose” represents an improvement over “will expose”, however, CHPA continues to believe that current Proposition 65 language stating “this product *contains* [emphasis added] a chemical known to the state of California to cause” adequately conveys the necessary information and is most recognizable to consumers.

Response: As explained in the ISOR for these regulations, the regulations set out the message that must be provided in each warning in order to qualify for a safe harbor. The most significant change to the content of the message in these regulations versus the existing safe harbor regulations is the use of the phrase “can expose you to”, rather than the word “contains”. Since the existing regulations were adopted over 25 years ago, it has become clear that using the word “contains” does not communicate the fact that individuals can actually be exposed to a chemical if they use a given product or enter an affected area. The statute clearly states that warnings are required for knowing and intentional *exposures* to listed chemicals. Warnings are not required where a product simply “contains” a listed chemical but may not actually have the potential to cause an exposure. Using the word “contains” in the warning is confusing for both businesses and the individuals receiving the warning. For example, under the existing regulations it is not clear to many businesses that a warning is not required for a chemical that is contained in a product in such a way that it cannot foreseeably cause an exposure (e.g., where the chemical is bound in a matrix, such as carbon black embedded in plastic, or sealed inside the product like a battery that contains lead, but is inaccessible to the average user of the product). On the other hand, individuals who see a warning for the content of a product often will not know if they actually can be exposed to a listed chemical and might not take such a warning seriously. Therefore, OEHHA has determined that the phrase “can expose you to” provides greater clarity and consistency with the requirements of the Act than the “contains” language in the existing regulations.

Some stakeholders have objected to the use of the word “expose” in product warnings because they are concerned that it will cause unnecessary alarm and because they allege that an exposure may not actually occur. These concerns are anecdotal and are contrary to the data generated in the UC Davis Warnings Regulations Study. Further, Proposition 65 is a right-to-know law. The purpose of the statute is to provide people with notice concerning their exposures to listed chemicals. The preamble to the law states in part that:

> “Section 1. The people of California find that hazardous chemicals pose a serious threat to their health and well-being . . . .
> The people therefore declare their rights: . . . .
> (b) To be informed about *exposures* to chemicals that cause cancer, birth defects, or other reproductive harm . . . .” (Emphasis added)

Clearly, the citizens who voted for the law wanted to be informed about actual exposures to carcinogens and reproductive toxicants. They did not anticipate that they would receive vague warnings about the content of the products they purchase and use without providing any context for that information. Such general warnings generate confusion and encourage businesses to provide a warning even when none is required, precisely because they are so vague and meaningless. Requiring that the warnings include more specific, relevant information will further the right-to-know purposes of the law and reduce the likelihood that businesses will provide unnecessary warnings for non-existent or insignificant exposures.

Using the “can expose you to” language in the regulations furthers the purposes of the statute. No changes to the regulations were made based on this comment.

173. Comment (AASA et al.): The proposal better reflects the reality of risk which is exhibited through a combination of hazard plus exposure. The term "may" best reflects potential exposure and urge OEHHA to change "can expose" to "may expose" throughout the full proposal.

Response: A prior draft of the proposed regulations used the term “will expose”. Some stakeholders expressed concerns that some products might or might not expose the public to a listed chemical, depending on how they are used. There were also concerns because some products contain varying levels of a listed chemical, so any individual sample of the product may or may not actually expose the consumer. For these reasons OEHHA chose the term “can expose” rather than “will expose”. Changing the language to “may expose” would not add any further clarity to the regulations so the change was not made.

174. Comment (Environmental Coalition): The Coalition supports changing the warning’s wording to specify that a product “will expose you to a chemical.” The

wording informs the consumer that the product contains a chemical at a level that will result in an exposure. If OEHHA does not agree, the Coalition suggests that the required warning state that the product "contains and can expose you to a chemical." This language, while not as strong as "will expose," emphasizes that the product does contain the listed chemical, yet allows for some doubt about whether exposure will occur. A stronger warning language requirement incentivizes better science, more responsible behavior by business, and gives the consumer greater clarity. Also by encouraging more testing by industry, it furthers the Governor's goals of decreasing over-warning. The language "can expose" is still stronger than the current regulations and support that change.

Response: As explained in response to previous comments, a prior draft of the proposed regulations used the term "will expose". Some stakeholders expressed concerns that some products might or might not expose the public to a listed chemical, depending on how they are used. There were also concerns because some products contain varying levels of a listed chemical, so any individual sample of the product may or may not actually expose the consumer. For these reasons OEHHA chose the term "can expose" rather than "will expose". OEHHA declines to add the additional language suggested in the comment because it would not increase clarity (the chemical is necessarily present or it cannot cause an exposure) but would add to the length of the warning message.

175. Comment (TVC): TVC cannot support the proposed change to the product exposure warning language. Both the existing and proposed language warn of the presence of a listed substance in a product; however, the proposed language "can expose you" suggests that exposure could occur even if none actually would. This can be misleading or even incorrect depending on the listed substance, the product in which it is found, and the use of that product. The proposed warning language will not benefit the product user and is inconsistent with existing statute HSC section 25249.7(h)(1)-(2) where the claim is not based on "actual or threatened exposure" and can be deemed frivolous by the reviewing court. TVC fails to see how the proposed language promotes either consumer education or the reduction of "stick-up" lawsuits where the goal of the plaintiff is to settle before it is put to proving actual or threatened exposure.

Response: Health and Safety Code section 25249.6 requires that businesses provide warnings for exposures to listed chemicals. The regulation only applies where a business has already decided to provide a warning (subsection 25600(a)). As noted in response to similar comments submitted during this rulemaking, OEHHA has determined that the phrase "can expose you to" provides greater clarity and consistency with the requirements of the Act than the "contains" language in the existing regulations.

Health and Safety Code sections 25249.7(h)(1) and (2) relate to the Certificate of Merit requirements for filing Notices of Violation, not the warning requirements of the Act. The portion of the comment related to the reduction of litigation is outside the scope of this rulemaking.

Naming listed Proposition 65 chemicals

176. Comment (TVC, ABA, AHPA): Including the name of one or more chemicals makes the warning cumbersome, lengthy, potentially unmanageable and creates additional costs to labelers. It would require testing for all substances to determine the presence in a product or the environment. Currently the drafted regulations suffer from ambiguous drafting, leaving room for conflicting interpretations and undoubtedly result in increased "bad warning" enforcement actions. ABA requests eliminating the requirement that warnings provide the name of one or more chemicals. TVC commented that adding chemical names in a warning does not improve communication to the public. The regulation needs clarification on how to determine which one chemical to include in the warning if more than one chemical is present. AHPA also objected to the naming of chemicals.

Response: OEHHA has determined that requiring the name of a chemical for each endpoint is consistent with the purposes of the Act and does not believe the change makes the warning cumbersome, lengthy, unmanageable or significantly add costs. As stated in the ISOR, OEHHA contracted with the UC Davis Extension Collaboration Center to conduct a study to better assess the effectiveness of the existing and proposed new warnings. The purpose of the study was to assess whether the existing or proposed safe harbor warnings more clearly communicate that the chemical in question is known to the State of California to cause cancer, birth defects or other reproductive harm. The effectiveness of the warnings was assessed in terms of helpfulness. The results showed that over 75 percent of the participants selected the warnings based on the proposed regulations as being more helpful than the existing regulations. More specifically, 66 percent of the respondents said the warnings that named chemicals were more helpful than warnings that did not.

The regulation does not require businesses to test their products. The regulation simply provides safe harbor warning methods and content for businesses that have already determined they are causing an exposure to a listed chemical and need to provide a warning. In regards to determining which chemical to include in the warning, given that Proposition 65 does not establish any clear hierarchy of concern for listed chemicals, OEHHA determined that the decision concerning which chemical to name on the warning should be left to the business causing the exposure. Under the regulations, a business can claim safe harbor protection by naming any one or more of the chemicals

for which the warning is being provided, as long as one chemical name is included for each endpoint covered by the warning, unless the chemical is listed for both endpoints. OEHHA declines to eliminate the requirement as recommended by the commenter. For further discussion on the requirement that chemicals be named see responses to comments above on subsection 25601(c) (now 25601(b)).

177. Comment (ACC): For the same reasons stated previously opposing the use of the 'list of 12' that such a super list was inappropriate and unauthorized by the statute, no specific chemicals should be designated for any particular product or area of exposure. If any chemicals must be named, the choice of which chemicals should be at the discretion of the business, as provided for in Section 26301 [citation in error, should refer to Section 25601].

Response: The list of twelve chemicals that must be included in the warning was in the withdrawn proposed regulation published in January 2015, and does not occur in the November 2015 version of the regulations. Given that Proposition 65 does not establish any clear hierarchy of concern for listed chemicals, OEHHA determined that the decision concerning which chemical to name on the warning should be left to the business causing the exposure. Under the regulations, a business can claim safe harbor protection by naming any one or more of the chemicals for which the warning is being provided, as long as one chemical name is included for each endpoint covered by the warning, unless the chemical is listed for both endpoints. For further discussion on the requirement that chemicals be named see responses to comments above on subsection 25601(c) (now 25601(b)).

178. Comment (Auto Alliance et al.): The commenter believes OEHHA's intent is to establish a compromise position between a business listing all chemicals on the warning and not having to identify any specific chemical. However, the proposal would open a business to litigation over chemicals that are not identified in the warning. Suggest a change to "… expose you to chemicals, including [at least one specifically identified chemical] known to the State of California…." This is the language used in OEHHA's UC Davis Study, which participants said provided clear information.

Response: The regulatory provisions have been modified based on this and other comments. However, the suggestion to use "[at least one specifically identified chemical]" was not adopted because it would be less clear than "one or more" chemicals which is used in the regulations. As stated in responses to earlier comments to subsection 25601(c) (now 25601(b)), a business may choose to name any one or more chemicals for which the warning is being provided. All warnings must include the name of at least one chemical, but some warnings must include one chemical for each endpoint. The regulations essentially retain the language used in the UC Davis Study.

Inclusion in warning of website link www.P65Warnings.ca.gov

179. Comment (CPSA): Because OEHHA does not have information on exposure assessments for the product as this is done by the company, a link to the OEHHA website will provide little help to the consumer on this point.

Response: OEHHA is not depending on exposure assessments to provide supplemental information on its website about listed chemicals and products that commonly carry warnings. The website went live in March 2016, and contains general information for the public on the health effects of listed chemicals, how individuals in general may be exposed to chemicals from various kinds of products, and steps they can take to reduce or avoid exposures. The website is not intended to contain information on exact levels of exposures from specific products. To the extent that OEHHA requires information about chemicals in products that bear warnings, exposures to those chemicals, or steps to reduce or avoid exposures, OEHHA already has the authority to request that information from a business that is providing a warning.

180. Comment (AHPA): In response to the previous version of the regulations released in January 2015 that was withdrawn and replaced in November 2015, AHPA objects to the link to OEHHA's website, particularly for small package sizes. The requirement should be similar to the federal labeling regulations with provisions for less information without cryptic and frightening alternate warnings.

Response: As stated in the ISOR for these regulations, “The regulation would also require the inclusion of a Uniform Resource Locator (URL) in all warnings so that the information on OEHHA’s website can be accessed easily by most consumers. The internet did not exist when voters approved Proposition 65 in 1986, but most modern-day Californians expect that important or meaningful information will be accessible on the internet. The UC Davis Warning Regulations Study assessed how likely participants would be to visit the Proposition 65 website if they wanted additional information. Over half of the respondents said they are “very likely” or “somewhat likely” to visit the website. Having the OEHHA website URL available on the warnings will allow individuals who receive warnings to easily access additional information regarding the potential exposure. As noted earlier in the document, many current warnings incorporate a URL. OEHHA believes that this approach will allow businesses to continue to provide a short warning message that complies with the Act, while pointing interested persons to a location where they can obtain more information. A companion regulation outlines the structure for the website and the general kind of content it provides.

“Subsection (b) sets out a specific short version of the warning that may only be used for on-product warnings. This provision proposes a very limited level of content to be

included in an on-product warning to accommodate some product manufacturers' stated concern that a longer warning message will simply not fit on the labeling or packaging of some small products. OEHHA is proposing a label that strikes a balance between this concern and the requirement in the statute that a person receive a warning prior to exposure. OEHHA believes that this approach will provide useful information to individuals while avoiding unwieldy on-product warnings. Further, the warning is clearer and more direct than the existing safe harbor warnings being used by many businesses. Recognizing the potentially limited space available for a warning, under subsection (c) the name of the listed chemical being warned for is not required."

For the reasons stated OEHHA declines to remove the requirement to include the URL in the safe harbor warnings.

Font size

181. Comment (AHPA): In response to the previous version of the regulations released in January 2015 that was withdrawn and replaced in November 2015, AHPA appreciates that there are no type size requirements proposed in subsection (a)(2)(A)-(D).

Response: Comment noted, no response required.

182. Comment (Environmental Coalition): In response to the previous version of the regulations released in January 2015 that was withdrawn and replaced in November 2015, the Coalition recommends using a sliding scale for font size.

Response: Based on these and other comments, the font size requirements in the previous draft of the regulations were changed throughout the regulations.

Short-form on product warning content

183. Comment (CalChamber): In response to the previous version of the regulations released in January 2015 that was withdrawn and replaced in November 2015, the short-form warning for on-product use in subsection 25603(b) would not likely be used and thus would not be a meaningful warning option.

Response: Comment noted. The regulations provide the short-form warning as an option for providing a safe harbor warning. It is not required to be used.

184. Comment (DRoe): Subsection 25603(b)(2) should be re-drafted to refer not to a product that causes exposure to a listed chemical, but to a consumer product that is the source of exposure to a listed chemical.

Response: OEHHA determined that the suggested changes would not add clarity to the regulations. No change was made based on this comment.

185. Comment (TVC): Need clarification on what constitutes, "on-product" in subsection (b).

Response: For purposes of subsection 25603(b), on-product refers to the product itself, as well as the immediate container, box, or wrapper of the product, but would not include other types of “labeling” as defined in subsection 25600.1(j).

186. Comment (ACMI): In subsection (b), the exclamation point symbol is required to be used for certain Federal Hazardous Substances Act hazard warnings. (See, e.g., 15 U.S.C. section 1278(a)(2)). Some products are subject to these specific requirements, and are required to bear such warnings with the associated symbol to alert the user to certain imminent hazards like choking hazards. Use of the same symbol for Proposition 65 warnings likely will confuse product users, and certainly will dilute the symbol’s meaning in these other critical safe use contexts. OEHHA should craft another symbol that users will learn to specifically associate with Proposition 65.

Response: Using the exclamation point symbol in this manner is not inconsistent with other signage requirements under other laws. OEHHA believes that the instances of overlaps, such as with choking hazard warnings, will be rare, and will not dilute the impact of either warning. The UC Davis Study found that the symbol did not cause confusion among its participants, and that it was interpreted as being intended to draw attention and highlight the warning, just as is the case with other warnings using a similar symbol.

Internet and mail order catalog warning for products that use the short-form

187. Comment (CalChamber, ACA, CTA, and FWC): CalChamber noted that while the required safe harbor language for truncated warnings is clear in subsections 25603(b) and (c), it is unclear whether internet or mail order catalog retailers who sell products bearing on-product warning labels must also warn online or within the catalog using the methods identified in subsections 25602(b) and (c). It can be interpreted to promote an unprecedented warning regime where certain products would require two Proposition 65 warnings merely because of the manner in which they are sold. Several commenters recommended a new subsection (d) that states a retail seller that sells a product containing an on-product warning label via mail order catalog or the internet is not required to provide an additional warning for that product. Some stated it creates unfairness between brick-and-mortar stores and online and catalog retailers.

Response: In response to this and other comments, changes were made to subsections 25602 (b) and (c). Under subsection 25602(b), where a product is sold on the internet in order to take advantage of the safe harbor provided in the regulation, the warning must be provided on the product display page or be otherwise prominently displayed prior to the customer completing the purchase. The warning label used on

the product may be reproduced or pictured on the internet website. Similar changes were made to subsection 25602 (c). Also in response to this and other comments, subsection 25600.2(b)(3) was modified to require product manufacturers, producers, packagers, importers, suppliers, and distributors to provide retail sellers with warning language to use on their websites for the product. Where the product manufacturer has included the warning on a product label or labeling, the retail seller may use the same warning language on their website, or provide a picture of the label or labeling for the product to the extent that the warning is readable and legible in the picture. This should alleviate any significant cost burdens for retail sellers, while ensuring that consumers are warned prior to exposure to a listed chemical from products sold over the internet. OEHHA declines to add a new subsection as requested by commenters.

188. Comment (ACA): ACA supports providing abbreviated warning requirements for on-product labels to accommodate size constraints.

Response: Comment noted, no response required.

189. Comment (ACA): OEHHA must ensure it does not exceed its statutory authority by regulating products outside of California. If manufacturers providing on-product warnings are exempted from online sales and catalog warning requirements, then it should be clarified in subsections 25603(b) and (c) .

Response: OEHHA disagrees that it is attempting to regulate products outside of California. Many products that are sold outside California carry Proposition 65 warnings because the product manufacturer has determined that it is infeasible to only provide warnings to California purchasers. However, nothing in the regulations requires the manufacturers to provide warnings outside California. As the lead agency for implementation of Proposition 65, OEHHA "may adopt and modify regulations, standards, and permits as necessary to conform with and implement this chapter and to further its purposes."[31] The regulations do not provide an exemption from the internet and catalog warning requirements for products that also carry an on-product warning. Subsection 25600.2(b)(3) was modified to require product manufacturers, producers, packagers, importers, suppliers, and distributors to provide retail sellers with warning language to use on their websites for the product. Where the product manufacturer has included the warning on a product label or labeling, the retail seller may use the same warning language on their website, or provide a picture of the label or labeling for the product to the extent that the warning is readable and legible in the picture.

190. Comment (CRN): The short-form warning labels present a conflicting message with the existing Federal labeling requirements and are misleading to consumers.

[31] Health and Safety Code section 25249.11(a)

Response: The regulations provides the short-form warning as an option for providing a warning. It is not required to be used. OEHHA is not aware of any situation in which the warning directly conflicts with Federal law other than those already addressed by the regulations (i.e. prescription drug warnings). In the event a business determines that providing the warning using this method would conflict with other requirements, the business can use another method for providing the warning.

191. Comment (ACA): If OEHHA requires two Proposition 65 warnings for products with on-product warnings that also are sold online or in a catalog, ACA encourages OEHHA to consider requiring that the internet or catalog warnings be the shorter warning that is prescribed for on-product warnings.

Response: In response to this and other comments, OEHHA modified subsection 25602(b) of the regulations to allow product manufacturers to use the same warning language for internet warning as they use for on-product warnings.

192. Comment (ACA): OEHHA should confirm that an on-product warning label is consistent with the term “affixing a label” under subsection 25600.2(b).

Response: OEHHA agrees with the commenter that a warning may be provided on a product by “affixing” a label. For example, the warning can be “affixed” by printing the warning on the product, its immediate container or wrapper or applying a sticker to the product, immediate container or wrapper.

Recommendations to establish de minimis concentration in products

193. Comment (Auto Alliance et al., ITW): Auto Alliance et al. noted that the intent of Proposition 65 is to warn of exposures rather than of chemicals contained in a product. However, without de minimis exemptions, companies would need to perform testing on all listed chemicals to ensure trace amounts of the listed chemicals do not exist. The costs of not establishing de minimis levels for listed chemicals are unreasonably high for all involved in the process. Requiring warning labels for de minimis levels that pose little or no risk dilutes the intended impact of the warning labels. The additional cost of over-labeling does not result in an additional benefit to consumers. De minimis levels are commonly used by other regulatory bodies, including the European Union, various state chemical laws and the Department of Toxic Substances Control. Weight-percent data, such as a de minimis level, is more accurate than exposure levels. The auto industry uses the International Material Data System (IMDS) and the Global Automotive Declarable Substance List (GADSL) to identify certain chemicals in vehicle components. OEHHA should include de minimis levels for all listed chemicals. It would help to address concerns of unavoidable impurities and the thresholds for determining when an exposure assessment is required or a warning is needed, and would provide consistency with information available in existing auto industry databases. OEHHA

should adopt de minimis levels for the Proposition 65 chemicals either from other authoritative sources or use GADSL de minimis levels applicable at the component level.

ITW similarly recommended OEHHA consider allowing a de minimis chemical content standard along the lines of the REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) protocol. The REACH protocol promotes similar objectives to warn consumers about exposure risk. Using an internationally recognized standard of what would be considered minimal would help to promote greater certainty about whether there is an actual exposure potential from a given product or not.

Response: These comments are beyond the scope of this rulemaking. Other regulations adopted by OEHHA provide guidance concerning how to determine when a warning is required.[32] OEHHA notes that it does develop “safe harbor” levels for many Proposition 65 listed chemicals, and these, when combined with product use information, could be used to calculate de minimis levels for purposes of deciding when a warning is required.

Section 25604 Environmental Exposure Warnings – Methods of Transmission

General

194. Comment (CAA): This section states that a warning can be provided "using one or more of the following methods." It is not clear whether use of a single method is sufficient.

Response: As stated in the regulations, the warning can be provided using one or more of the stated methods. Thus, a business may use a single method, or a combination of the methods listed in subsection 25604(a).

195. Comment (Environmental Coalition, CAA): The Environmental Coalition expressed approval of the organization of Section 25604 compared to the version withdrawn in November 2015, but stated that the definition of 'affected area' is crucial to crafting an effective environmental exposure warning. The current definition is too loose and should be tightened. CAA questioned the definition of "affected area" and how it relates to the location of the sign, in stating the need for clarity and guidance in Section 25604.

Response: Subsequent to these comment, several changes were made regarding environmental exposure warning methods and content, as well as to the definition of

[32] Title 27, Cal. Code of Regs., sections 25701 and 25801 *et seq*.

"affected area". "Affected area" was modified in subsection 25600.1(a) from "is at a level that requires a warning" to "can occur at a level that requires a warning". The term "affected area" relates to environmental exposures (defined now in subsection 25600.1(f)). Methods and content requirements for such warnings are provided in Section 25604. Section 25605 requires the identification of the name of one or more sources of exposure in addition to one or more names of chemicals.

196. Comment (CH&LA): The terms, "affected area," "identifies the area," "clearly identify the area," and "reasonably associated with the location and source of the exposure," are all practically and legally insufficient to guide a business about what must be done to comply with safe harbor provisions. Therefore they fail the Administrative Procedure Act clarity test.

Response: The term "affected area" is defined in the regulation as "the area in which an exposure to a listed chemical can occur at a level that requires a warning" (Section 25600.1). Under Proposition 65, it is the responsibility of the business causing the exposure to determine when a warning is required for a given exposure. Existing regulations provide guidance concerning determining when a given exposure requires a warning.[33] The definition of "environmental exposure" was modified to provide additional guidance concerning sources of exposure (subsection 25600.1(f)). It is reasonable to require that the warning be provided close enough to the source of exposure in order for individuals seeing the warning to determine where and how they may be exposed. Examples of how a warning can identify the source of the exposure and be provided in a manner that clearly associates it with the exposure can be found in the tailored warning section of the regulations (see Sections 25607.20 and 25607.21 (enclosed parking facilities), Sections 25607.24 and 25607.25 (petroleum products), Sections 25607.26 and 25607.27 (service stations and repair facilities), and Sections 25607.28 and 25607.29 (Designated Smoking Areas)).

Subsection 25604(a)(1)

Warning signs

197. Comment (CalChamber): The warning sign description in subsection (a)(1)(A) is duplicative of the definition of 'sign' in Section 25600.1(k) and is confusing.

Response: Based on this comment, the regulation was modified to remove the word "sign" and replace it with the word "warning" for clarity.

198. Comment (CAA, DRoe): What is meant by "public entrance"? There is no definition of public entrance.

[33] Title 27, Cal. Code of Regs., section 25701 and 25801 et seq.,

Response: The term 'public entrance' means the entrance into the facility used by members of the public, which can include residents and non-residents in the context of an apartment complex.

199. Comment (CH&LA): Subsection 25604(a)(1) requires the use of "at least 72-point type" for signs posted at public entrances to an affected area, but subsection 25607.5(a)(1) provides that signs posted at restaurants are required to be no smaller than 28-point type. CH&LA requests that the two provisions be harmonized.

Response: Subsection 25604(a)(1) applies generally to environmental exposure warnings. The type size specified is designed to ensure that the warning message is likely to be seen and understood prior to exposures that can occur in outdoor environments or indoor spaces with clearly defined entrances. On the other hand, the restaurant-specific warnings set out in Section 25607.5 are specifically designed for warnings for exposures from foods sold at restaurants. The type size specified for each of these warnings is appropriate for that purpose. OEHHA is considering an informal request for the development of a “tailored warning” pursuant to Section 25607, *et seq.* for exposures to listed chemicals in hotels and apartments, covering content and methods for providing warnings for these types of exposures.

200. Comment (CH&LA): Request that OEHHA amend subsection (a)(1) to read “A sign posted at all public entrances to *the establishment or* the affected area …that clearly identifies *the establishment or* the area …” and subparagraph (a)(1)(B) to read “Clearly identify *the establishment or* the area…”, that is include “the establishment or” to the area in these subsections.

Response: Modifying the regulation as suggested would not add clarity. The regulations apply to any environmental exposure, including those that may occur at “establishments” such as hotels. OEHHA declines to make any changes to the general regulations based on this comment.

201. Comment (DRoe): The regulations require posted signs at “public entrances” to an affected area, but there is no provision for situations where there are no specific “public entrances” (e.g., a forest, an open field, a shoreline).

Response: Based on this and other comments the regulations were modified significantly for clarity during the first and second modification of text. For spaces with clearly defined public entrances, subsection 25604(a)(1) provides safe harbor method for warning signs. For spaces without clearly defined public entrances, methods laid out in subsections 25604(a)(2) and/or 25604(a)(3) may be employed, or, more generally a safe harbor warning meeting the criteria for environmental exposure warning of subsection 25601(d):

> "Environmental exposure warnings must be provided in a conspicuous manner and under such conditions as to make the warning likely to be seen, read, and understood by an ordinary individual in the course of normal daily activity."

202. Comment (CalChamber): CalChamber requests that the existing provision in the regulations allowing warnings for exposures to pesticides to be provided in the manner set out in Title 3, California Code of Regulations, section 6776(d) be added to these regulations, as it is in the current safe harbor environmental warning regulations. The reference to Section 6776(d), which is found in the current safe harbor environmental warning regulations, is not a mere duplication of the occupational exposure warning regulations. The reference was intended to establish a means for businesses to transmit warnings, particularly for unfenced areas. As noted in the Health & Welfare Agency's 1989 revised FSOR for Division 2, Section 12601 of Clear and Reasonable Warning, that "section provides for the posting of entrances and every 600 feet where a facility is unfenced and adjacent to a right-of-way".

Response: Pesticides and Worker Safety requirements (Title 3, California Code of Regulations section 6700 *et seq*., apply to occupational exposures under Section 25606(a). However, OEHHA declines to adopt this warning method as a safe harbor provision for non-occupational exposures to pesticides. OEHHA believes that warnings for environmental exposures to listed chemicals should be provided as set out in the regulations. This promotes consistency and ensures that a clear and reasonable warning is provided prior to exposures to listed pesticides, in the same manner as other listed chemicals.

203. Comment (DRoe): The requirements for warning signs for environmental exposures should require maps that are meaningfully related to the size and configuration of the affected area. At a minimum, every map receiving safe-harbor protection should clearly delineate the affected area including its boundaries, and the map should clearly distinguish the affected area from the surrounding areas that are not affected. Maps should be required for all environmental exposure warnings for ambient air exposures except for those within a physically enclosed area, where the warning refers to "this area" and the area referred to is obvious. The same should be true for exposures from water bodies (for example, warning for an exposure within a contamination plume in a lake or bay should include a map of the relevant section of the lake or bay, with the affected area clearly delineated).

Response: Based on this and other comments the regulations were modified significantly for clarity during the first and second modification of text. OEHHA agrees with the commenter that maps created pursuant to these regulations should clearly delineate the affected area as distinct from the surrounding unaffected areas, and should include landmarks such as street names, rivers, or other identifying features to

allow people to readily recognize the area indicated. While for a variety of circumstances, maps on signs can provide clarity to the warning, in other situations a written description of the source of exposure, a floor plan or other graphic may be more clear. Therefore, OEHHA declined to make maps a requirement for all warning signs.

204. Comment (CAA): A sign must "clearly identify the area for which the warning is being provided, including the location and source of exposure." This is not clear enough for owner/manager to determine how to describe area or determine how many signs to provide.

Response: The regulation has been modified to address this and other comments. The regulation now provides the safe harbor option for spaces with clearly defined entrances, that warning signs clearly identify one or more sources of exposure to a listed chemical. For example, the entrance could be to a lobby, laundry room, barbecue area, workout room, loading area or similar location, where exposures can occur at a level that requires a warning. The number of signs required is dependent upon the number of “public entrances" to affected areas, and should follow a rule of common sense as to whether most people visiting the affected area would see, read, and understand a warning. In some cases, the source of exposure will be the same as the affected area (e.g., for a designated smoking area, the source would be obvious – cigarette smoke). In other cases, the source of the exposure would not be obvious unless specifically indicated; for example, if the source is an electroplating facility in a neighborhood, the facility would need to be clearly indicated as the source on any map of the affected area. In an indoor environment, at least one source would need to be specifically identified, for example, for lead exposures, paint on the woodwork might be indicated as a source. OEHHA is considering an informal request for the development of a “tailored warning” pursuant to Section 25607, *et seq.* for exposures to listed chemicals in hotels and apartments.

205. Comment (CAA): A warning must be provided "in a conspicuous manner and under such conditions as to make it likely to be read, seen and understood by an ordinary individual in the course of normal daily activity and must be reasonably associated with the location and source of exposure." CAA requests more detailed guidance about how to comply with this provision for environmental warnings.

Response: The commenter is quoting language from the regulation that was proposed in January 2015 and later withdrawn in November 2015. The regulatory proposal that replaced it, released in November 2015, had the same elements: Subsection (a)(1)(A) specified that the warning “Be provided in a conspicuous manner and under such conditions as to make it likely to be seen, read, and understood by an ordinary individual in the course of normal daily activity.” Subsection (a)(1)(B) specified that it

"Clearly identify the area for which the warning is being provided, including the location and source of the exposure."

The requirement that a warning be provided "in a conspicuous manner" and "under such conditions as to make it likely to be read, seen and understood by an ordinary individual in the course of normal daily activity" is intended to apply rules of common sense to the provision of environmental warnings. OEHHA recognizes that environmental warnings will be provided under a wide array of conditions, including various lighting conditions and various spatial scales. If a warning is in a place that is expected to be dimly lit, either because it is in a dim indoor space or because it will be viewed by many people at night, then the sign should either be lit, or should be larger than if it were routinely viewed in well-lit conditions. If most people will be viewing the sign from a distance, then the sign and font would need to be larger than if it is to be viewed from close proximity. If most people will be viewing the sign from a moving vehicle, it would need to be larger than if it is to be viewed by people standing nearby. A simple test would be to evaluate whether, if a number of uninformed people pass the sign in the lighting conditions, speed and distance typical in that environment, most of those people will notice, read and understand the warning; if not, then the warning likely does not meet the conditions for a safe harbor under these regulations. The definition of "environmental exposure" was modified to provide additional guidance concerning sources of exposure (subsection 25600.1(f)). It is reasonable to require that the warning be provided close enough to the source of exposure in order for the person seeing the warning to determine where and how they may be exposed. The environmental warnings regulation now requires that environmental warnings clearly identify one or more sources of exposure (now in subsections 25604(a) (1)(A), (2)(A) and (3)(A)). Examples of how a warning can identify the source of the exposure can be found in the tailored warning section of the regulation (see Sections 25607.20 and 25607.21 (enclosed parking facilities), Sections 25607.24 and 25607.25 (petroleum products), Sections 25607.26 and 25607.27 (service stations and repair facilities), and Sections 25607.28 and 25607.29 (Designated Smoking Areas)). Again, a simple test of this provision would be to evaluate whether most uninformed people who see and read an individual warning understand the location and source of the exposure for which the warning is intended.

206. Comment (CAA): As it relates to the requirement for translation of warnings into languages used to communicate with the public, "Signage in the affected area" is unclear. Does it apply only to signage provided by the regulated business? Does it apply only to legally mandated signage? Does it apply to signage posted by residents?

Response: Other "signage in the affected area" applies to signage provided by the business, and only to business-related signage (e.g., rules, policies, or other safety

warnings). In addition, legally-mandated signage from another government agency that must be posted in an alternative language would trigger the requirement to provide the warning in that language. OEHHA is considering an informal request for the development of a "tailored warning" pursuant to Section 25607, et seq. for exposures to listed chemicals in hotels and apartments.

Subsection 25604(a)(2)

Notices sent to occupants in the affected area

207. Comment (CAA): The provision allowing warnings to be provided to the occupants by mail, electronically, or otherwise delivered is unclear. Is it sufficient to provide warnings only to "occupants" rather than any person who enters the area? What is the basis for the frequency of every three months if nothing has changed and all occupants received notice already?

Response: The business should consider whether visitors to an area are likely to be exposed to a listed chemical at a level that requires a warning. If the answer is affirmative, then multiple methods of transmitting the warning may be needed. For example, if the warning is being provided for exposures that occur in common areas where both occupants and members of the public may be exposed, providing a warning only to the occupants of the facility would be insufficient. With regard to the question of occupants, OEHHA believes it is reasonable to assume, if a notice is provided by mail, electronically, or otherwise delivered to an occupant of a single-family house or apartment, that all residents of that house or apartment have an opportunity to read and understand the warning. OEHHA is considering an informal request for the development of a "tailored warning" pursuant to Section 25607, *et seq.* for exposures to listed chemicals in hotels and apartments, that will more specifically address the issues raised in this comment.

208. Comment (CAA): In commenting on the warnings delivered to occupants, the regulations require an environmental exposure warning to include a map. Does that mean a floor plan of property, map of the area showing location?

Response: The "map" referenced in the regulations (now in subsection 25604(a)(2)(B)) could be a floor plan delineating the affected area(s). OEHHA is considering an informal request for the development of a "tailored warning" pursuant to Section 25607, *et seq.* for exposures to listed chemicals in hotels and apartments, that will more specifically address the issues raised in this comment.

209. Comment (CAA): Notices must be provided in English and "any other language ordinarily used by the business to communicate with the public." It is not clear why the

language requirement is different than that for signs, i.e., language used on signage on the property versus communications with the public.

Response: The "other language" requirement is not intended to be different when providing signage on a property or providing notification delivered by mail or electronically. If other signage on a property is provided in a language other than English, the warning should be provided in that language also. Similarly, if notifications ordinarily delivered by mail or electronically by the business to the public (or in the case of apartments, to tenants) are in a language other than English, the warning should be provided in that language also.

210. Comment (CalChamber): The requirement to provide warnings in other languages imposes significant burdens on business and makes them vulnerable to lawsuits. It may require a business to canvas a particular area to make factual determinations necessary to determine whether a warning in another language must be given. Using the term "ordinarily used" in subparagraph (a)(2)(D) sets up a dispute of fact and should be eliminated.

Response: The regulations provide that the safe harbor warning must be provided in an alternative language where a business ordinarily uses that language to communicate with the public. The purpose of the provision is to ensure that warnings are provided in the same language or languages used by the business to communicate with the public. This was determined to be the most feasible method to ensure that a warning is likely to be understood by non-English speaking members of the public without burdening a business with language requirements beyond those already being used by them. These provisions will allow people to read and understand the warning and should not create a significant hardship for businesses, since it only applies where the business is already communicating with the public using a language other than English. Given California's linguistic diversity, OEHHA believes this safe harbor requirement in the proposed regulations will further the purposes of the statute by expanding the number of individuals who can understand the warning, thus ensuring it is "clear and reasonable".

Subsection 25604(a)(3)

Warnings published in newspapers

211. Comment (Environmental Coalition): Newspaper notices are insufficient warnings. The regulations do not define any minimum circulation, or even that the newspaper be published in the area of the exposure. If OEHHA does not eliminate newspaper warnings, it should implement strict standards governing minimum circulation and geographic scope. OEHHA should look into developing more advanced and effective methods of reaching people and providing warnings for environmental

exposures. Such an approach should be tailored towards the types of media that the affected population actually reads. If OEHHA retains newspaper warnings, support retaining the language currently numbered subparagraph (D), requiring warnings to be circulated in newspapers published in languages other than English.

Response: As discussed in the ISOR for these regulations, subsection 245604 (a)(3) provides more detail concerning safe harbor requirements for warnings published in newspapers, including minimum warning size, concurrent publication in the electronic version of the newspaper, and publication in languages other than English if such a newspaper is circulated in the affected area. This requirement is intended to refer to local and regional newspapers that serve the affected area, including local and regional foreign language newspapers that circulate in the affected area. It is not intended to refer to general-circulation newspapers with a state-wide or national audience in English or other languages. Further, the warning must also contain a map showing the area in which an individual can be exposed. These provisions are consistent with guidance from the Attorney General's office regarding settlements of cases alleging environmental exposures, and are intended to make it more likely that individuals who are or can be exposed to a listed chemical actually receive and understand the warning prior to exposure. Proposition 65 warnings have been provided in newspapers for many years. OEHHA believes that providing warnings in newspapers can still be an effective way to reach people who may be exposed to listed chemicals from certain types of businesses. Therefore, OEHHA declines to eliminate this option for providing warnings.

212. Comment (CAA): The phrase, "largest circulation in the area for which the warning is given" is not clear. How and how often is a business to determine the "largest circulation"? What does "area" mean among the residents of the property, neighborhood, or city? What is the basis for the three months repetition? How would a "map that delineates the affected area" apply in rental housing exposures that can vary by floor and by day? If a newspaper published in a language other than English is circulated in the affected area, the warning must also be published in that newspaper and in that language. There is no limit on the number of potential languages or newspapers. It is unclear how an owner/manager (of an apartment building) would know what non-English newspapers are circulated in a particular community. It is also unclear what the "affected area" is in this context. In other parts of the regulations the term refers to the area where the exposure can occur. In this section it is likely that a larger area is intended when referring to an affected area where a newspaper is circulated.

Response: OEHHA does not anticipate a circumstance where an apartment building would find it advantageous to provide a newspaper warning. Newspaper warnings have been a desirable option for industrial facilities that need to provide a warning to

surrounding communities. OEHHA is considering an informal request for the development of a "tailored warning" pursuant to Section 25607, *et seq.* for exposures to listed chemicals in hotels and apartments, that will more specifically address the issues raised in this comment. No additional changes to the regulations were made based on this comment.

213. Comment (CalChamber): Subsection (a)(3)(C) may require a business to canvass a particular area to make the factual determination necessary to determine whether a warning in another language must be given.

Response: A business should make a good-faith effort to determine whether newspapers in languages other than English circulate in the affected area. This could be done via a simple internet search, or contact with local community groups or the local Chamber of Commerce who should be aware of the various newspapers that are circulated in the area.

Section 25605 Environmental Exposure Warnings – Content

214. Comment (DRoe): The environmental exposure definition includes all media, but the safe harbor language as drafted would apply only for exposures from ambient air. Because of the over inclusive coverage of Section 25605 as drafted, using that language would immunize the party responsible from Proposition 65 liability for exposures through 'any' medium. Separate new safe harbor language is needed for each separate type of environmental exposure for example, indoor air; dermal exposure; water-borne exposure from water bodies or other water sources; etc.

Response: Based on this and other comments, OEHHA extensively modified the regulations concerning environmental exposure warnings to increase clarity [May 20, 2016 2nd modification of text]. If situations come to OEHHA's attention that are not well-addressed by the current environmental exposure warning methods or content, OEHHA may develop tailored warnings to address these specific situations or environments.

215. Comment (DRoe): The likelihood of unlikely or unforeseen types of exposures must be taken into account, instead of assuming that all "environmental exposures" will fit into pre-conceived categories. If the exposure is not of a defined type for which appropriate safe harbor language has been provided, the regulations should make it clear that Section 25605 does not apply.

Response: Based on this and other comments, OEHHA extensively modified the regulations concerning environmental exposure warnings to increase clarity [May 20, 2016 2nd modification of text]. If unlikely or unforeseen situations come to OEHHA's attention that are not well-addressed by the current environmental exposure warning methods or content, OEHHA may develop tailored warnings to address these specific

situations or environments. If the general environmental exposure warning methods and/or content does not fit the exposure, the regulations allow a business to use any other warning that meets the “clear and reasonable” standard in the law (subsection 25600(f)).

216. Comment (CH&LA): In subsection (a)(1) the term, "reasonably associated" is extremely ambiguous and troublesome and will continue to fuel enforcement actions. The term should be defined.

Response: The comment refers to the previous version of Section 25605 released in the now-withdrawn January 2015 version of the regulations. The term, “reasonably associated” is not included in the current regulations.

217. Comment (DRoe): Each safe harbor prescribed language should also require clarity as to the activity by which the persons being warned will be exposed. For example, the warning language in subsections 25605(a)(3)-(5) should read “Entering this area can expose you to breathing [name of one or more chemicals]…” so that the form of exposure is clear to the lay reader. Suggested language for other media exposures would include: “touching "; “drinking” and/or “bathing in”; or “eating” etc.

Response: Based on this and other comments, OEHHA extensively modified the regulations concerning environmental exposure warnings to increase clarity, including a requirement that the source of the exposure be identified. Additional information on the form of exposure will be provided on the OEHHA website, where readers can learn about specific listed chemicals and whether people can be exposed via breathing, touching, or other pathways.

218. Comment (CAA): In subsection (a)(6), it is unclear how specific the description must be and whether a specific area must be described for each source of exposure or for each chemical present, or only for the chemical listed in the warning. It is also unclear whether only the areas where exposure to the named chemical occurs must be described or whether all areas where an exposure to any listed chemical can occur must be described.

Response: The specific area must be described only for the chemical or chemicals for which the warning is being provided. The warning should be provided close enough to the source of exposure for the person seeing the warning to determine where and how they may be exposed. Examples of how a warning can identify the source of the exposure and be provided in a manner that clearly associates it with the exposure can be found in the tailored warning section of the regulation (see Sections 25607.20 and 25607.21 (enclosed parking facilities), Sections 25607.24 and 25607.25 (petroleum products), Sections 25607.26 and 25607.27 (service stations and repair facilities), and Sections 25607.28 and 25607.29 (Designated Smoking Areas)). Where a warning is

being provided for multiple chemicals and/or multiple exposures, the warning should describe the area in which an exposure to those chemicals can occur. It may be appropriate in some circumstances to provide different warnings in more than one location in a facility so that the warning will be clearly associated with the source(s) of exposure. For example, posting a sign at the entry of a facility that purports to provide a warning for an exposure that is only likely to occur in one area on the third floor of the facility would not be sufficiently associated with the source of the exposure. Such a warning should be more appropriately posted at entrances to that area of the third floor. On the other hand, if a particular chemical exposure can occur throughout a facility, for example exposures to a chemical being emitted from carpeting, a warning at the facility entrance naming the chemical and the source (carpeting) would be appropriate.

219. Comment (CH&LA): In subsection (a)(7), the sentence is ambiguous, unclear and requires a level of infeasible exactness that private enforcers would seize upon. "Specific area" can mean different things to different people. Without very specific concrete guidance about what OEHHA intends, the provision is unworkable and fails to meet the APA clarity standard. Subsection (a)(6) violates the APA for clarity, further if "specific area" means anything other than the entire hotel itself, it violates the APA for 'necessity'.

Response: The comment refers to a previous version of Section 25605 released in the now-withdrawn January 2015 version of the regulations. “Specific area” was revised to “affected area”, which is defined in the regulations (subsection 25600.1(a)).

Section 25606 Occupational Exposure Warnings

220. Comment (ACA): Regulations should exempt products labeled pursuant to the Hazard Communication Standard from the warning requirements if the products are sold for industrial or professional use only.

Response: Occupational warnings for exposures to listed chemicals in the occupational setting that are being provided pursuant to federal or state hazard communication standards are deemed to comply with Proposition 65. If such products are sold to consumers, and used outside the occupational setting, the Hazard Communication Standard does not apply and warnings would be required as for any consumer product under Section 25603. No change was made based on this comment.

221. Comment (CRLA): Urge deletion of the phrase. "…or, for pesticides, the Pesticides and Worker Safety requirements (Title3, California Code of Regulations section 6700 et seq)" from Section 25606. Request adding a new subsection (b): "Warnings for agricultural pesticide exposures shall meet the requirements set forth in Section 25604(a) and 25605(a)."

Response: This provision is essentially carried over from the existing regulations and is limited to warnings for occupational exposures to pesticides. The safe harbor provisions for environmental exposure warnings and consumer products warnings would apply for pesticides in the non-occupational setting. No changes to the regulations were made based on this comment.

222. Comment (ACA): “Occupational exposure” is defined as “an exposure to any employee at his or her place of employment.” It does not specify that it applies to exposures coming from the occupational area as well as industrial products. And, “consumer product exposure” is defined as “an exposure that results from a person’s acquisition, purchase, storage, consumption, or any reasonably foreseeable use of a ***product***, including consumption of food” (emphasis added). By saying “product” and not “consumer product” in that definition, it is unclear that the consumer product exposure warning requirements do not apply to products used in an occupational setting. In contrast, the current Clear and Reasonable Warnings regulation (versus this proposed draft language) does specify in its "Consumer products exposure" definition that this includes “an exposure that results from a person's acquisition, purchase, storage, consumption, or other reasonably foreseeable use of a **consumer good**, or any exposure that results from receiving a **consumer** service” (emphasis added).

ACA urges OEHHA to clarify that, consistent with OEHHA’s intent, warning requirements for occupational exposures applies to warnings not only in the occupational area, but also to the products used in the occupational setting. For clarification, ACA suggests the following changes to section 25606: "Occupational Area and Industrial Product Exposure Warnings" and in subsection (a) "a product or area warning to an exposed employee or downstream professional user…"

Response: As stated above, a product that is used exclusively in an occupational setting would be deemed compliant if a warning for an exposure to a listed chemical from that product is provided under the Hazard Communication Standard, or Pesticides and Worker Safety requirements.

Based on this and other comments, the regulations were modified to add subsection (b) to clarify that where a warning is not already being provided for an exposure pursuant to subsection (a), warnings may be provided pursuant to the general provisions for consumer product and environmental warnings. These changes should address the issue of product exposures that occur in the industrial or occupational setting where an OSHA standard does not apply.

223. Comment (CSPA): CSPA requests clarification for products that contain a Proposition 65 listed chemical that does not meet an OSHA warning cut-off or is not a chemical considered under the Hazard Communication Standard.

Response: Subsequent to this comment, subsection 25606(b) was added to address occupational exposures to a product used in an occupational setting that requires a Proposition 65 warning and is not subject to the Hazard Communication Standard and is therefore not covered under subsection (a). Subsection 25606(b) permits warnings consistent with Sections 25601, 25602, 25603, 25604, 25605, and 25607 *et seq.*

224. Comment (Environmental Coalition): The Coalition opposes the occupational exposure warning regulation because it endorses weak warning regimes. Pesticide and Worker Safety regulations do not require any warning about carcinogenicity or reproductive toxicity. This section does not comport with the purposes of Proposition 65.

Response: This provision is essentially carried over from the existing regulations and is limited to warnings for occupational exposures to pesticides. The safe harbor provisions for environmental exposure warnings and consumer products warnings would apply for pesticides in the non-occupational setting. No changes to the regulations were made based on this comment.

Based on this and other comments, the regulations were modified to add subsection (b) to clarify that where a warning is not already being provided for an exposure pursuant to subsection (a), warnings should be provided pursuant to the general provisions for consumer product and environmental warnings. These changes should address the issue of product exposures that occur in the industrial or occupational setting where an OSHA standard does not apply.

225. Comment (ILMA): The Hazard Communication Standard (HCS) 2012 does not explicitly require that a company provide Proposition 65 warnings in its Safety Data Sheet (SDS). So although Section 25606 states that a warning that fully complies with federal HCS meets the requirement of this article; the section does not agree with what HCS 2012 and Proposition 65 require. ILMA does not understand how compliance with the federal HCS 2012 would prove sufficient for relevant Proposition 65 warnings and the section should be revised to address the issue.

Response: Based on this and other comments, the regulations were modified to add subsection (b) which clarifies that where a warning is not already being provided for an exposure pursuant to subsection (a), warnings should be provided pursuant to the general provisions for consumer product and environmental warnings. These changes should address the issue of product exposures that occur in the industrial or occupational setting.

226. Comment (TVC): The existing regulatory language is sufficient and provides clearer direction and more options to the employer than the proposed language,

including the use of signs specifically developed to comply with Proposition 65. Retaining the existing language will enhance compliance in the workplace.

Response: Subsequent to this comment, subsection 25606(b) was added to address occupational exposures not covered under subsection (a). Under these circumstances, subsection 25606(b) permits warnings consistent with the methods and content for consumer and environmental warning provisions. OEHHA has determined that this modification will provide guidance to employers seeking to provide warnings specific for compliance with the Act.

Section 25607 Specific Product, Chemical and Area Exposure Warnings

227. Comment (AHFA): [Note: AHFA's comment refers to Section 25608 from the now withdrawn January 2015 proposed rulemaking; the corresponding provision in the currently proposed rulemaking is Section 25607.] AHFA requests that OEHHA clarify that compliance with the tailored warnings is not necessary to establish a clear and reasonable warning. As written, it could be misinterpreted to mean that compliance with the proposed section is necessary to establish a clear and reasonable warning rather than to just comply with the safe harbor requirement. Many furniture companies may choose to comply with the specific furniture safe harbor warning, but others may choose to comply with the general consumer product safe harbor warning for various reasons. There is no reason to make a distinction for 'furniture' from 'consumer product'. Requests that the second sentence of subsection 25607(a) be deleted or alternatively, the phrase, "excepting section 25607.12 and 25607.13" be inserted before the second sentence.

Response: The commenter is correct that compliance with the tailored warnings in Section 25607 *et seq*. is not necessary to establish a clear and reasonable warning under the Act. However, a business providing a warning for an exposure covered by a tailored warning in a section of 25607 would need to provide the warning using the methods and content established in that section for that exposure if it wishes to achieve safe harbor protection under Subarticle 2 of the regulations. If the business opts to provide warnings using different methods or content and is subject to an enforcement action, the business would not have safe harbor protection and would need to defend its warning as clear and reasonable under the Act if it were legally challenged. OEHHA declines to make the proposed changes to the regulations.

228. Comment (Auto Alliance et al. and AASA et al.): Clarify that specific section warnings override general section warnings. Suggest adding "…and would not need to apply the label under Section 25602."

Response: OEHHA agrees with the commenter. As stated in subsection 25607(a), a business that wishes to obtain safe harbor protection for its warning must comply with the specific requirements of the regulations that apply to that exposure. It follows that an alternative warning need not also be provided. The language in subsection 25607(a) is clear in this regard and no change to the regulation was made in response to this comment.

229. Comment (CalChamber): With the understanding that subsection 25607(b) provides an exception to subsection 25607(a), CalChamber recommends revising subsection (a) by adding "...Unless otherwise specified in Section 25607(b)…"

Response: In response to this comment, OEHHA modified the text to read "Except as provided in subsection (b)…"

230. Comment (CalChamber): The ISOR notes that if a listed chemical that is required to be included in the tailored warning "is not present at a level requiring a warning," a person is not required to include that chemical in the warning. This language is unnecessary and should be replaced with language that does not unnecessarily raise potential issues regarding statutory legal burdens. The ISOR would benefit from providing an example illustrating what OEHHA intends by including subsection 25607(b).

Response: As stated in subsection 25600(a), these regulations do not determine when a warning is required. It only applies where a business has decided to provide a warning. This provision simply allows a business that is providing a warning to delete a particular chemical name if a warning is not needed for that chemical. For example, if a dental office does not use nitrous oxide, it need not include that chemical on the tailored warning it provides to its patients. However if a dental office does not use mercury, it should still include the warning if it drills on or removes old mercury amalgams, since such procedures can cause exposures. This provision helps ensure that the tailored warnings are not over inclusive. No change to the regulations was needed based on this comment.

231. Comment (CRN): The regulations are confusing as written and seem to suggest that businesses have the burden of proving that a warning is in fact required. Recommend OEHHA revise the language in accordance with suggestions provided in the CalChamber comments to improve the clarity of this subsection and avoid unnecessary confusion.

Response: As stated in subsection 25600(a):

> "Nothing in Article 6 … shall be interpreted to determine whether a warning is required for a given exposure under Section 25349.6 of the Act."

Thus, these regulations do not determine when a warning is required, but rather, as also stated in subsection 25600(a), “apply when a clear and reasonable warning is required”. No change to the regulations was needed based on this comment.

232. Comment (CH&LA): In addition to providing environmental exposure warnings, hotels may be required to provide separate warnings for other specific situations. The method of transmission for each "specific" warning is not clear as to whether separate warnings are required for each situation thereby plastering a hotel's entrance with signage. There is no evidence to show these warnings are necessary and thereby they are in violation of the APA.

Response: As stated in subsection 25600(a), these regulations do not determine when a warning is required, and they apply when a clear and reasonable warning is required. Further, a business is not required to use the safe harbor warnings; they can choose not to do so (subsection 25600(f)). Regardless, these regulations would not require “plastering a hotel’s entrance with signage”, as the warnings are required to be posted at the entrances to the affected areas. For example, an alcohol warning would be required at the bar, a restaurant warning at the restaurant inside the hotel, and a parking garage warning would be required in an underground parking garage. OEHHA is considering an informal request for the development of a “tailored warning” pursuant to Section 25607, *et seq.* for exposures to listed chemicals in hotels and apartments, that will more specifically address the issues raised in this comment. No change to the regulations was made based on this comment.

Section 25607.1 Food Exposure Warnings – Methods of Transmission

Subsection 25607.1(a)

233. Comment (ABA and CGA): The product-specific warning content allows shelf tags and signs to be in a "type size no smaller than one half the largest type size used for other consumer information" on the tag or sign. However, food exposure warnings require that "type size shall be no smaller than the largest type size used for other consumer information on the product". ABA requests a revision to subsection 25607.1(a) to "…Except as set forth in Section 25602(a)(1), the type size shall be no smaller than the largest type size used for other consumer information on the product." CGA expressed similar concerns, including issues with the alternative language requirements.

Response: In response to this and other comments, the provisions pertaining to type size have been removed from subsection 25607.1(a). The type size requirements now depend on the methods for providing the warning, as provided in warning in section 25602. Where the warning is provided on a sign or shelf tag, the size requirement

relates to information provided *on the sign or tag* for that product. Where the warning is provided on the product, the type size is determined based on the size of other consumer information *on the product.* The same logic applies to the alternative language requirements for warnings.

234. Comment (CRN): "Consumer information" (used in subsection 25607.1(a) in the November 2015 regulatory proposal) is not defined. The US Food and Drug Administration has strict requirements regarding font, content, placement and foreign language usage on product labeling. CRN strongly urges OEHHA to reconsider Section 25607.1 in its entirety until OEHHA has conducted a thorough review of the relevant federal labeling requirements for dietary supplement and food products and expressly identifies potential conflicts, and also explains to stakeholders how its proposed regulations should be reconciled with the federal requirements.

Response: Based on this and other comments, OEHHA added a definition in subsection 25600.1(c) for “consumer information” that is based on the definition used in the federal Consumer Product Safety Act. It should be noted that warnings need not be provided directly on product labels. There are other methods available in the event that the safe harbor provisions conflict in some way with federal requirements.

235. Comment (Environmental Coalition): OEHHA should clarify what is meant by consumer information.

Response: Based on this and other comments, OEHHA added a definition in subsection 25600.1(c) for “consumer information” that is based on the definition used in the federal Consumer Product Safety Act.

Subsection 25607.1(b)

236. Comment (ABA): The "enclosed in a box" requirement could cause a consumer to think that other protective or precautionary warnings which are not ‘in a box' are less significant or of less significant risk concern. Request the removal of the “in box” requirement.

Response: Because the warning symbol is not required in the safe harbor warning content for food exposure warnings, the requirement to enclose the warning message in a box is intended to provide an alternate means of drawing attention to the warning that is consistent with labeling conventions for foods. Because of this, OEHHA declines to modify the regulatory text as requested by the commenter.

237. Comment (Environmental Coalition): The Coalition supports the decision to require a warning to be placed in a box. It will make the warning more visible to consumers. OEHHA should require use of the triangle symbol for food. There is no reason to treat food different from other products that cause cancer or reproductive

toxicity. This comment also applies wherever the symbol is not required under these proposed regulations.

Response: As explained in the ISOR, food product labeling does not generally include warning symbols. A warning enclosed in a box along with the signal word "**WARNING"** should effectively alert the consumer that important information follows. OEHHA declines to require a warning symbol for food exposure warnings.

238. Comment (GMA): It is not necessary or appropriate to set the warning off in a box in order for consumers to see or read warnings. There is no precedent for the requirement. It is not commonly used under other laws, but when they are, it is for the most significant hazards such as "black box" warnings under the US Food and Drug Administration for serious or life-threatening risks. Consumers routinely read food labels so it is not necessary to set off the warning for consumers to notice. Lastly, food labels can be small and space limiting and setting off a Proposition 65 warning may be at the sacrifice of other relevant and useful information. GMA urges OEHHA to remove the requirement to set off box warnings on food labels.

Response: Subsection 25607.1(b) follows the safe harbor content requirements for on-product warnings but additionally requires that the warning be set off from other surrounding information by enclosing it in a box to ensure that the warning is likely to be seen and understood prior to exposure. Requiring the warning to be enclosed in a box is included in this subsection because food product labeling does not generally include warning symbols. A warning enclosed in a box along with the signal word "**WARNING"** should effectively alert the consumer that important information follows. It should be noted that warnings need not be provided directly on product labels. There are other methods available in the event that the safe harbor provisions conflict in some way with other labeling requirements. OEHHA declines to remove the requirement to include box warnings on food labels.

Section 25607.2 Food Exposure Warnings – Contents

239. Comment (ABA): The same concerns that exist for consumer goods exist for food and beverage products in that they also have limited space for long messages. Since OEHHA believes the truncated warnings will provide useful information to individuals while avoiding unwieldy on-product warnings, such language should also be allowed for food exposure warnings. Request that new subsections (b) and (c) be added to Section 25607.2 that follows the truncated message provided for on-product warning labels.

Response: This section incorporates by reference the warning methods provided in Section 25607.1, which incorporates the methods in Section 25602, which in turn incorporates the short-form warning in Section 25603(b). Therefore, use of the

short-form warning on food products is allowed by the regulations. Where the short form warning is not used, the content requirements of section 25607.2 would apply.

240. Comment (AHPA): In response to the previous version of the regulations released in January 2015 that was withdrawn and replaced in November 2015, specific font type size requirements for food differ from general products with no justification for the variance. The font is impractically large. The alternate warning statements are appropriate for foods.

Response: Based on this and other comments, the font size requirements were modified throughout the regulations.

241. Comment (CRN): OEHHA should keep the current language with "may contain" which is more flexible and more accurately describes potential chemical content in a food product.

Response: As explained in the ISOR for these regulations, the regulations set out the message that must be provided in each warning in order to qualify for a safe harbor. In the case of food, a manufacturer is expected to have knowledge of ingredients in their products, and are only required to warn of contaminants where they have knowledge of them, and the exposure levels are above the warning exemption thresholds in the statute[34], so words such as “may” as a universal qualifier are not appropriate. If a food contains a listed chemical, then the food “can expose” a person to that chemical if that person eats the food, so the current language is accurate and is more consistent with the statute than the much vaguer words “may contain”. The regulations universally replace the word “contains” with “can expose”, and the replacement is clearly merited in the case of food, where people eat the food and therefore can be exposed.

242. Comment (CRN): Given the complex nature of dietary supplements and other food products, as well as the comprehensive federal regulatory structure in place to address possible contaminants and overall safety concerns, CRN requests OEHHA reconsider its proposed warning language for food exposures and maintain the current safe harbor language.

Response: As a voter-approved state law, Proposition 65 requires businesses to provide warnings for knowing exposures to listed chemicals. Businesses are not automatically exempted from this requirement simply because their products are also subject to federal regulations. OEHHA has determined that these regulations will further the purposes of the Act by providing for more informative warnings. There is no reason to conclude that consumers of any dietary supplement and food products that

[34] Health and Safety Code section 25249.10

carry Proposition 65 warnings will not benefit from the improved warnings resulting from these regulations. No changes to the regulations were made based on this comment.

243. Comment (Environmental Coalition): The Coalition suggests replacing the word "can" with "will" in subsection (a). This language makes it clear that an exposure will occur.

Response: As explained in the ISOR, in an earlier draft of the proposed regulations, OEHHA used the phrase "will expose" you to X chemical. Some stakeholders expressed concerns that some products might or might not expose the public to a listed chemical, depending on how they are used. There were also concerns because some products contain varying levels of a listed chemical, so any individual sample of the product may or may not actually expose the consumer. For these reasons OEHHA chose the term "can expose" rather than "will expose". OEHHA declines to make the replacement suggested by the commenter.

Section 25607.3 Alcoholic Beverage Exposure Warnings - Methods of Transmission

244. Comment (ARC-UCP): Warning signs for alcoholic beverages should be displayed so that they are clearly visible under all lighting conditions normally encountered during business hours, be unobstructed, be at eye level for persons in the range from adult women of average height standing to adult women of average height in wheelchairs, and be stationery.

Response: The definition of "sign" in subsection 25600.1(m) already includes requirements that are similar to those suggested by the commenter, and subsection 25607.3(a)(1) requires the sign be "placed at eye level so that it is readable and conspicuous to customers as they enter" the areas where alcoholic beverages are being served. No change was made based on this comment.

245. Comment (CCBA): It is not possible to control the languages used by the 83,000+ retail premises throughout California. Warnings should be limited to languages used in materials provided by the manufacturer in labeling or advertising the product at those specific retail locations. CCBA requests that subsection (b) be amended to replace "on the premises" to "as provided by the manufacturer to the retail premise."

Response: The alternative language requirements in these regulations are intended to ensure that the warning message is provided in a manner that is clear and reasonable. Where a manufacturer or distributor is already providing information to a retailer in a language other than English, OEHHA believes it should also provide the warning in that language. Similarly, where a retailer provides advertising or other consumer information about the product in an alternative language, the retailer should provide the warning in

that language. In general, for alcohol warnings, it is reasonable to provide warnings at least in Spanish, due to the common occurrence of Spanish language signage at beverage retailers in California. Most warnings for alcoholic beverages are currently covered by a consent decree and are not affected by these regulations (subsection 25600(e)), thus the number of alternative language warnings that will need to be provided should be small and manageable for those businesses that are not parties to the settlement. Further, to the extent resources are available, OEHHA intends to provide translated warnings on its website.

246. Comment (CAPA): CAPA urges OEHHA to amend subsection (a)(1) to replace "…alcoholic beverages are served" with "…alcoholic beverages may be served." The change is consistent with the intent expressed in regulation to permit a warning for the area encompassed by permit or license to sell alcoholic beverages.

Response: OEHHA declines to make the change suggested in this comment because it would not add clarity to the regulations. If a business is licensed or permitted to sell alcoholic beverages, it may use the safe harbor warning provided in the regulations.

247. Comment (CGA): Relevant provisions of the current Section 25603.3 should simply be renumbered and included in this proposal. If challenges exist with regard to litigation tied to defaced, damaged, or missing signage, manufacturers and distributors should be given a 14-day opportunity to cure after receiving notice of the alleged violation.

Response: The provisions in the regulations relate to actual knowledge, rather than an opportunity to cure. Because alcohol retailers are presumed to already have actual knowledge of the exposure, they would not benefit from the five business day period after receiving a notice, as some retailers might. It is beyond the scope of these regulations to provide a general opportunity to cure for manufacturers and distributors. No changes were made based on this comment.

248. Comment (CGA): CGA mistakenly referred to Section 25608.3 instead of Section 25607.3. Subsection 25607.3(a)(1) calls for a sign to be placed at “eye level” where patrons enter the area. “Eye level” is so subjective as to be meaningless. Adults vary widely in height and thus eye level varies significantly.

Response: This provision was carried over from existing regulations. The term ‘eye level” simply requires placement of the signs in the area a person would normally see and read a sign. Where a sign is posted where customers are normally standing, it should be placed at the average height of a standing person. On the other hand, if the sign is posted where individuals are normally sitting, it should be placed so that it will be seen by the average sitting person.

249. Comment (CGA): Given the generalized statement in subsection 25600.2(b) relieving a manufacturer of all actual and legal liability for warnings if they essentially notify retailers and offer to provide warning materials, it appears Section 25608.3 [should be referring to Section 25607.3] seeks to fundamentally alter standards for warnings on alcohol by shifting the actual and legal liability to retailers. Subsection 25603.3(e)(7) in the existing regulations state that the burden of placement and maintenance of warnings is the responsibility of manufacturers and distributors. There is no justification for instead forcing retailers to assume new actual and legal obligations.

Response: The new retailer responsibilities provisions in Section 25600.2 apply equally to retailers of alcoholic beverages as other consumer products sold at the retail level. There is no justification for treating retailers of alcoholic beverages differently in this regard and doing so would likely cause unnecessary confusion since many food retailers also sell alcoholic beverages.

250. Comment (CRA): Sections 25607.3 and 25607.4 are similar in structure to, and should be harmonized with, Sections 25607.5 and 25607.6. Incorporate by reference all comments to 'food and non-alcoholic beverages exposures' to 'alcoholic beverage exposures'. Many restaurants serve alcoholic beverages and warning requirements should be harmonized so there are not two different sets of requirements for restaurants to comply with.

Response: The provisions in the regulations are similar but relate to different products. Sections 25607.3 and 25607.4 relate to exposures to alcoholic beverages and Sections 25607.5 and 25607.6 relate to foods and non-alcoholic beverages sold at restaurants. It is true that in certain circumstances a restaurant would need to post both warnings. However, because federal law preempts on-product warnings for alcoholic beverages, the only method that can be used for the warning is a sign. Given the significant adverse human health effects that can occur from drinking alcoholic beverages during pregnancy, OEHHA declines to include those exposures in the safe harbor warning for exposures to listed chemicals in foods and non-alcoholic beverages sold at restaurants.

251. Comment (Environmental Coalition): A warning placed in the shipping container or delivery package is not sufficient. The warning should be given before the purchase. For internet and catalog sales of alcohol, sellers should be required to comply with subsections 25603(b) and (c), governing those purchases.

Response: The provision of the regulations (25607.3) being referred to in the comment provides as follows:

> "(4) For alcoholic beverages sold or distributed to purchasers within California through package delivery services, a warning provided by incorporating or

> placing the warning message on or in the shipping container or delivery package in a type size no smaller than the largest type size used for other consumer information on the product. In no case shall the warning appear in a type size smaller than 8-point. The warning message must be readable and conspicuous to the recipient prior to consumption of the alcoholic beverages."

This provision was carried over from the existing regulations. It does not specifically address the situation where products are purchased over the internet or through catalogs. Warnings would still be required for internet and catalog sales pursuant to subsections 25603(b) and (c). Thus, this provision would apply only where the product is provided in California by a package delivery service. In the specific case of alcoholic beverages, OEHHA believes the warning specified in the regulation is clear and reasonable. Most consumer-product warnings pertain to a listed chemical contained in a product or food, but in this case, the listed chemical (alcoholic beverages) is the product being purchased. It is unlikely that a purchaser of alcoholic beverages through a package delivery service would be seeing the alcoholic beverages warning for the first time when receiving the package and would want to return the purchase. No change to the regulations is needed.

252. Comment (Environmental Coalition): The Coalition recommends replacing "purchasers" with "consumers" in the provision dealing with package delivery services. Not all consumers of alcoholic beverages are the individuals who purchased the beverage, and yet the consumer is the one exposed. The warning should focus on the consumer. OEHHA should consider a global policy stating that warnings targeted at intermediate purchasers are not sufficient. Warnings should be directed at the person actually exposed, the consumer.

Response: OEHHA declines to make the requested change to the regulations. The term "purchaser" is clearer in context since it is referring to *purchases* made through package delivery services.

Section 25607.4 Alcoholic Beverage Exposure Warnings – Content

253. Comment (ARC-UCP): The warning should begin with the words "ALCOHOL WARNING," not simply "WARNING." Most people stop reading at the heading, and they should at least be aware that there is something about alcohol that requires a warning. To stand out more, the warning should be in red. The words "birth defects" should come before "cancer risk" on the sign. Suggest the following: "Drinking alcohol while pregnant can cause birth defects. This includes any amount of alcohol, in any form, at any time during pregnancy. Alcohol also increases cancer risks. For more information go to..."

Response: The regulations carry over the existing warning for alcoholic beverages with the exception of the addition of the URL for the OEHHA website. OEHHA believes the existing warning adequately conveys the warning message. OEHHA is posting additional information online at the link given in the warning concerning the dangers associated with consumption of alcoholic beverages during pregnancy and the cancer risks associated with ethyl alcohol in alcoholic beverages to help educate the public on these important issues.

254. Comment (CAPA): CAPA supports the change made in subsection (a)(3).

Response: Comment noted, no response required.

Section 25607.5 Food and Non-Alcoholic Beverage Exposure Warnings for Restaurants – Methods of Transmission

255. Comment (CRA): The language used in subsection 25607.6(a) should be harmonized with subsection 25607.5(a) to refer to food or beverages intended primarily for immediate consumption, whether on or off the restaurant premises. The first sentence of subsection 25607.5(a) should be revised to refer to food or beverages intended primarily for immediate consumption, on or off premises. The phrase, "primarily intended for immediate consumption on or off premises" is used in HSC section 25249.7(k)(1)(B) and should be used in the regulations as well.

Response: OEHHA declines to add the phrase “on or off premises”. The regulations apply to facilities that sell food for both on and off premises consumption as provided in the definition referenced (HSC section 113789). The phrase is unnecessary.

256. Comment (CRA): The dimensions of the sign are unnecessarily restrictive. Existing Proposition 65 signs are 10 x 10 inches and the regulations should have the flexibility to provide either size, 8 1/2 x 11 or 10 x 10. The phrase, "each public entrance to the restaurant" is unclear. Many facilities have multiple public entrances. Customers regularly frequent many restaurants and it is unnecessary to provide a warning to every customer on every visit. A more balanced approach would be to require that a sign be placed so it is readable and conspicuous to "most" customers either as they "enter the restaurant" or "before they place an order". Request amendments to subsection (a)(1): "An 8 1/2 by 11 inch or 10 by 10 inch sign…to most customers before they place an order or as they enter…where food or beverages are sold or served."

Response: OEHHA adopted the 8 ½ by 11 inch sign requirement to make it easier for businesses to print warning signs without the need for special services and to ensure the warning message is clear and readable. A business may use a different size sign, if they are able to show that the different size provides a clear and reasonable warning under the statute. The term 'public entrance' means the entrance into the facility used

by members of the public, which can include patrons and other non-employees in the context of a restaurant.

257. Comment (CRA): The regulations are unnecessarily burdensome with respect to placement of a warning. The phrase, "placed at each point of sale" is not clear. Request an amendment to subsection (a)(2): "…each point of sale at or on the counter or on a wall behind, adjacent to, or parallel to the counter where customers place orders or pick up food or beverage items so as…" which is based on language in court-approved consent judgments filed by Attorney General.

Response: To the extent warnings are being provided pursuant to a consent judgement, the terms of that judgement supersede the regulations. OEHHA agrees that the point of sale would include placement of a sign at or on the counter or on a wall behind, adjacent to, or parallel to the counter where customers place orders or pick up food or beverage items.

258. Comment (CRA): Subsection (a)(3) appears to allow a warning to be printed on a menu board. The regulations should be revised to clearly state that it is allowed.

Response: OEHHA agrees that the regulations allow for a warning to be posted on a menu board.

259. Comment (CRA): Subsection 25607.5(b), requiring certain warning signs to be in two or more languages, creates uncertainty and litigation risk. It is therefore necessary to rewrite proposed subsection 25608(b) to provide greater clarity and to limit the circumstances in which the warning must be provided in languages other than English. This requirement needs to be clear that the use of languages other than English to identify foods, to provide ambiance or décor, or to communicate with employees do not trigger a requirement to provide Proposition 65 warnings in a language other than English. The approach of stating what is excluded from “consumer information” is less likely to lead to disputes, at least for restaurants, rather than attempting to define “consumer information” more generally.

Response: In response to this and other comments, the regulations were modified to add a definition for “consumer information” in subsection 25600.1(c) that clarifies the types of information that would and would not trigger a warning in an alternative language.

260. Comment (CRA): Add a new subsection (a)(4) stating: "On a poster providing the nutritional content of foods served in the restaurant, in a bordered box no smaller than 5 by 5 inches, so long as the poster is placed in accordance with subsections (1) or (2), above." The new subsection is based on the poster method approved in court-approved consent judgements filed by Attorney General.

Response: The warning requirements in a court settlement supersede the requirements of the regulations (subsection 25600(e)). However, OEHHA declines to adopt the option to provide the warning in the information poster as a safe harbor method since it is less likely to be seen and understood prior to exposure if it is placed there versus on a sign more closely associated with the purchase of the food.

261. Comment (CAPA): CAPA supports the changes made in subsection (a)(1).

Response: Comment noted, no response required.

262. Comment (CGA): The regulations are an egregious example of disparate treatment for identical food products based solely on business model. Food offered for sale in restaurants is substantially similar to that offered in the grocery store setting except for time of expected consumption. There is no logical rationale to provide a different warning scheme for a food product simply because it is sold in a restaurant versus a grocery store. Different food vendors should not be held to different standards and requirements for what are in some cases identical food products.

Response: Grocery stores and restaurants are very different types of facilities and require different safe harbor warning methods and content to ensure that a clear and reasonable warning is provided under the circumstances.

263. Comment (CH&LA): The regulations are not clear because "restaurant" is not defined.

Response: The regulations define a restaurant or food facility by reference to HSC section 113789 which provides in part:

> "(a) "Food facility" means an operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption at the retail level, including, but not limited to, the following:
>
> (1) An operation where food is consumed on or off the premises, regardless of whether there is a charge for the food.
>
> (2) A place used in conjunction with the operations described in this subdivision, including, but not limited to, storage facilities for food-related utensils, equipment, and materials.
>
> (b) "Food facility" includes permanent and nonpermanent food facilities."

That law provides a list of other facilities that would also qualify as a "restaurant" for purposes of this regulation.

Section 25607.6 Food and Non-Alcoholic Beverage Exposure Warnings for Restaurants – Content

264. Comment (CRA): Request an amendment to subsection (a): "…food or beverage intended primarily for on-site immediate consumption on or off premises, …"

Response: OEHHA declines to add the phrase “on or off premises”. The regulations apply to facilities that sell food for both on and off premises consumption as provided in the definition referenced (HSC section 113789). The phrase is unnecessary.

265. Comment (CRA): It is not necessary to identify any specific chemicals in the warning because the proposed language refers customers to the OEHHA-maintained website where more detailed information will presumably be found. For accuracy, OEHHA should qualify that mercury found in certain fish is not generally found in freshwater or anadromous species or in some species of ocean fish at levels that require a warning. Propose that the items be identified as examples in subsection (b).

Response: The warning language specifically identifies the chemicals acrylamide and mercury because these types of exposures commonly occur through foods such as coffee and fish that are sold at many restaurants. The safe harbor warning also contains a link to the OEHHA URL related to food and beverage exposures for supplemental information. This information will include more details on the types of fish that contain the highest mercury levels. That said, if a restaurant does not cause an exposure to mercury because it does not serve seafood or the seafood it is serving does not require a warning, it does not have to include the “mercury in fish” warning, per subsection 25607(b).

266. Comment (Environmental Coalition): This proposal is better than the previous draft because it specifies foods that contain certain chemicals. However, it does not identify which menu items contain the chemicals at a level requiring a warning. Not all fish contain mercury, and not all fried or baked foods contain acrylamide at levels requiring a warning. Request that the warning list the menu items for which warnings are required.

Response: The warning content gives more information than the existing warning which merely states that some foods sold here may contain chemicals known to the state to cause cancer, birth defects or other reproductive harm. OEHHA believes the new warning is more informative. Individuals who are interested in more information can utilize the link in the warning to the OEHHA website where OEHHA expects to identify restaurant foods that are likely sources of exposures to listed chemicals. It may be difficult for a restaurant to know which of its foods served on a given day may require a warning as levels of these chemicals vary and the sources and types of food on the menu may change frequently.

Section 25607.9 Dental Care Exposure Warnings – Content

267. Comment (CDA): Support Sections 25607.8 and 25607.9.

Response: Comment noted, no response required.

268. Comment (Environmental Coalition): Dental offices should be required to list the procedures where exposures to chemicals would require a warning.

Response: The text of the warning lists the types of procedures that can cause exposures, including sedation, root canals, placement or removal of crowns, etc. as will the consent forms used by the dentist. The warning also advises the patient to discuss these issues with their dental care provider to obtain more information. OEHHA also has fact sheets posted on its website regarding some of these exposures, and expects to be posting additional information on exposures that occur when receiving dental care.

Section 25607.10 Raw Wood Product Exposure Warnings – Methods of Transmission

269. Comment (Environmental Coalition): Warnings given after purchase do not comply with the statute. Confusion stems from an ambiguity about whether this regulation is aimed at consumer purchasers of wood, at contractors purchasing wood for use on a job site, or at large deliveries of wood to a construction site. Subsection (b) seems to address this concern, but it does not clear up the question of whether warnings are intended for consumers or employees. In order to make this regulation clear and effective, OEHHA should completely rewrite this section to make it clear what kinds of wood purchases it is envisioning.

Response: Proposition 65 requires warnings prior to exposure to a listed chemical. This safe harbor provision expressly applies to raw wood sold as a “consumer product” at the retail level either as individual pieces or in bulk. Warnings for occupational exposures to listed chemicals are covered by Section 25606. Under Section 25606(b) where occupational exposures to wood dust occur and no OSHA compliant warning is being provided, a warning can be provided to affected workers using the content in this section, but would need to be provided via a method that ensures the affected workers receive the warning prior to exposure, such as by posted the warning in the area where wood is being drilled, sanded or cut. No changes to the regulations were made based on this comment.

Section 25607.12 Furniture Product Exposure Warnings – Methods of Transmission

270. Comment (Environmental Coalition): These regulations appear to be aimed at consumer purchase of furniture. For institutional purchases, such as furniture for a hospital waiting room, the regulations would not provide a warning to the end user of the furniture. The warning should target the people exposed, not just the person or institution making the purchasing decision. Do not support post-purchase warnings.

Response: The methods of transmission for providing a furniture product exposure warning consists of a process that includes 1) a warning affixed to the product in the same way that other consumer information or warning materials are provided on the product, and 2) either a notice or sign at each public entrance to a retail facility that sells the product or point of display, or a notice on each receipt. If a business chooses to purchase items, such as furniture bearing a Proposition 65 warning, that person will need to consider whether an environmental warning will be needed for users of that furniture. A consumer product warning is not designed to address this issue, and such issues if they exist would be addressed through an environmental warning.

In regard to post-purchase warnings, in general OEHHA believes that warnings should be provided prior to purchase in the case of consumer products. In the case of environmental exposures, the warnings must be provided prior to exposure.

271. Comment (AHFA): Tailored warning for furniture requires additive methods of warning beyond that of other industries. Requiring the furniture industry to provide a public entrance notice or point of display or receipt warning and a warning on the product places a disproportionate burden on the furniture industry. The methods should be stated as alternatives.

Response: OEHHA has determined that a combination of methods is necessary to increase the likelihood a consumer will receive a warning prior to exposure. If only one method is used, a consumer may not see the warning prior to exposure. Furniture is unique in that consumer information and other (non-Proposition 65) warnings typically appear on tags placed on the underside of the furniture, where they are unlikely to be seen by the consumer prior to exposure. It is reasonable for Proposition 65 warnings to be located with these other warnings and consumer information, but only if the additional methods cited in the regulations are employed to ensure consumers are aware of the full warning and have the opportunity to read it prior to exposure. The tailored warning applies only to safe harbor warnings under Subarticle 2; a business not wishing to follow the safe harbor warning methods may provide warnings that otherwise comply with the Act as provided in subsection 25600(f).

272. Comment (CAA): Some rental units, model units or common areas will be furnished. It is not clear how, if at all, these provisions apply to rental housing.

Response: As noted above, to the extent that intermittent use of furniture in a common area causes an exposure high enough to require a warning, the business should post a warning for that exposure based on the provision in the environmental warnings sections of the regulations (Sections 25604 and 25605). OEHHA is considering an informal request for the development of a "tailored warning" pursuant to Section 25607, *et seq.* for exposures to listed chemicals in hotels and apartments, that will more specifically address the issues raised in this comment.

Section 25607.13 Furniture Product Exposure Warnings – Content

273. Comment (AHFA): It is not clear whether a safe harbor would apply only for exposures to the chemical listed in the warning text. AHFA understands from OEHHA's presentation at the public hearing that the safe harbor warning is required to name at least one listed chemical for which the warning is being given, but that the safe harbor warning is clear and reasonable as to all exposures under Proposition 65. Propose two alternatives to subsection 25607.13(a)(1)(C) for clarification that it is "chemicals, including [name of one or more chemical]" or "[name of one or more chemical] or other chemical".

Response: If a business provides a warning using the content provided in subsection 25607.13(a), the business will receive safe harbor protection for exposures to all the listed chemicals in the product, not just those specifically called out as examples in the warning as long as one chemical is named for each endpoint (cancer and reproductive toxicity) covered in the warning.

Section 25607.14 Diesel Engine Exposure Warnings (Except Passenger Vehicle Engines) – Methods of Transmission

274. Comment (Environmental Coalition): It is not clear why subparagraph(a)(2) ends with "or." It should either be replaced with "and," or subparagraph(a)(3) should be placed in a different subsection to avoid confusion.

Response: Subsections (a)(2)-(3) have been subsequently renumbered to subsections (a)(1)(A)-(B) and have been restructured to address this comment.

275. Comment (Environmental Coalition): The term "passenger vehicle" is undefined. Unless it means a vehicle where the carrying of passengers is physically impossible, then this section must structure the method of transmission so that passengers receive the warning. Section 25607.16 defines "passenger vehicle" by reference to Vehicle Code § 465, which excludes buses. If OEHHA intends this section to cover buses and

other vehicles that are capable of carrying passengers, the Coalition strongly suggests that OEHHA rewrite it to ensure that passengers receive a warning before boarding. An even stronger regulation would require a warning before booking a bus ticket.

Response: The provisions for diesel engines in this section are meant to address stand-alone diesel engines used for items like back-up generators. OEHHA has not adopted a specific warning provision for buses but may do so if one is requested.

276. Comment (NMMA): Unlike passenger vehicle engines, marine engines are frequently bought aftermarket by consumers. This is not unique to the recreational boating industry, as many other non-passenger vehicle engines are sold in California. An amended stand-alone warning that encompasses diesel and non-diesel engines, by striking out “diesel,” is necessary to sufficiently protect the consumer above and beyond the requirements outlined for consumer products found in Section 25602.

Response: Component parts of consumer products such as replacement engines for vehicles and vessels would be covered by the general warning provisions for consumer products in Sections 25602 and 25603. The provisions for diesel engines in this section are meant to address stand-alone diesel engines used for items like back-up generators.

277. Comment (NMMA): Revise the allowable placement of warnings in the owner's manual, and revise the font size constraints to using the same size and font as other operator warnings.

Response: The requirements for placement and font size for warnings in owner’s manuals are designed to ensure the warning is seen and understood prior to exposures. The regulation requires that the warning to be provided in the owner’s manual is in no smaller than 12-point type and enclosed in a box. The requirements for placement and font size for warnings in owner’s manuals are designed to ensure the warning is seen and understood prior to exposure. In response to these and other comments the type size specification in subsection (a)(2) for the window label has been deleted. In adopting these regulations, OEHHA intends to codify an existing process being used by California car dealers. The size of the warning label and text therein need not change from the existing practice, that is they are consistent with the safe harbor method in these regulations. OEHHA has only slightly changed the content of the warning message by shortening it. No changes were made to the regulation based on this comment.

Section 25607.16 Vehicle Exposure Warnings – Methods of Transmission

278. Comment (Auto Alliance et al.): The commenters suggest incorporating by reference the definition in the California Vehicle Code (CVC) Sections 670[35] and 410[36] and 49 CFR sections 523.5[37] and 523.6[38] [for easy reference OEHHA has provided

[35] CVC 670 defines a "vehicle" as "…a device by which any person or property may be propelled, moved, or drawn upon a highway, excepting a device moved exclusively by human power or used exclusively upon stationary rails or tracks."

[36] CVC 410 defines a "motor truck" or "motortruck' as "…a motor vehicle designed, used, or maintained primarily for the transportation of property."

[37] Section 523.5 Non-passenger automobile. A non-passenger automobile means an automobile that is not a passenger automobile or a work truck and includes vehicles described in paragraphs (a) and (b) of this section:(a) An automobile designed to perform at least one of the following functions: (1) Transport more than 10 persons; (2) Provide temporary living quarters; (3) Transport property on an open bed; (4) Provide, as sold to the first retail purchaser, greater cargo-carrying than passenger-carrying volume, such as in a cargo van; if a vehicle is sold with a second-row seat, its cargo-carrying volume is determined with that seat installed, regardless of whether the manufacturer has described that seat as optional; or (5) Permit expanded use of the automobile for cargo-carrying purposes or other nonpassenger-carrying purposes through: (i) For non-passenger automobiles manufactured prior to model year 2012, the removal of seats by means installed for that purpose by the automobile's manufacturer or with simple tools, such as screwdrivers and wrenches, so as to create a flat, floor level, surface extending from the forwardmost point of installation of those seats to the rear of the automobile's interior; or (ii) For non-passenger automobiles manufactured in model year 2008 and beyond, for vehicles equipped with at least 3 rows of designated seating positions as standard equipment, permit expanded use of the automobile for cargo-carrying purposes or other nonpassenger-carrying purposes through the removal or stowing of foldable or pivoting seats so as to create a flat, leveled cargo surface extending from the forwardmost point of installation of those seats to the rear of the automobile's interior.(b) An automobile capable of off-highway operation, as indicated by the fact that it:(1)(i) Has 4-wheel drive; or(ii) Is rated at more than 6,000 pounds gross vehicle weight; and(2) Has at least four of the following characteristics calculated when the automobile is at curb weight, on a level surface, with the front wheels parallel to the automobile's longitudinal centerline, and the tires inflated to the manufacturer's recommended pressure—(i) Approach angle of not less than 28 degrees.(ii) Breakover angle of not less than 14 degrees.(iii) Departure angle of not less than 20 degrees.(iv) Running clearance of not less than 20 centimeters.(v) Front and rear axle clearances of not less than 18 centimeters each. (Sec. 9, Pub. L. 89-670, 80 Stat. 981 (49 U.S.C. 1657); sec. 301, Pub. L. 94-163, 89 Stat. 901 (15 U.S.C. 2002); delegation of authority at 41 FR 25015, June 22, 1976.) [74 FR 14449, Mar. 30, 2009].

[38] Section 523.6 Heavy-duty vehicle. (a) A heavy-duty vehicle is any commercial medium- and heavy-duty on highway vehicle or a work truck, as defined in 49 U.S.C. 32901(a)(7) and (19). For the purpose of this part, heavy-duty vehicles are divided into three regulatory categories as follows:(1) Heavy-duty pickup trucks and vans;(2) Heavy-duty vocational vehicles; and (3) Truck tractors with a GVWR above 26,000 pounds.(b) The heavy-duty vehicle classification does not include:(1) Vehicles defined as medium duty passenger vehicles.(2) Vehicles excluded from the definition of "heavy-duty vehicle" because of vehicle weight or weight rating (such as light duty vehicles as defined in Section 523.5).(3) Vehicles excluded from the definition of motor vehicle in 40 CFR 85.1703. [76 FR 57491, Sept. 15, 2011].

definitions in these sections in footnotes] for both gasoline and diesel vehicles and provide the same safe harbor vehicle-specific labeling requirements as for vehicles defined in CVC Section 465.

Response: Vehicle Code Section 465 was used in the definition based on input from the California New Car Dealers Association and is intended to cover passenger vehicles and light trucks. Different provisions may be needed if these regulations are expanded to cover other types of vehicles. In the interim, the safe harbor warning provisions in Sections 25607.16 and 25607.17 provide a good model for clear and reasonable warnings for sellers of other passenger vehicles not specifically covered by these sections. Also, OEHHA is considering an informal request for the development of a "tailored warning" pursuant to Section 25607, *et seq.* for exposures to listed chemicals in other vehicles.

279. Comment (Auto Alliance et al.): Section 25607.16(a) should be amended to make it clear that this section includes not only passenger cars, but also light-duty trucks, medium-duty vehicles, and heavy-duty vehicles. Subsection (a) is applicable to "passenger vehicle" as defined in Vehicle Code Section 465, or an "off-highway motor vehicle" as defined in Vehicle Code Section 38012(b); however, there are cases in which a vehicle is heavier than the light duty definition in Vehicle Code Section 465, but are not classified as heavy-duty vehicles. In cases where neither definition is applicable, OEHHA needs to clarify which label should be used, or allow for the use of one label for all vehicles. This change would provide better consistency for vehicle types that have similar content and should be treated the same under the Proposition 65 warning requirements.

Response: OEHHA is considering an informal request for the development of a "tailored warning" pursuant to Section 25607, *et seq.* for exposures to listed chemicals in other vehicles. The definition from Vehicle Code Section 465 was incorporated by reference based on input from industry stakeholders and is intended to cover passenger vehicles and light trucks. Different provisions may be needed if the regulation is expanded to cover other types of vehicles. In the interim, sellers of these vehicles should be able to use the methods and content established here for other passenger vehicles.

280. Comment (Auto Alliance et al.): The commenters urge OEHHA to provide more flexibility for vehicle labels. Section 25607.16 requires two methods of label transmission. First, a warning printed in the owner's manual, and second, a warning attached to the driver's side window. Because a dealer cannot control what is printed in owner's manual, and a manufacturer cannot control how a window appears at a dealership, these two requirements should be separated. The relative duties of manufacturer and retailer should be specified. Maintaining a prominent Proposition 65

warning in the owner's manual is appropriate, and no additional labels should be required.

Response: OEHHA understands the existing warning programs for most new and used cars sold in California use the process set out in these regulations. OEHHA encourages these businesses to continue to use this process by adopting this process as a safe harbor method for providing warnings. For the reasons given in response to other comments requesting that a stand-alone warning in an owner's manual be adopted as a safe harbor method, OEHHA declines to do so.

281. Comment (Auto Alliance et al.): The commenters suggest text changes to subsection 25607.16(a) to remove "both" and replace with "either"; remove "and" and replace with "or"; and insert "or provided on a hang tag which is hung from the rear view mirror. The warning is…" and delete "If the vehicle does not have a driver's side window, the warning may be provided on a hang tag which is hung from the rear view mirror."

Response: For the reasons given in response to other comments requesting that a stand-alone warning in an owner's manual be adopted as a safe harbor method, OEHHA declines to do so.

282. Comment (Auto Alliance et al.): If OEHHA continues to require both methods of transmitting a warning, subsection 25607.16(a)(2) and the FSOR should state that the warning labels are intended to be easily removable. OEHHA should provide an option for the removable label to either be a temporary sticker or a hang tag hung from the rear view mirror. Currently suppliers make the stickers or hang tags with the warning, and dealers place the stickers or hang tags on the vehicles upon delivery at the dealership.

Response: Nothing in the regulations require that the labels be permanently affixed to the windows of the vehicle. The stickers currently in use in California are removable.

283. Comment (Auto Alliance et al.): Subsection (a)(2) states that the type size on the label must be "no smaller than the largest type size used for other consumer information affixed to the vehicle." This would make the warning equivalent to the fuel economy rating which is 72-point font and would be unfeasible. The commenters suggest a minimum font size of 12. The regulations should also specify the size of the sticker and hang tag for example, a minimum 3x3 sticker with text on a clear background placed on the bottom-right corner of driver-side window and a hang tag with a minimum size based on existing sizes.

Response: In response to these and other comments the type size specification in subsection (a)(2) has been deleted. In adopting these regulations, OEHHA intends to codify an existing process being used by California car dealers. The size of the warning label and text therein need not change from the existing practice, that is they are

consistent with the safe harbor method in these regulations. OEHHA has only slightly changed the content of the warning message by shortening it.

Section 25607.17 Vehicle Exposure Warnings – Content

284. Comment (AASA et al. and Auto Alliance et al.): The commenters suggest including replacement parts in the vehicle-specific warning. The regulations should include an exemption from the warning requirements for all after-market replacement and service parts. If OEHHA is unwilling to provide a full exemption, then a model year based exemption should be included according to the warning requirements in place at the time the vehicle was produced. For parts that apply to multiple model years, the earliest model year would be basis for the warning. If OEHHA is unwilling to provide a special allowance for aftermarket, replacement, and service parts from the proposed new warning requirements, OEHHA is urged to include a safe harbor warning for aftermarket replacement and service parts as part of the vehicle-specific warning language. Chemicals within replacement parts are typically the same as those in vehicles, so it is reasonable to include replacement parts in the passenger vehicle warning. An owner's manual is in every vehicle; therefore, providing a replacement part warning within the owner's manual would satisfy the need to provide a warning to consumers prior to purchase.

Response: Any exposures from after-market component parts sold directly to the consumer are consumer product exposures and are covered by the safe harbor approaches in Sections 25602 and 25603. Parts installed by a dealer or repair shop would be treated as an occupational exposure, with safe harbor provided in Section 25606. The owner's manual is not an appropriate place for providing warnings for replacement parts, as these warnings should be provided with or in close proximity to the product. Similarly, a general warning statement about after-market parts in an owner's manual would not be clear and reasonable because it would not inform the consumer which specific after-market part is the subject of the warning and which chemical(s) is involved in the exposure. A consumer's chemical exposures in handling replacement parts can differ from exposures incurring from servicing.

285. Comment (Auto Alliance et al.): OEHHA should consider amending the language for labels on battery and fuel cell electric vehicles (EVs) which do not produce engine exhaust or carbon monoxide. Either there should be a separate label for EVs or include language stating that for batteries or EVs it is not necessary to include engine exhaust and carbon monoxide on warning.

Response: OEHHA is considering an informal request for the development of a "tailored warning" pursuant to Section 25607, et seq. for exposures to listed chemicals in other vehicles. In response to this and other comments, subsection 25607(a) has

been amended to make clear that, as provided for in subsection 25607(b), a business can eliminate the name of a chemical from a warning where a given product does not cause an exposure to it. For fuel cell and EVs, carbon monoxide and engine exhaust could be omitted from the warning. In that case it is possible that no warning is required for such vehicles. If the manufacturer determines that a warning is required, however, at least one chemical must be named on the warning. Such a warning would be consistent with the safe harbor if it is provided according to the provisions in this section.

286. Comment (CNCDA): Does a non-English word in a product name trigger a non-English warning? There is no definition for "consumer information", therefore, it is vague and lacks clarity.

Response: OEHHA subsequently adopted a definition for “consumer information” in subsection 25600.1(c) which should address this issue. A non-English word in a product name would not trigger the need for a non-English warning to comply with the safe harbor.

287. Comment (CNCDA): Section 25607.17 requires a warning that includes engine exhaust and carbon monoxide and recommends that "[t]o minimize exposure, avoid breathing exhaust, [and] service your vehicle in a well-ventilated area. ..." The recommendations are appropriate for traditional combustion engine vehicles. However, it does not account for zero emissions vehicles. While subsection 25607(b) would allow manufacturers to remove references to engine exhaust and carbon monoxide when appropriate for warnings on zero-emissions vehicles, it would not allow them to remove use recommendations that address breathing in such chemicals. Request OEHHA amend Section 25607 to allow for the removal of use recommendations that accompany an inapplicable chemical or amend Section 25607.17 to exclude zero-emissions vehicles from the larger group of passenger vehicles. OEHHA could rely on HSC section 44258(d), which states " 'Zero-emissions vehicle' means a vehicle that produces no emissions of criteria pollutants, toxic contaminants, and greenhouse gases when stationary or operating, as determined by the state board."

Response: OEHHA is considering the development of a “tailored warning” pursuant to Section 25607, et seq. for exposures to listed chemicals in other vehicles. Subsection 25607 (b) allows a business to eliminate the name of a chemical from a warning where a given product does not cause an exposure to it. If a vehicle such as a zero-emission vehicle does not cause exposures to vehicle exhaust and carbon monoxide, then it would not be necessary for the warning to contain instructions on how to avoid exposure to these chemicals.

288. Comment (Auto Alliance et al.): OEHHA should clarify if additional chemicals should be included beyond those on the vehicle specific warning label.

Response: The regulations do not prohibit the inclusion of additional chemical names in the warning if a manufacturer wishes to provide them.

Section 25607.18 Recreational Vessel Exposure Warnings – Method of Transmission

289. Comment (CH&LA): It is unclear what is included as a 'recreational vessel'. Are rowboats or canoes included?

Response: The term "recreational vessel" is defined by reference in California Harbors and Navigation Code Section 651(t) as "a vessel that is being used only for pleasure." There is no intent to exclude rowboats or canoes from this section of the regulations if such vessels do cause exposures under the Act.

290. Comment (NMMA): Subsection (a)(1) limits the manufacturer to only three locations for a warning label in an owner's manual. The regulation contradicts the definition of "labeling" in subsection 25600.1(g) and the label requirements for consumer products found in Section 25602. The regulation should have flexibility to include the warning label in the owner's manual at the business's own discretion and/or as an insert or addendum included in owner's manual package.

Response: OEHHA disagrees that subsection 25607.18(a)(1) contradicts the definition of "labeling". Subsection 25600.1(j) in the new regulations states:

> (j) "Labeling" means any written, printed, graphic, or electronically provided communication that accompanies a product including tags at the point of sale or display of a product.

Neither of these definitions expressly refers to an owner's manual as an example of "labeling" that might "accompany a product" that would be sufficient for purposes of providing a Proposition 65 warning. OEHHA is aware that some businesses currently provide Proposition 65 warnings in the owner's manual for their products. This method of providing a warning has never been sanctioned as a general safe harbor method for consumer products by OEHHA.

OEHHA believes that providing a warning in an owner's manual is a very good adjunct to providing a warning in a more immediate location on a recreational vessel. OEHHA has developed a "tailored" warning for exposures to listed chemicals from recreational vessels that requires the placement of the warning in the owner's manual as well as a warning provided on a hang tag readily visible from the helm of the vessel. Placing the primary warning where it will be seen prior to individuals entering the vessel ensures

that the warning is seen and understood prior to exposure to chemicals that can occur upon entering or using the vessel. The three locations within an owner's manual where the safe-harbor warning may be printed or affixed were selected because OEHHA believes they are areas that can easily be seen by individuals reading an owner's manual. OEHHA does not believe that a warning placed elsewhere in the owner's manual would be clear and reasonable. A business is free, however, to put a warning anywhere else in the owner's manual that it believes would be clear and reasonable, but it would not be considered a safe-harbor warning.

291. Comment (NMMA): Request an amendment to subsection (a)(1), remove, "…to the inside or outside of the front or back cover of the manual or on the first page of the text, and " replace with, "...in any appropriate warning section of the manual or as an insert included with the owner's manual, and".

Response: OEHHA declines to make the change requested. The areas identified in the regulations for placement of the warning will help ensure it is seen and understood prior to exposure. OEHHA does not believe that a warning placed elsewhere in the owner's manual would be clear and reasonable.

Section 25607.20 Enclosed Parking Facility Exposure Warnings – Method of Transmission

292. Comment (CH&LA): It is unclear what 'enclosed' means. Does it mean enclosed except for entrances and exits or enclosed only on two or three sides?

Response: "Enclosed" has its ordinary meaning.[39] It is intended to differentiate parking facilities that are open parking lots or open structures from those that are underground or have walls that enclose them to such a degree that engine exhaust can accumulate sufficiently to cause an exposure.

Section 25607.22 Amusement Park Exposure Warnings – Method of Transmission

293. Comment (CAPA): The description of "amusement park" and the definition of "amusement ride" are acceptable.

Response: Comment noted, no response required.

294. Comment (DRoe): The regulations are captioned as setting out the specific safe harbor prescriptions for amusement parks, but there is no limiting definition of "amusement park." The language for the application of Sections 25607.22 and 25607.23 are both inclusive and ambiguous. The term "including" can and would be

[39] See for example: http://www.merriam-webster.com/dictionary/enclose

read as “including but not limited to". OEHHA should revise the text to precisely reflect its intent and connect the defined terms with the safe harbor prescriptions.

Response: Subsequent to this comment, the definition for amusement park was modified for clarity.

295. Comment (CH&LA): CH&LA strongly urges OEHHA to treat hotels the same way as amusement parks in Sections 25607.22 and 25607.23. Propose method and content language similar to that which is proposed for amusement parks.

Response: OEHHA is considering an informal request for the development of a “tailored warning” pursuant to Section 25607, *et seq.* for exposures to listed chemicals in hotels and apartments.

Section 25607.25 Petroleum Products Warnings (Environmental Exposures) – Content

296. Comment (ILMA): The proposed regulations are inappropriate in the context of industrial operations where refined petroleum products are used. Almost without exception, highly-refined petroleum oils used in machining and grinding applications do not contain toluene or benzene. By adoption of this proposal for general manufacturing shops, employees are overwarned for non-present toluene and benzene and not warned of other chemicals unless employers choose to provide warnings.

Response: Occupational exposures are covered under Section 25606. The title of the section specifically calls out environmental exposure as the focus for the section. Nonetheless, subsequent to this comment, in subsection (a) the regulations were modified to further clarify that this warning provision applies to *environmental* exposures from these facilities. Also, if a person does not cause an exposure to a listed chemical named in a tailored warning, the name of that chemical need not be included (subsection 25607(b)).

Section 25607.26 Service Station and Vehicle Repair Facilities Warnings (Environmental Exposures) – Methods of Transmission

297. Comment (Environmental Coalition): The regulations should not allow the warning to be placed on the back or sides of the pump where a consumer cannot easily read it. The Coalition recommends adding the sentence, "The warning must face the consumer when he or she is operating the pump."

Response: This issue is addressed in the general definition of a “sign” (now in subsection 25600.1(m)) which requires a sign to be posted in a conspicuous manner that is associated with the exposure requiring a warning under the Act, is clearly visible

under all lighting conditions normally encountered during business hours and under such conditions as to make it likely to be seen, read, and understood by an ordinary person.

Section 25607.28 Designated Smoking Area Exposure Warnings (Environmental Exposures) – Method of Transmission

298. Comment (CAA and CH&LA): What is the definition of "designated smoking area"? It is not clear how this sign relates to the general environmental exposure sign; do two signs need to be given? Health and Safety Code section 25249.7(l) assumes posting of a warning is required where "exposure to environmental tobacco smoke is caused by entry of persons . . . on premises owned or operated by the alleged violator, where smoking is permitted at any location on the premises". It is not clear how the statute would be satisfied by either the safe harbor environmental exposure warning or the safe harbor designated smoking area warning, suggesting that three warnings may be needed. The regulations do not address smoking medical marijuana.

Response: The comment is referencing HSC section 25249.7(k)(1)(C) which relates to enforcement of Proposition 65 regarding warning about environmental tobacco smoke. These regulations are not intended to interpret this provision of the HSC. To the extent the commenters reference that section as defining a "smoking area", it is not inconsistent with the intent of OEHHA in adopting a safe harbor warning for such exposures. A business may use the safe harbor warning identified in Sections 25607.28 and 25607.29 for environmental exposures to tobacco smoke or nicotine, i.e., from tobacco smoke or "vaping" in areas it has designated for smoking. OEHHA did not include a reference to medical marijuana in the language for designated smoking area warnings because, in our experience, the use of medical marijuana in such areas is relatively rare at this time. Operators of designated smoking areas where medical marijuana is used are encouraged to add a reference to marijuana smoke in their warning, but are not required to do so to meet the safe harbor requirements for environmental tobacco smoke. Marijuana and tobacco smoke share many of the same, but not all, chemical constituents; over 30 separate Proposition 65 listed carcinogens occur in both in marijuana and tobacco smoke.[40]

Section 25607.29 Designated Smoking Area Exposure Warnings (Environmental Exposures) – Content

[40] OEHHA, Evidence on the Carcinogenicity of Marijuana Smoke, OEHHA Reproductive and Cancer Hazard Assessment Branch, California Environmental Protection Agency, August 2009. Available online at: http://oehha.ca.gov/media/downloads/proposition-65/chemicals/finalmjsmokehid.pdf

299. Comment (CAA): Is it sufficient to warn about nicotine and other listed chemicals from 'third hand' tobacco or marijuana smoke or is an additional environmental exposure warning required?

Response: A business may use the safe harbor warning identified in Sections 25607.28 and 25607.29 for environmental exposures to tobacco smoke or nicotine, i.e. from tobacco smoke or "vaping" in areas it has designated for smoking. As discussed in the response to the previous comment, such warnings do not require marijuana smoke to be mentioned in the warning, although businesses that operate smoking areas where medical marijuana is used are encouraged to voluntarily add marijuana smoke to the warning.

Economic Impact Comments

300. Comment (NPA): OEHHA did not present an economic impact analysis for costs to OEHHA or costs to businesses. NPA foresees a considerable impact that will create a barrier to attract new businesses to California and force existing ones to leave for a more business-friendly state.

Response: OEHHA assessed the economic impact of the regulations as required by state law. The Economic Impact Assessment was included as Appendix B to the ISOR and is included in the rulemaking record. The assessment estimates both the direct costs to California businesses as well as the economic impact of the regulation on California. The fiscal impact of the regulations on OEHHA is minimal and consists mostly of staff time devoted to development of the regulations.

301. Comment (ACC): OEHHA must conduct an economic impact assessment.

Response: The commenter submitted this comment on the now-withdrawn January 2015 version of the regulations. Based on stakeholder comments at that time, OEHHA assessed the economic impact of these regulations. The Economic Impact Assessment was included as Appendix B to the ISOR and is included in the rulemaking record.

302. Comment (CCEEB): The economic analysis is inadequate. A meaningful economic analysis is necessary and is a critical missing component of the regulation.

Response: The commenter submitted this comment on the now-withdrawn January 2015 version of the regulations. Based on stakeholder comments at that time, OEHHA assessed the economic impact of these regulations. The Economic Impact Assessment was included as Appendix B to the ISOR and is included in the rulemaking record.

303. Comment (CRN): CRN disagrees that regulations will not have significant economic impact.

Response: The commenter submitted this comment on the now-withdrawn January 2015 version of the regulations. Based on stakeholder comments at that time, OEHHA assessed the economic impact of these regulation The Economic Impact Assessment was included as Appendix B to the ISOR and is included in the rulemaking record.

304. Comment (CSPA): The Economic Fiscal Impact Statement significantly underestimates the impacts upon CSPA members. A sliding scale used to determine the number of products based upon the number of employees is not a reasonable means and often underestimates the number of products. The cost estimates for relabeling significantly underestimates the costs to manufacturers. The cost estimate for web site updates also significantly underestimates actual costs.

Response: OEHHA appreciates that costs relating to modification of warnings will likely vary significantly from business to business but points out that this comment is not supported by any data. Without data, OEHHA is unable to address the commenter's concern. The cost estimates for individual businesses presented in the assessment was based on information from two manufacturers that are providing Proposition 65 warnings on a significant percentage of their products and that were willing to cooperate with OEHHA by providing information. OEHHA attempted to obtain a broader range of cost estimates from various businesses and trade associations but most businesses were unwilling to provide cost estimates, limiting OEHHA's ability to refine the analysis. The "sliding scale" of the estimated numbers of products manufactured by an individual business based on its number of employees was also based on discussions with those two manufacturers. While it is likely that some businesses may produce a greater number of products than OEHHA's sliding scale estimated, another key variable not cited by the commenter is how many of those products carry Proposition 65 warnings. Only the subset of products with Proposition 65 warnings would be potentially affected by the regulations. Because businesses are not required to provide OEHHA or any other government entity with any notice that they are providing a warning, the number of products with Proposition 65 warnings is unknown. Given this lack of information, OEHHA determined that the "sliding scale" is a reasonable way to estimate the number of products with Proposition 65 warnings manufactured by California businesses using available economic data along with the information OEHHA gained from its discussions with the two manufacturers.

The Economic Impact Assessment is not required to estimate the regulation's potential impact on individual businesses or specific sectors of the California economy. Instead, the assessment must estimate the regulation's potential cost on California businesses as a whole and on California's economy. California's economy is larger than that of most countries, and encompasses a very large number of businesses manufacturing and marketing a vast array of products. OEHHA's assessment likely underestimated

potential costs for some of these businesses and some classes of products while overestimating the potential cost for other businesses and classes of products. OEHHA believes its assessment provides a reasonable estimate of the overall cost and impact of relabeling those products that require warnings to incorporate the new safe harbor warnings created by the regulations.

Similarly, OEHHA consulted with information-technology professionals to identify an average per-product cost for providing an internet warning. As with relabeling, this may underestimate the cost for some businesses and products while overestimating the cost for others.

305. Comment (Wine et al.): Based on the now-withdrawn January 2015 regulatory proposal, the commenter states that OEHHA's proposals (1) will have a major impact upon the creation/elimination of jobs in California; (2) will have a negative impact upon the creation of new businesses in California and create various barriers of entry in that marketplace; (3) will have a major impact upon the expansion of existing businesses (that would like to grow beyond 10 employees); and (4) will not benefit the health, safety and welfare of California residents.

Response: OEHHA disagrees with the four numbered points raised in this comment. OEHHA has thoroughly considered these issues as part of the Economic Impact Assessment required by Government Code Section 11346.3(b). The comprehensive analysis is provided in the ISOR[41] and Appendix B to the ISOR which consists of the Economic Impact Assessment for this rulemaking. These documents are part of the rulemaking record and were properly made available to the public as part of the initially proposed rulemaking.

Miscellaneous or General Comments

306. Comments (ACA): ACA applauds the efforts to improve warnings for the public and provide businesses clarity as to what constitutes a clear and reasonable warning under the Act. ACA supports separating the lead agency website provision.

Response: Comment noted, no response required.

307. Comment (ACC): The UC Davis Study does not demonstrate that the proposed changes would improve the statutorily required warning to make them more "clear" or more "reasonable". The Study does not support OEHHA's regulatory proposal due to the flawed charge instructions and design of survey; the unrepresentative survey sample; the improper survey instrument design; and flawed execution. Many conclusions cannot be drawn from the UC Davis Study because the researchers were

[41] ISOR, at 55.

not charged to, and did not, ask certain questions that relate to how consumers actually perceived the information being offered. The Study did not ask and thus cannot answer what information the participants understood was being communicated to them, therefore, severely limiting the utility of study findings. The Study shortcomings are described more fully in an independent assessment commissioned by ACC. [(An Assessment of Proposition 65 Clear and Reasonable Warning Regulations Study, January 14, 2016, Evolving Studies LLC)]

Response: OEHHA requested a response from the UC Davis researchers to the ACC's critique of its study. Their response is attached to the FSOR as Attachment "A" and is incorporated here by reference.[42] For the reasons stated in the response, OEHHA disagrees with the ACC's comments.

308. Comment (CHPA): The UC Davis survey suffers from a number of limitations which impact its ability to make meaningful conclusions. OEHHA should provide a separate breakdown of the participants who viewed the warning favorably into two groups; those familiar and those not familiar with the Proposition 65 regulations as it relates to 'knowledge of Proposition 65' and 'inclusion of specific chemical names', 'knowledge of chemicals', and 'inclusion of a QR Code'. OEHHA should also provide more information on why the particular chemicals were chosen for inclusion in the survey.

Response: The commenter correctly notes that the level of familiarity with the Proposition 65 regulations was not separately considered in the UC Davis Study. OEHHA does not agree that a person's knowledge of Proposition 65 regulations is necessary to assess whether that person feels a warning they are viewing is helpful. The chemicals included in the Study were chosen because they were chemicals on the Proposition 65 list, for which a person could receive a warning under the Act. Although the Study demonstrated that the inclusion of a chemical name was more helpful, OEHHA does not believe that the particular chemicals were relevant in the assessment of helpfulness of warnings, and the Study was not designed to assess helpfulness of any particular chemical names.

309. Comment (AdvaMed): Medical devices should be given a safe harbor similar to prescription drugs. The right-to-know and consent of consumer are properly achieved as some devices are dispensed via prescription and by medically licensed personnel. Medical devices are subject to the jurisdiction and approval for use by US Food and Drug Administration (USFDA) and should be exempted. The regulations overreach in its applicability to medical devices and could be preempted by federal law. Also, the

[42] The letter response was not relied on in the development of the regulation but is included here for reference.

regulations increase the labeling and financial burden on the medical device industry and have the potential to increase frivolous lawsuits, among other potential problems. Proposition 65 is not only illegal per federal law, but is preempted and unconstitutional. USFDA regulates the marketing and sale of medical devices and expressly preempts state law (21 CFR Part 360k(a)). The 2001 court case Public Media Center against tuna canning companies found that Proposition 65 frustrates the USFDA's more balanced approach of benefits and risks.[43] AdvaMed supports the comments of the CalChamber Coalition and urges OEHHA to reexamine its stance on a safe harbor for medical devices.

Response: OEHHA considered issues related to medical devices during the development of this proposal but decided not to provide a separate provision covering these devices at this time. Medical devices have been subject to warnings for many years and are treated differently than prescription drugs in the existing warning regulations. While OEHHA notes the commenter's dissatisfaction with Proposition 65, OEHHA is not aware of any specific warning issues unique to medical devices that merit special treatment in this rulemaking.

310. Comment (NEMA): Medical imaging devices should be given a safe harbor option under Proposition 65 similar to prescription drugs. Medical imaging devices are performed by licensed personnel and are prescribed and directed by physicians in a process recognized and controlled by the State of California. USFDA regulates the marketing and sale of medical devices to ensure they are safe and effective and to ensure national uniformity expressly preempts state law requirements. Request that devices subject to the jurisdiction of, and approved for use by, USFDA be granted an exemption under the proposed rule.

Response: OEHHA considered issues related to medical devices during the development of this proposal but decided not to provide a separate provision covering these devices at this time. Medical devices have been subject to warnings for many years and are treated differently than prescription drugs in the existing warning regulations. OEHHA is not aware of any specific warning issues unique to medical devices that merit special treatment in this rulemaking.

311. Comment (AHPA): Warnings for exposures to listed reproductive toxicants would be much more informative if they consisted of instructions that the product should not be used by those populations who could be negatively affected by exposure, rather than requiring declaration of the presence of a chemical. A warning that the product should

[43] The commenter appears to be referencing the holding in *The People ex rel. Brown v. Tri-Union Seafoods, LLC*, 171 Cal.App.4th 1549, 90 Cal.Rptr.3d 644 (2009). The *Tri-Union Seafoods* case consolidated a case that was filed by the Public Media Center in 2001.

not be used by specific consumers who might be harmed by it would be much more clear, understandable, and useful for consumers.

Response: Proposition 65 does not ban or regulate the use of listed chemicals or the products that contain them, and therefore it would be beyond the scope of Proposition 65 to require a warning telling certain individuals not to use a product. Businesses could certainly provide such advice on their own. OEHHA has determined that providing information regarding the identity of a chemical will improve the information available to a person being exposed to a listed chemical. Proposition 65 is a right to know law that requires warning of exposures to chemicals that are on the Proposition 65 list and supports decisions by individuals regarding the extent to which they wish to be exposed. The Proposition 65 warnings website (www.P65Warnings.ca.gov) provides additional information regarding the effects caused by chemicals and the extent of exposure. Information regarding populations that could be negatively affected by exposure to a listed chemical could be useful supplemental information to the information provided on the OEHHA warnings website.

312. Comment (CAA): In a residential rental property where there is the potential for multiple exposures, including occupational and food and alcohol exposures, it is unclear how all the different warning requirements overlap. It is also unclear whether safe harbor warnings for restaurants can be used for food and non-alcoholic beverages that are offered by a business at a social function but not for sale.

Response: There is not sufficient information in the comment regarding the scenarios listed by the commenter to be able to provide a specific answer. The commenter's concerns about complying with multiple warning requirements are not inherently specific to this rulemaking, as there have been regulations governing occupational, food, alcohol and restaurant warnings since the late 1980s. In general, a business would need to consider the exposures to listed chemicals that it knows about, and determine if each exposure requires a warning. If the business causes an occupational exposure to a listed chemical, a warning provided in accordance with Section 25606[44] would provide a safe harbor for that occupational exposure. If there is a consumer product exposure, the person may also need to provide a warning for that exposure. The safe harbor warning for restaurants in Sections 25607.5 and 25607.6 expressly apply to a restaurant, or a "food facility" as defined in HSC section 113789, and would not normally apply to other kinds of businesses providing food at a social function.

[44] Under subsection 25606(a), a warning that complies with the federal HCS, California HCS, or Pesticides and Worker Safety requirements; or a warning under subsection 25606(b) for occupational exposures not covered by subsection (a).

313. Comment (CAA): This proposal fails to achieve the Governor's Proposition 65 reform. Compliance will be more difficult for the rental housing industry and greatly increase frivolous lawsuits. CAA supports the comments and concerns presented by the CalChamber Coalition.

Response: OEHHA disagrees that compliance will be more difficult and will increase frivolous lawsuits. The comment expressing support of the CalChamber Coalition's comments is noted.

314. Comment (CH&LA): There is no definition for "intentional". If the phrase, "knowingly and intentionally" were applied in its normally understood and accepted sense, no business could possibly be deemed to have acted knowingly and intentionally, because the proposed regulations make it impossible for a business to have the requisite scienter (i.e., the fact of an act having been done knowingly). It is virtually impossible for any business to analyze and understand which of the 800+ listed chemicals are present in its operations, and therefore no business can be said to be knowingly and intentionally creating an "exposure" that requires a warning.

Response: The commenter correctly noted that there is no definition for the term "intentional". The term appeared in the phrase "knowing and intentional" in subsection 25600.2(d)(2) [now 25600.2(e)(2)]. However, the term "intentional" was stricken from the regulatory text in March 2016, for alignment with the relevant statutory framework. The term "knowingly"[45] for purposes of these regulations is used only in subsection 25600.2(e)(2) to describe circumstances in which a retail seller may be responsible for providing a warning. The phrase "knowingly and intentionally" relates to the decision of whether to provide a warning under the Act; such a determination is addressed in other regulations and as such is outside the scope of this regulatory action.

315. Comment (CH&LA): OEHHA's guidance is faulty and inaccurate on several different levels. For years CH&LA provided its members with detailed information about listed chemicals likely present in a typical hotel and when and where exposures might occur that warrant a warning. OEHHA's position that relying on advice from a trade association is not sufficient for environmental exposures, but no rationale was provided for this position.

Response: OEHHA is considering an informal request for the development of a "tailored warning" pursuant to Section 25607, *et seq.* for exposures to listed chemicals in hotels and apartments. No change was made to the regulation in response to this comment.

[45] The term "knowingly" in subsection 25600.1(h) is defined by reference to Article 1, section 25102(n).

316. Comment (CH&LA): OEHHA is faulty in its presumptions: (1) that most businesses will have or can easily obtain "knowledge" of listed chemicals that might be used in its operations in "detectable" amounts; (2) that all businesses have knowledge whether or not the "level of exposure" requires a warning; (3) that all businesses have knowledge of whether a safe harbor level is exceeded; (4) for chemicals lacking safe harbor levels that businesses have knowledge of whether the anticipated exposure level will or will not pose a significant risk; (5) that all businesses can determine the concentration of each chemical and have information about how an exposure might occur; (6) that all businesses can make the necessary determinations by requesting an Interpretive Guideline or Safe Use Determination. Very few businesses have the financial and technical wherewithal to determine the applicability of a warning.

Response: This comment appears to be directed at the determination made by a business about whether a warning is required under the Act for a given exposure. These issues are addressed in other regulations and are outside the scope of this rulemaking. No further response is required.

317. Comment (CH&LA): The existing regulations give comprehensible guidance on how to post clearly defined warnings in specific defined locations without having to jump through impossible hoops. The proposed regulations require businesses to engage in extremely complex and expensive scientific investigation that virtually no business can accomplish. It is not feasible for any hotel to determine definitively and beyond legal challenge whether a warning is required and then safely and reliably understand when and how to comply with the warning requirements. That is why the relatively straightforward safe harbor in the existing regulations is critical.

Response: OEHHA disagrees that a business will have to perform testing for the purpose of complying with these regulations. The safe harbor warning methods and content contained in these regulations only apply where a business has decided to provide a warning, they do not determine when a warning is required. As noted previously, OEHHA is considering an informal request for the development of a “tailored warning” pursuant to Section 25607, *et seq.* for exposures to listed chemicals in hotels and apartments, to provide additional certainty to hotels providing warnings while improving the effectiveness of warnings for people who can be exposed to a listed chemical.

318. Comment (CH&LA): The proposed regulations are invalid and unenforceable because the safe harbor provisions are void for vagueness, unconstitutionally deny businesses their due process rights, and destroy the purpose of Proposition 65 to give the public information they can use to understand the risks they might be facing.

Response: OEHHA disagrees that the regulations are vague and unconstitutional. The regulations contain safe harbor method and content requirements for more informative Proposition 65 warnings that businesses can choose to utilize, or they can use their own warning methods and content that comply with the Act's requirements for clear and reasonable warnings. OEHHA has determined that the various provisions of the regulations will improve the effectiveness of warnings; provide more certainty regarding the relative responsibilities of businesses within the chain of distribution, ensure warnings are received by the person prior to being exposed; and will increase information available to the public regarding exposure to listed chemicals.

No changes were made to the regulations based on this comment.

319. Comment (CH&LA): CH&LA strongly believes the regulations should contain express language that providing an unnecessary warning is not prohibited.

Response: The recommendation made by the commenter would contribute to over-warning, which is contrary to the principles of Proposition 65 reform articulated by the Governor and by OEHHA. OEHHA therefore declines to make the change requested by commenter.

320. Comment (CMTA): At the public hearing, CMTA expressed support for the comments made by the business community at that hearing. When the regulations are finalized, CMTA would like to see clear instructions about what is necessary to comply with and under what timelines.

Response: Comment noted. Since the regulations are safe harbor provisions, there are no specific compliance deadlines. Pursuant to Section 25600(b) the regulation becomes effective two years after it is adopted. This will provide a transition period for those businesses who are currently providing safe harbor warnings to comply with the new requirements. Further, the regulations provide for an unlimited sell-through period for products that have compliant warnings when they are manufactured.

321. Comment (TEMA): TEMA is generally supportive of the proposal to adopt revised Article 6. In particular, supports the safe harbor requirement in Sections 25607.14 and 25607.15; supports the two-year implementation period in subsection 25600(b); and supports grandfathering court-approved settlements and final judgments in subsection 25600(f).

Response: Comment noted, no response required.

322. Comment (NPA): NPA urges OEHHA to reconsider and abandon the latest proposal until OEHHA conducts a more thorough assessment of its impact on businesses. NPA questions how many lawsuits were based on inadequate or inconsistent warnings. A review of recent Proposition 65 lawsuits and settlements

indicate that the vast majority were not over content of the warning, but whether a warning was required at all. Imposing additional prescriptive requirements without addressing the core cause of litigation will likely trigger more frivolous lawsuits.

Response: OEHHA performed a comprehensive Economic Impact Assessment that was included as Appendix B to the ISOR. The ISOR and economic analysis were made available to the public for comment during the 45-day public comment period. OEHHA thus declines the recommendation to abandon the current rulemaking, but notes that a number of changes were made to the regulations in the two modifications of text that were made available to the public. Statistics regarding lawsuits are outside the scope of this rulemaking, however, the California Office of the Attorney General does provide a searchable online database of 60-day notices for additional research https://oag.ca.gov/prop65/60-day-notice-search. The portion of the comment discussing addressing the core cause of litigation is outside the scope of this current rulemaking.

323. Comment (NPA): The proposal does not achieve the goal to provide greater clarity, but rather it will be counterproductive and have the opposite effect of more 'over warning'. It will result in tremendous financial and resource challenges to businesses. It is arbitrary to move forward with the proposal without actual empirical data to support the perceived benefits to consumers and without an assessment of risk and legal vulnerability for businesses.

Response: As noted in response to earlier comments, the ISOR for this rulemaking includes a study of the effectiveness of the warnings and an Economic Impact Assessment. Assessment of individual businesses' legal vulnerability and litigation risk are beyond the scope of the Economic Impact Assessment and this rulemaking. The ISOR and attachments were properly noticed and made available to the public for review and comment. As stated in the response to earlier comments, the UC Davis study found that 75 percent of those surveyed felt the warnings conforming with this regulation were more helpful than the current warnings.

324. Comment (KHamilton-Roth): The commenter is concerned about bromine being used as a dough conditioner in bread because it takes the place of the much needed iodine in our bodies and causes multiple problems, especially thyroid issues.

Response: This comment is not related to the current rulemaking.

325. Comment (LAyers): Include all five changes proposed in Article 6. The commenter appears to be referring to the five benefits of the proposed regulation listed in the Notice of Proposed Rulemaking:

- Making warnings more visible (due to the use of the familiar exclamation point symbol for most warnings)

- Stating that the product or the location can expose them to a listed chemical (as opposed to the current general practice of simply warning of the presence of a chemical)
- Identifying at least one listed chemical to which they would be exposed
- Providing the URL for an OEHHA web site which will provide general information about listed chemicals, products or locations commonly associated with those chemicals, and general advice for how to reduce or avoid exposures to those chemicals.
- Providing for warnings in non-English languages in instances where product labeling contains information in alternative languages or at locations where signs are posted in those language

Response: Comment noted, no response required.

326. Comment (GMA): Although OEHHA's efforts are appreciated, other reform issues are of greater priority to GMA, for example, the naturally occurring regulation.

Response: Comment noted. This comment is outside the scope of the current rulemaking.

327. Comment (DRoe): Gaps in drafting the regulations give safe harbor shelter to wider than intended situations, and the result is safe harbor warnings that would be meaningless, confusing, unintelligible, or actively misleading in those unintended contexts. Structurally, because the safe harbor shelter (e.g., for a sign saying "Entering this area") applies to the full extent of the defined term (exposures via all media), the legal shelter is much larger than the set of situations that the shelter is meant to cover (at most, ambient-air exposures within "this area"). Full safe harbor shelter for over-inclusive or under-exclusive terms appears regularly throughout proposal. Imprecision in drafting shows up in contexts that create confusion at best and absurd over-application of safe harbor shelter at worst. OEHHA should take advantage of its re-start of this regulatory proceeding to give this draft a thorough and precise technical review and tighten its drafting throughout.

Response: Comment noted. The regulations have been modified twice since the initially proposed rulemaking. These changes were intended to improve clarity and consistency throughout the regulations and should address many of the commenter's concerns.

328. Comment (TVC): The proposed regulations do not cap legal fees collected by attorneys representing the enforcer groups, or reapportion the settlements to better benefit the State rather than the private parties and attorneys. There are no changes proposed to require a petitioning party at the time of filing a notice of action to present actual evidence of a violation.

Response: This comment is outside the scope of the current rulemaking and generally outside the scope of OEHHA's authority.

Summary and response to comments on the March 2016 proposed regulations

After careful consideration of the comments received during the initial comment period, OEHHA published a **Notice of Modification to Text of Proposed Regulation** on **March 25, 2016**. OEHHA modified the text of the proposed regulation as follows:

- Section 25600(b) was modified to clarify that a warning that complies with Article 6 that is provided before the two-year effective date will be deemed to be clear and reasonable.
- Section 25600(c) was revised to clarify that a person may request the adoption of a warning method or content for a "specific product, chemical or area exposure warning" rather than a specific consumer product.
- Section 25600(d) was revised and moved from the general provisions of Subarticle 1 to the safe harbor provisions of Subarticle 2, Section 25601(f) based on stakeholder comments.
- Section 25600(e) [formerly numbered as (f)] was modified by striking the phrase "for a consumer product or environmental warning" in response to stakeholder comments. The word "warning" was added before "method" for clarity.
- Section 25600.1 was revised as follows:
    - In the definition of "affected area", "listed" was added before "chemical" for clarity and the phrase "known to the state to cause cancer or birth defects or other reproductive harm" was removed as being unessential and redundant. The term "is" was changed to "can occur" for consistency with rest of the regulation.
    - The phrase "producers, packagers, importers" was added to the definition of "authorized agent" for internal consistency; this change was made throughout the regulation.
    - The term "consumer information" was added as a defined term for clarity.
    - The term "consumer product" was added as a defined term for clarity.
    - The existing definition for "consumer product exposure" was moved and renumbered for purposes of alphabetization.
    - The phrase "or otherwise provides" was added to cover the distribution of consumer products to consumers. The phrase "including foods" was removed as redundant in light of the definition of consumer products which already incorporates foods. The term "purchasers" was changed to "consumers" and "internet" was capitalized in the definition of "retail seller;" these changes were made throughout the regulation for internal consistency.
    - The subsections were renumbered to reflect the addition of new definitions
- In Section 25600.2(b) "supplier" was added for consistency, and "section" was changed to "article" for clarity.
- Section 25600.2(b)(3) was modified to remove the offer to provide warning materials at no charge. Based on comments received, OEHHA believes that the manufacturer, producer, packager, importer, supplier or distributor should provide

the warning materials to the retailer unless the parties agree otherwise pursuant to subsection (i) [formerly (h)]. The phrase “and warning language for products sold on the Internet” was added to clarify the responsibility to provide warning language for consumer products sold online.

- Section 25600.2(b)(4) was modified to include “producer, packager, importer, supplier or distributor.” The subsection was also revised to clarify that confirmation of receipt of the notice must be provided “electronically or in writing,” in response to stakeholder requests for the ability to provide electronic confirmation of receipt.
- Section 25600.2(b)(5) was renumbered to subsection (c) and subdivided into two paragraphs for clarity. Subparagraph (c)(1) clarifies that the renewed notice must be confirmed electronically or in writing within six months during the first year after the effective date of the regulation and annually thereafter. The term “new” was stricken in subparagraph (c)(2) and replaced with the phrase “different or additional” added to clarify when an additional notice is required under the subsection.
- Section 25600.2(d) [formerly numbered as (c)] was modified to clarify that the retail seller is responsible for posting and maintaining warning materials for products sold over the Internet and a reference was added to the new subsection (c).
- Section 25600.2(e)(2) [formerly numbered as (d)(2)] was modified to remove “and intentionally” and to add “knowingly” before “caused…” for alignment with the relevant statutory framework.
- In Section 25600.2(e)(3) [formerly numbered as (d)(3)], a reference was added to the new subsection (c) for clarity.
- Section 25600.2(e)(4) [formerly numbered as (d)(4)] was modified to remove the offer to provide warning materials consistent with the change in 25600.2(b)(3), and a reference was added to the new subsection (c) and “or displaying” was added for clarity.
- In Section 25600.2(e)(5) [formerly numbered as (d)(5)] “supplier” was added for consistency.
- Section 25600.2(f) [formerly numbered as (e)] was modified to simplify the explanation of the notice requirement, and to allow a business five (5) business days, rather than two (2) in response to stakeholder requests for an extension of the time period in which a retail seller is deemed to have “actual knowledge” of an exposure.
- Section 25600.2(g) [formerly numbered as (f)] was modified to clarify that a retail seller must “promptly” provide the requested information; this change was made to require action on behalf of the retail seller in response to the request. The term “supplier” was also added for consistency.
- Section 25600.2(g)(2) [formerly numbered as (f)(2)] was modified to clarify that it is a “consumer” product that causes an exposure.
- Section 25600.2(i) [formerly numbered as (h)] was modified to clarify that provided that the consumer receives a compliant warning prior to exposure, the

responsible parties may enter into a written agreement with the retail seller that allocates responsibility differently. "Supplier" was added for consistency. Also a reference to subsection (e) was added. The phrase "to the extent that the warning provided to the purchaser of the product meets the requirements of Section 25249.6 of the Act" was removed.

- Section 25601(c) was modified to clarify that any one of the listed chemicals for which the person has determined a warning is required can be included in the warning and that if the warning is for more than one endpoint, then one or more chemicals for each endpoint must be included in the warning unless the named chemical is listed for both endpoints. The phrase "to the extent an exposure to that chemical is at a level requiring a warning" was also removed in response to stakeholder comments.
- A new subsection (d) was added to Section 25601 to clarify how a consumer product exposure warning must be provided. This provision was included in Section 25601 to provide safe harbor guidance regarding consumer product exposure warnings.
- A new subsection (e) was added to Section 25601 to clarify how an environmental exposure warning must be provided. This provision was included in Section 25601 to provide guidance regarding safe harbor environmental product exposure warnings.
- New subsection (f) to Section 25601 was moved from Section 25600(d) and modified to clarify the types of supplemental information that may be provided in a warning.
- Section 25602(a)(1) was modified to remove reference to type size consistent with the addition of the new Section 25601(d), and "posted sign" was added.
- Sections 25602(a)(3) was modified to remove reference to type size consistent with the addition of the new Section 25601(d).
- Section 25602(b) was modified to clarify that for products sold on the Internet the warning must either be included on the product display page or provided as a clearly marked hyperlink on the product display page or otherwise displayed "prior to completing the purchase". The subsection was also modified to remove reference to type size consistent with the addition of the new Section 25601(d). Language was also added to clarify that if the product has an on product label, the website warning can use the same warning content.
- Section 25602(c) was modified to remove the reference to type size consistent with the addition of the new Section 25601(d). In response to stakeholder comments, language was also added to clarify that if the product has an on product label, the catalog warning can use the same warning content.
- Section 25603(a)(2)(A) and (B) were modified for clarity and readability.
- Section 25603(a)(2)(C) was modified to clarify situations in which a warning is required for multiple chemicals that each cause a different toxicity endpoint.
- Section 25603(a)(2)(D) was added to clarify the situation in which a warning is required for a chemical that causes both toxicity endpoints.

- In response to stakeholder comments concerning adequacy of the safe harbor environmental exposure provisions, Section 25604 was modified to more clearly state the requirements for transmitting an environmental exposure warning and clarifying that for indoor environments or outdoor spaces with clearly defined entrances, the specified warning method in subsection (a)(1) must be used.
- Sections 25605(a)(3), (a)(4) and (a)5) were modified to clarify that a description of the exposure source should be included in the warning.
- Section 25605(a)(6) was added to clarify the situation in which a warning is required for a listed chemical that causes both toxicity endpoints.
- Section 25606 was modified for clarity and readability. The term “warning” was added to clarify the type of information related to occupational exposures meet the warning requirements of Article 6.
- Section 25607 was modified to clarify that a specific tailored warning must be used unless the conditions of subsection (b) apply.
- Section 25607.1(a), Section 25607.2(a)(1), Section 25607.3(a)(3), Section 25607.12(a)(1), Section 25607.14(a)(1)(A), and Section 25607.16(a)(2) were modified to remove reference to type size consistent with the addition of the new Section 25601(d). Section 25607.1(a), Section 25607.3(a)(3), Section 25607.12(a)(1), Section 25607.14(a)(1)(A), and Section 25607.16(a)(2) were modified to remove the minimum type size requirement size consistent with the addition of the new Section 25601(d).
- Section 25607.1(c) was modified for clarity by striking “label, labeling, or sign” and requiring that if “any consumer information” for a “specific food product” is provided in a language other than English, the warning must also be provided in that language. This modification is in response to concerns that unrelated signs such as advertising could trigger a foreign language requirement for a retailer.
- Section 25607.2(a)(4) was modified to clarify situations in which a warning is required for multiple chemicals that each cause a different toxicity endpoint.
- Section 25603(a)(5) was added to clarify the situation in which a warning is required for a chemical that causes both toxicity endpoints.
- In Section 25607.5(a)(3), “A warning” was added for clarity.
- Section 25607.8(a) “either” was changed to “one or both” for consistency.
- Sections 25607.10(a), 25607.11(a), 25607.12(a), 25607.14(a), and 25607.15(a) were modified to include “consumer product” to clarify the type of anticipated exposure. Section 25607.11(a) “one or more” was changed to “one or both”. In Section 25607.12(a)(1)(A) “and” was added and in subsection (a)(1) and subparagraphs (a)(1)(A) and (a)(1)(B) “is” was added.
- In Section 25607.13(a) “from furniture” was added for clarity and consistency.
- Section 25607.13(a)(1)(C) was modified to clarify how to identify the chemical names depending on the situations in which a warning is required for multiple chemicals that each cause a different toxicity endpoint.
- Section 25607.15(a)(3) was modified to add an additional caution, “Do not idle the engine except as necessary”.

- Section 25607.17(a)(3) was modified to add, “do not idle the engine except as necessary” to provide an additional caution for a person to minimize exposure to diesel engine exhaust.
- Section 25607.22(a) was modified to move the definition of “amusement park” to subsection (b) and to define “amusement ride”.
- Section 25607.23(a) was modified to clarify that the identity of the affected area and the source of exposure must be included in the warning and that the warning refers to the particular amusement park for which the warning was being provided.
- Section 25607.25 the term “environmental” exposures to petroleum products was added for consistency and clarity.
- Sections 25607.26 and 25607.28, “sign” was changed to “warning” for consistency and clarity.
- Sections 25607.27(a)(3) and (b)(3) were modified to include an additional caution statement, “Do not stay in this area longer than necessary” in the warning.

Non-substantive, grammatical changes were also made throughout the regulation for consistency.

The comment period was originally scheduled to close on **April 11, 2016**. However, OEHHA received and granted a request from the California Chamber of Commerce to extend the comment period. The comment period closed on **April 26, 2016**.

The following organizations submitted comments on the modifications of text during the 15-day comment period (March 25, 2016 to April 26, 2016):

Alliance of Automobile Manufacturers, Association of Global Automakers, Inc. and Motor & Equipment Manufacturers Association (Auto Alliance et al.)

American Beverage Association (ABA)

American Chemistry Council (ACC)

American Coatings Association (ACA)

American Herbal Products Association (AHPA)

American Home Furnishings Alliance (AHFA)

Association of Home Appliance Manufacturers (AHAM)

Automotive Aftermarket Suppliers Association (AASA)

Joe Agliozzo (JAgliozzo)

California Chamber of Commerce Coalition (CalChamber)

California Attractions and Parks Association (CAPA)

California Council for Environmental and Economic Balance (CCEEB)

California Dental Association (CDA)

California Grocers Association (CGA)

California Hotel & Lodging Association and California Association of Boutique and Breakfast Inns (CH&LA)

California Restaurant Association (CA Restaurant)

California Retailers Association (CA Retailers)

Council for Responsible Nutrition (CRN)

Environmental Law Foundation, As You Sow, Center for Environmental Health, Lexington Law Group, and Mateel Environmental Justice Foundation (Environmental Coalition)

Flavor and Extract Manufacturers Association (FEMA)

Grocery Manufacturers Association (GMA)

Independent Lubricant Manufacturers Association (ILMA)

Intercontinental Chemical Corporation (ICC)

Mateel Environmental Justice Foundation (Mateel)

North American Insulation Manufacturers Association (NAIMA)

National Marine Manufacturers Association (NMMA)
Pacific Coast Building Products (PCBP)
Roger Kratz (RKratz)
Rubber Manufacturers Association (RMA)
David Roe (DRoe)
Western States Petroleum Association (WSPA)
Wine Institute, the Beer Institute and the Distilled Spirits Council (Wine et al.)

Section 25600 General

Subsection 25600(b)

329. Comment (Auto Alliance et al., AASA, CRN, and WSPA): The two-year implementation period is inadequate. The period should be at least three years. The longer transition period would benefit the motor vehicle and dietary supplement industries.

Response: This comment is not related to the modification of text. A response to this comment is provided with the responses for the first set of comments on the proposal.

330. Comment (CDA): CDA supports the two-year implementation period. It allows adequate time to educate CDA's members and also allows those entities that choose to change their warnings sooner than two years to do so. The two-year implementation period provides the needed flexibility.

Response: This comment is not related to the modification of text. Comment noted, no response required.

331. Comment (CA Retailers): Retailer responsibility for providing warnings should become effective immediately. There is no reason for retailers to be exposed to enforcement actions for two years when they do not fit one of the scenarios specified in subsection 25600.2(e).

Response: This comment is not related to the modification of text. It should be noted that a retailer may comply with the regulation at any time after the date of adoption of the regulation (subsection 25600(b)).

332. Comment (AHAM): Although the implementation period is not long enough for all product types, support the proposal to allow a warning that complies with the regulation prior to the two-year transition period. Support the ability to sell through products already in the chain of commerce.

Response: This comment is not related to the modification of text. Comment noted, no response required.

333. Comment (ACA): ACA appreciates the sell-through provision in subsection (b). However, the provision is limited because an entire class of products is not allowed to

use the sell-through period. Recommend striking "consumer" to broaden the application beyond consumer products.

Response: This comment is not related to the modification of text. The changes made to subsection 25606(b) should alleviate this concern.

Subsection 25600(c)

334. Comment (RMA): Supports the petition for rulemaking process or guidance for product, area or chemical specific warning methods or messages in subsection (c) because providing this process allows businesses the opportunity to seek product specific warning methods.

Response: Comment noted, no response required.

Subsection 25600(d)

335. Comment (CCEEB): Objects to the complete elimination of the previous subsection 25600(d) that allowed supplemental information to be given provided it did not contradict the warning.

Response: Subsection (d) was not "completely eliminated" as indicated by the commenter, but rather, was revised and relocated to subsection 25601(e) based on stakeholder comments that the provision should be located in the safe harbor methods and content found in Subarticle 2.

Subsection 25600(f) (now 25600(e))

336. Comment (Wine et al.): Commends OEHHA for including an express provision recognizing that parties to a pre-existing consent judgment are exempt from any and all inconsistent part of the proposed rulemaking. However, subsection (e) [formerly numbered as (f)] does not meet OEHHA's objective of ensuring that the "proposed regulations will not impact pre-existing settlements". The alcohol consent judgment reaffirmed and embraced the existing alcoholic beverage Proposition 65 warning requirements. In light of this, the proposed language *establishing* a warning method or content could be misinterpreted in terms of the full scope of the settlements and final judgments OEHHA intends to preclude or exempt.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

337. Comment (Wine et al.): In the ISOR, pp. 13-14, it recognizes that a non-party to a consent judgment should have the option of petitioning OEHHA for inclusion in a court-approved settlement and references proposed subsection 25600(c); however

Section 25600 does not specifically identify this option. The commenters urge OEHHA to amend the proposed rule to explicitly allow industry members to opt into these settlements via a petition to OEHHA. The 'opt-in' provision avoids undue retailer and consumer confusion. It is only equitable to provide a "safe harbor" to alcohol companies entering the California marketplace in the future, small businesses growing to 10 or more employees, and businesses where a notice of violation could not be found to qualify as a party to the consent judgment.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

338. Comment (CalChamber and Wine et al.): The phrase, "if the warning fully complies with the order or judgment" is unnecessary because the court that ordered the settlement or final judgment retains jurisdiction to enforce the settlement. The phrase opens the door to allow third parties to initiate litigation against companies subject to that court order or judgment which is time-consuming and burdensome. Request that the phrase be removed or in the alternative, provide revisions to the phrase.

Response: This comment is not related to the modification of text. However, OEHHA considered the issue based on this and other comments and has stricken the term "fully" to address concerns that the language could encourage third parties to initiate litigation against companies based on compliance with the applicable settlement or judgment.

339. Comment (PCBP): There needs to be flexibility in the warning regulations for businesses with some products subject to a court order and similar products that are not subject to the court order, but must meet the proposed regulation in both cases. PCBP urges OEHHA to include an alternative to subsection (e) that a business required to provide a warning and that does so in a manner complying with this regulation is deemed to comply notwithstanding a prior warning pursuant to a consent judgment or settlement not complying with the warning standard of this Article.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

340. Comment (WSPA): OEHHA fails to explain why court-approved warnings are entitled to deference under the regulation as being valid evidence that warnings are "clear and reasonable", but state-approved warnings including those approved by the State Attorney General are not.

Response: This comment is not related to the modification of text. As explained in the ISOR for these regulations, this provision is intended to be a statement of current law which binds parties to the requirements of court-ordered settlements and judgments.

Section 25600.1 Definitions

341. Comment (ACC): Suggests adding a definition for "in the course of doing business" because non-profit organizations may not always realize that they are doing business for purposes of the statute.

Response: This comment is not related to the modification of text. However, OEHHA notes the term “in the course of doing business” is already defined in Title 27, Cal. Code of Regs., section25102(k). OEHHA declines to make the change requested by commenter.

342. Comment (ACC): There is an inconsistent use of various definitions throughout the regulation. "Warning" and "warning content" are used at various places in the regulation. "Information", "consumer information", and "supplemental information" are also used throughout the regulation. "Warning materials" appears in subsection 25600.2(b)(3), but is undefined. The term however is already described in Health Safety Code section 25249.11 to include labels. "Consumer product" and the unqualified term "product" are also both used. "On-product", "on-product warning", and "on-product label" are used in Section 25602 without definition and without clarification as to whether "on-product" means printed on the actual product and/or on the label attached or affixed to product or packaging.

Response: Subsequent to this comment, OEHHA modified the text for consistency in the usage of these terms throughout the regulations.

Subsection 25600.1(a): “Affected area”

343. Comment (CH&LA): The definition for “affected area” is vague and potentially misleading. Understand that it is OEHHA’s intent that “affected area” refers to an entire facility and not the limited zone within a facility where the exposure might or does occur. Although OEHHA can further explain the intent of the definition within the FSOR, it is better to modify the definition to read, “… the entire facility in which exposure … can or does occur…”

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

344. Comments (DRoe): By defining “affected area” in objective physical terms, it sets up a potential debate about what area is involved as a matter of physical fact. Environmental exposure warnings are required only in areas the responsible party ‘knows and intends’ the exposure take place. The definition should be revised as, “the area in which the person responsible for an exposure knows that the exposure can occur at a level that requires a warning.”

Response: This comment is not related to the modification of text. However, OEHHA has modified the regulatory text by adding “can occur” at a level that requires a warning. OEHHA declines to revise the definition to incorporate the intent of the person responsible for the exposure as the term “knowingly” is already defined in the regulations (Title 27, Cal Code of Regs., section 25102(n)).

Subsection 25600.1(c): “Consumer information”

345. Comment (ACC): The definition for “consumer information” is overly broad and ambiguous and will invite unnecessary litigation. Consumer packaging and products often include third party certifications and seals. This raises issues about whether third party certifications or seals count as manufacturer-provided consumer information and whether third party certifications next to warnings would be deemed supplemental information. Some retailers still use pricing guns to hand label discount prices. It would be prudent to exempt price discount, special, coupon, or related information about product price from the definition.

Response: In response to this and similar comments regarding the breadth of the “consumer information” definition, OEHHA has stricken the phrase “but not limited to” and has modified the text to exclude the company name and location of manufacture. Generally, “third party certifications or seals” and “price discount, special, coupon, or related information about product price” would not fall under the definition of consumer information, nor would “third party certifications next to warnings” be considered information that is supplemental to the warning.

346. Comment (CalChamber): The definition of “consumer information” is overly broad. The phrase, "but not limited to" suggests that virtually any information can be consumer information. OEHHA should eliminate the phrase. In addition, OEHHA should include "company name" and “location of manufacture" as items that do not constitute consumer information to avoid unnecessary translation and possible litigation.

Response: As noted in response to previous comment, OEHHA has modified the regulatory text, by striking the phrase “but not limited to” in the definition for “consumer information” found in subsection 25600.1(c). OEHHA has also added text to the definition clarifying that “company name” and “location of manufacture” do not constitute consumer information.

Subsection 25600.1(d): “Consumer product”

347. Comment (FEMA): The definition of “consumer product” appears to include food ingredients. As such it places an unworkable, unjustified burden on food ingredient suppliers who normally have no relationship with or understanding of how their ingredients are used or where they will be sold and therefore have no ability to label. The phrase, "or component part thereof" should be removed from the definition. The

addition of the phrase is a significant reversal of 30 years of Proposition 65 implementation, was proposed with no initial statement of reasons, was not signaled by the November 2015 notice of the Article 6 amendments at issue, and violates the California APA; including Government Code section 11346.8.

Response: As noted in previous comments, these regulations do not determine when a warning is required. They simply apply once a business has determined it will provide one. To the extent ingredients in food contain listed chemicals, warnings are required in the same way a warning is required for any other component of a product.

The commenter is correct that the definition of "consumer product" includes food ingredients. Regarding the APA requirements cited by the commenter, the term "component part" was part of the newly proposed definition of "consumer product" that was noticed in the March 2016 Notice of Modification of Text for purposes of increasing clarity.[46] OEHHA proposed the definition of "consumer product" in response to various commenters on the November 2015 version who requested a definition of the term. The definition of "food" in subsection 25600.1(g) in the regulation remains as was proposed in November 2015 and includes component parts by reference to Health and Safety Code section 109935. This was discussed in the ISOR, where OEHHA noted the following:

> "Subdivision (d), adds a definition for 'food' that references the existing statutory definition of food found in Health and Safety Code Section 109935, which states:
>
> 'Food' means either of the following:
>
> (a) Any article used or intended for use for food, drink, confection, condiment, or chewing gum by man or other animal.
>
> (b) Any article used or intended for use *as a component of any article designated in subdivision (a)*[emphasis added]."

This has been consistent with policy for over 25 years. In the 1988 Revised Final Statement of Reasons for the Clear and Reasonable Warning regulation, the Health and Welfare Agency specifically rejected a comment that recommended a specific exclusion of the term "component parts" from the meaning of "consumer good":

> "…Similarly, two other commentators recommended that the regulation exclude aerospace parts and components from the meaning of "consumer good" and "consumer products". *These commentators misunderstand the purpose of this subsection. It is not designed to include or exclude businesses from the warning requirement of the Act. It is intended to provide "safe harbor" warnings which businesses may use for certain kinds of exposures. Limiting the scope of this*

[46] The Notice of Modification of Text states "The term "consumer product" was added as a defined term for clarity".

> *section would simply reduce the availability of the "safe harbor" warning. It is the Agency's intention that the "safe harbors" have broad availability* (emphasis added)."[47]

For these reasons OEHHA declines to make the change recommended by the commenter.

348. Comment (CH&LA): Hotels and apartments have a large variety of items such as furniture, power cords, soaps, shampoos, window treatments, flooring, cleaning supplies, etc. that fit into the current definition of "consumer product" yet have no knowledge what chemicals may be in such products. As currently drafted, hotels and apartments could be subject to 60-day notices for consumer products present at their facilities. OEHHA's statement that such products are not intended to be considered to be consumer products and exposures to such should not be subject to 60-day notices, is not consistent with that intent. CH&LA recommends that a clarifying statement be added in the FSOR and that the definition be revised to, "means any article...sold by a person generally engaged in consumer product sales for personal use..."

Response: The language proposed by the commenter would create a broad, categorical exemption from the warning requirements that is inconsistent with the purposes of the Act and beyond the scope of this rulemaking. These regulations expressly apply where a warning is being provided. It does not determine *whether* a warning is required (subsection 25600(a)). OEHHA is considering an informal request for the development of a "tailored warning" pursuant to Section 25607, *et seq.* for exposures to listed chemicals in hotels and apartments.

Subsection 25600.1(e): "Consumer product exposure"

349. Comment (CH&LA): CH&LA recommends a clarifying statement be added in the FSOR and that the definition for "consumer product exposure" be revised to include "consumer".

Response: OEHHA modified subsection 25600.1(e) by adding the term "consumer" product to the definition of "consumer product exposure".

350. Comment (ACA): By referring to "product" instead of "consumer product" in the definition for "consumer product exposure", it is not clear whether the consumer product exposure warning applies only to OEHHA's new proposed definition of consumer products or to products more broadly such that it would include products used in an occupational setting. ACA urges OEHHA to clarify that the scope of "consumer product exposure" warnings is for "products", including industrial products and references to "consumer product" should be amended to "product" throughout Article 6. Alternatively,

[47] Revised Final Statement of Reasons, 22 California Code of Regulations Division 2 (1988), at 9, available at http://oehha.ca.gov/media/downloads/crnr/12601fsornov1988.pdf.

OEHHA should eliminate the definition for "consumer product" and clarify in the FSOR that "consumer products" includes "industrial products".

Response: OEHHA disagrees that the scope of the definition of “consumer product exposure” should be expanded**.** To the contrary, OEHHA has added the term “consumer” to the term “product” for consistency and to increase clarity regarding the scope of the definition. Additionally, OEHHA has changed “product” to “consumer product” throughout the regulation for clarity and consistency. The changes made to subsection 25606(b) for exposures to chemicals in the occupational setting address this issue.

351. Comment (AHPA and CRN): The phrase, "any reasonably foreseeable use of a product" in the definition of “consumer product exposure” is excessively broad and contravenes the intended purpose of the Governor’s reform to end "frivolous shake-down lawsuits". Request the phrase be removed and instead include the use of a product in accordance with the product labeling recommendations or with other actual and accepted uses of the product.

Response: The approach suggested by the commenters is inconsistent with the overall approach to warnings being provided under the Act as it would unduly limit the potential exposure scenarios to those prescribed by the manufacturer.[48] If the use of a product is reasonably foreseeable even though it may not be consistent with the labeling recommendations, then any significant exposures to listed chemicals can be appropriately considered to be knowing and intentional on the part of the manufacturer and a warning should be provided. OEHHA declines to make the change requested by the commenters.

352. Comment (Mateel): The definitions for "consumer product exposure" and "consumer product” should be harmonized. “Consumer product exposure” should refer to a “…*consumer’s* acquisition…use of a consumer product…”

Response: OEHHA has modified the text to add “consumer” before the word “product” for clarity and consistency. OEHHA has determined that by modifying the term “product” the replacement of the term “person” with “consumer” is unnecessary.

[48] Note, for example that the Consumer Product Safety Act uses the term “reasonably foreseeable use” with reference to an exclusion under the CPSA for inaccessible component parts in children’s products, 15 USC 1278, available at https://www.cpsc.gov//PageFiles/129663/cpsia.pdf ; see also https://www.cpsc.gov/en/Business--Manufacturing/Business-Education/childrens-products/; the CPSC notes “To assess whether a product is commonly recognized by consumers as being primarily intended for a child, a manufacturer should evaluate the reasonably foreseeable uses of a product to determine how the product will be perceived and used by consumers of that product. https://www.cpsc.gov/en/Business--Manufacturing/Business-Education/childrens-products/

353. Comment (NMMA): The definition for "consumer product exposure" fails to define what constitutes a consumer product exposure. NMMA recommends defining exposure according to OSHA's Permissible Exposure Levels (PELs). It is important to distinguish between hazard and risk and it should be clearly outlined in the regulation to avoid misinterpretations.

Response: OEHHA believes that the definition of "consumer product exposure" adequately identifies the kinds of activities that may cause an individual to be exposed to a listed chemical from a consumer product. The question raised by the commenter of when an exposure poses a health risk and whether a warning is to be provided for that particular exposure is a decision for a business, and other regulations within Title 27 of the California Code of Regulations provide guidance for a business in making this determination[49]. In this regard, the recommendation to use the OSHA PELs is outside the scope of this rulemaking. Article 6 primarily focuses on the issue of how to provide a warning and what should be included in the warning, i.e., warning methods and content.

Subsection 25600.1(h): "Knowingly"

354. Comment (RKratz): As the term, "knowingly" is defined, a retail seller could be accused of being 'negligent' in a potential consumer product exposure if that retail seller allegedly received "specific knowledge of the consumer product exposure…from any reliable source", when "any reliable source" is not defined.

Response: This comment is not related to the modification of text.

Subsection 25600.1(l): "Retail seller"

355. Comment (DRoe): By adding the phrase, "or otherwise provides consumer products" to the definition of "retail seller", it broadens the application to any person who provides any consumer product for free to another person, including food banks distributing apples, charitable organizations donating blankets, even a department store Santa giving candy. The definition should return to the previous language.

Response: Section 25600.2 builds upon the statutory requirement for the lead agency to minimize the burden on retail sellers of consumer products, to the extent practicable. Under Section 25600.2, manufacturers must either include any required warnings on their product labels, or notify and provide warning materials at no charge to retailers, including the entities cited in the comment. If a warning is not provided by the manufacturer or distributor to the charitable organization, and the charitable organization does not have actual knowledge of an exposure, then they would not be responsible for providing a warning. The five business days following a notice in

[49] Title 27, Cal. Code of Regs., sections 25701 and 25801 et seq.

subsection 25600.2(f) before a business can be identified as having “actual knowledge” of exposure would apply to the charitable organization in the event that they were to receive a notice. OEHHA believes this will protect charitable organizations and other non-profit institutions from significant burdens for providing warnings. OEHHA declines to make the change requested by commenter and notes that exempting organizations that provide products free of charge to consumers would be a significant carve-out from the provisions of Proposition 65 that OEHHA is not authorized to make.

Subsection 25600.1(m): “Sign”

356. Comment (AHPA): In the definition for “sign”, the phrase "understood by an ordinary person" is impractically vague and implies that a business must conduct consumer research to ensure the sign will be understood. It is not necessary to specify that signs must be "understood" because "read" connotes a basic level of understanding. Request that the phrase be removed from the definition.

Response: This comment is not related to the modification of text.

Section 25600.2 Responsibility to Provide Consumer Product Exposure Warnings

357. Comment (ABA): It is not clear whether proposed Section 25600.2 is intended to articulate requirements for the entire warning article or whether it simply is an attempt to restate requirements that appear elsewhere in the context of assigning responsibility between the retailers and others. This should be clarified because at present it is neither clear from the words of the regulation nor from the ISOR.

Response: This comment is not related to the modification of text**.** Section 25600.2 applies to the entire article to the extent the provisions relate to the provision of warnings for exposures to listed chemicals from consumer products sold at the retail level.

358. Comment (CGA): CGA urges that the mandate in statute to minimize the burden on retail sellers when adopting regulations related to warnings be upheld.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

359. Comment (CA Retailers): The proposal allows manufacturers to comply by simply providing warning materials to retailers without obtaining consent from the retailer. It shifts the burden to retailers in contravention to the statute. Such allowance transforms the safe harbor nature of the warning methods into a mandatory requirement for retailers at the discretion of those supplying products to the retailers. Since Proposition 65 warnings are not required anywhere except California, it can be envisioned that

manufacturers move to signs and stickers as the warning option rather than labeling their products at significant costs. This violates the statutory direction to minimize the burden on retailers. The Economic Impact Analysis does not analyze and identify costs to the retailers.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

360. Comment (Environmental Coalition): OEHHA should remove Section 25600.2 because it will severely hamper Proposition 65's effectiveness in ensuring Californians are provided with clear and reasonable warnings. OEHHA should insist warnings be provided prior to the point of sale and that internet warnings be automatically viewed without the need to follow a hyperlink.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

361. Comment (RMA): RMA supports the revised provisions which make retailers responsible for the placement and maintenance of warning materials and/or warning language for products sold on the Internet. However, RMA remains concerned about the labeling for tires where only a small number of actual tires available for sale are on display. RMA recommends that the labeling requirements for retailers only apply to products that come into contact with consumers.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

Subsection 25600.2(a)

362. Comment (Environmental Coalition): Subsection 25600.2(a) inaccurately states OEHHA's obligation under Proposition 65. According to HSC section 25249.11(f), in order to “minimize the burden on retail sellers" OEHHA is directed "to the extent practicable" to place the obligation to provide warning materials on the producer or packager. Subsection (a) should be eliminated or amended to conform to the statute.

Response: OEHHA has added the phrase “to the extent practicable” for consistency with the definition of “warning” in HSC 25249.11(f).

Subsection 25600.2(b)

363. Comment (ACA): OEHHA has clarified that manufacturers have met their responsibilities by either affixing a warning on the product label or providing a written notice to the authorized agent of retail seller.

Response: Comment noted, no response required.

364. Comment (ABA): In subsection (b)(2) the requirement that the manufacturer identify the "exact name or description" of product is unduly burdensome and expensive. Where a clear product category description will suffice, there is no reason why that should not be an option.

Response: This comment is not related to the modification of text. The issue is probably best addressed through an agreement between the manufacturer and retailer, as allowed under subsection 25600.2(i).

365. Comment (ABA): The requirement in subsection (b)(3) that "all necessary warning materials" be included in the written notice from the manufacturer to the retailer is a substantial waste and unnecessary expense. Manufacturers do not know how many signs a retailer may need. It would be more efficient to allow retailers to order the warning materials for free rather than burden manufacturers with the duty to provide all that is necessary. It is not logical or efficient for a manufacturer to undertake the responsibility to know such information for each retailer. It is important for OEHHA to retain the phrase, "or offers to provide such materials at no charge to the retail seller" in subsections (b)(3) and (e)(4). Another example of where it is necessary, more efficient and more environmentally sensitive is when both the manufacturer and distributor need to discharge their Proposition 65 responsibility. Each should be able to give notice and offer materials that may be duplicative.

Response: Subsection 25600.2(i) allows the manufacturer, producer, packager, importer or distributor of a product to enter into an agreement with the retail seller that allocates warning responsibility between them in a manner that is different from the way in which the responsibility is allocated by the regulation. The agreement may set forth the specific manner in which warning materials are to be distributed to the retail seller. As long as the warning provided to the purchaser of the product meets the requirements of Section 25249.6 of the Act, the manufacturer or distributor could discharge their responsibility without the need to offer to provide duplicative materials.

366. Comment (CGA): Subsection (b)(3) is significantly problematic. It allows a manufacturer to shift all responsibility and liability for providing a warning to the retailer and dictates how the warning is provided regardless of specific retail needs. The deficiency is magnified, when unlike the emergency Bisphenol A (BPA) regulation that allow for a single general warning in the food setting, these proposed regulations

contemplate individual product warnings throughout store. It is an impossible task and will lead to increased litigation against retailers.

Response: This comment is not related to the modification text. This issue is addressed in responses to similar comments received during the first comment period.

367. Comment (ABA): In subsection (b)(4) it is not clear if the confirmation of retailer receipt is necessary to provide a clear and reasonable warning. If so, it creates a massive new possibility for litigation, expensive discovery, and a huge recordkeeping burden. A general proof of transmission should be adequate.

Response: Confirmation of receipt from the retail seller is not a separately enforceable provision under the Act. OEHHA therefore disagrees that the provision would increase litigation as suggested by the commenter. OEHHA has determined that confirmation of receipt is an important component of the process for allocation of responsibilities in the chain of distribution. Providing confirmation of receipt will help support a defense that an entity has satisfied the requirements to discharge the responsibility to provide warnings under the Act. A general proof of transmission would be inadequate for this purpose.

368. Comment (Wine et al.): There is a presumption of delivery upon transfer to USPS ("mailbox rule") so there is no need for a confirmation of delivery. Although it would be helpful to provide that a notice may be sent by email, since the California Department of Alcoholic Beverage Control does not require email addresses from its licensees it is wrong to assume that email is automatically an option.

Response: The commenter noted correctly that the California Department of Alcoholic Beverage Control does not require email addresses from its licensees. This issue is addressed in responses to similar comments received during the first comment period for the regulations.

Subsections 25600.2(b) & (c)

369. Comment (ABA): Subsections (b) and (c) require communication with the "authorized agent" of the retailer, but does not appear to permit or anticipate communication directly with retailer. This requirement seems odd, unjustified and probably unintended.

Response: The regulations are not intended to prohibit direct communication with the retail seller. The regulations place the responsibility on the retail seller to designate a person to receive warning information from product manufacturers, distributors, packagers, importers, and suppliers. Each of the entities in the chain of commerce will likely do this through contractual language. However, where a given retail seller has not designated such an agent, the manufacturers, producers, packagers, importers,

suppliers, and distributors could provide the notice and warning materials to the person they normally communicate with at the retail seller regarding their products. They may also wish to provide the materials with the product when it is delivered to the retail seller. In the unlikely event that it is impossible to locate an agent for a retail seller, the manufacturers, producers, packagers, importers, suppliers, and distributors may choose to label the product with a compliant warning in order to ensure the consumer receives a warning.

Similar comments are addressed in responses to comments received during the first comment period.

370. Comment (Wine et al.): Whether a notice is mailed or emailed, it would be reasonable to provide that warnings may be included or instruction provided on where and how a warning sign may be downloaded from the internet or ordered free of charge. It is reasonable that a smaller manufacturer, producer, packager, importer, or distributor (entities with revenues of less than $50,000 in California) may comply by posting a notice on its website advising retailers that a warning sign is available, free of charge and/or providing a link to a downloadable file with a warning sign. The commenters urge that OEHHA strike the proposed provisions of subsections (b)(4) & (c)(1) (formerly numbered as (b)(5)) as unnecessary, inappropriate and unduly burdensome upon businesses with no commensurate purpose. Instead, OEHHA should require a sworn declaration from a manufacturer, producer, packager, importer, or distributor of alcoholic beverage products to demonstrate compliance.

Response: OEHHA declines to incorporate the recommendation to strike subsections 25600.2(b)(4) & (c)(1) and to instead require a sworn declaration from the manufacturer, producer, packager, importer or distributor of alcoholic beverage products to demonstrate compliance with subsections (b)(4) and (c)(1). Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

Subsections 25600.2(b) & (d)

371. Comment (CalChamber): Subsections (b) and (d) place an affirmative burden to require online retailers and cataloguers to provide a warning for products already containing an on-product warning. None of the situations in subsections 25600.2(e)(1) -(e)(5) suggest that an online retailer would be required to provide a warning if a label is affixed pursuant to subsection (b). OEHHA has no statutory authority to require two warnings which was never contemplated by the Act or the voters' intent. Request that OEHHA clarify that online and catalogue warnings are not required for products already containing an on-product warning.

Response: OEHHA has the authority as the lead agency to interpret the Act and enact regulations. This includes providing safe harbor guidance on how to provide a "clear and reasonable" warning pursuant to the Act. When the voters passed Proposition 65 thirty years ago, the specific issue of warning methods and content for purchases over the internet was not contemplated. OEHHA, as the lead agency, has determined that providing a warning to a person who makes a purchase via the internet only after purchasing the product online and potentially exposing the person upon delivery of the product, is inconsistent with the purposes of the Act. Additionally, a person would then have to choose between keeping an item that exposes them to a listed chemical, or repackaging and returning the item while potentially incurring shipping costs and/or restocking fees depending on the return policy of the online vendor. To alleviate the burden on businesses, OEHHA has modified the text to permit the online or catalogue warning to use the same content as the on-product warning.

Subsection 25600.2(c)

372. Comment (ABA): Renewing the notice as specified in subsection (c)(1) every 18 months is more than adequate. There is no justification for it to be more frequent.

Response: The Notice renewal in subsection 25600.2(c) is only required within six months during the first year after the effective date of the regulation, and then annually thereafter. The provision is expressly limited to the time in which the product is sold in California by the retail seller. Given that the new regulation may represent a significant change from existing practices between businesses in the chain of commerce, it is reasonable to require a second notice that a warning must be provided within the first year after the new regulation is adopted to ensure that the process works smoothly and retailers receive all the necessary warning materials in a timely manner. OEHHA declines to make the change requested by commenter.

Subsection 25600.2(d)

373. Comment (ACA): Subsection (d) clarifies the retail seller's responsibility for placement and maintenance of warning materials, including warnings for products sold on the Internet. Interpret the subsection to say that once a manufacturer provides a compliant Proposition 65 warning on the label, they are compliant with their responsibility to provide a clear and reasonable warning, regardless of how it is placed into commerce by downstream retailers.

Response: This comment is not related to the modification of text.

374. Comment (CGA): If OEHHA continues with shifting the burden to retailers, at a minimum, the regulations should be revised to include: a requirement that the manufacturer provide retailers 30 days' notice that it intends to provide information regarding a Proposition 65 warning for a given product; allow retailers at least 30 days

to make adjustments to display areas, shelf tags, product displays, etc. to accommodate warnings once received from the manufacturer; allow retailers to sell through existing product when a new warning is required or a new warning method is employed; allow retailers a 14-day opportunity to cure any violations associated with the maintenance of the required warnings once received from the manufacturer and installed at the retail setting.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

Subsection 25600.2(e)

375. Comment (CGA): Subsection (e)(1) creates a new obligation for retailers if a product is manufactured by a third party yet is packaged under the retailer's own label. The entire burden for compliance falls to the retailer and absolves the product manufacturer. CGA suggests a revision to allow shifting of the actual and legal burden for warnings to a retailer only if the retailer consents in writing.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

376. Comment (Environmental Coalition): Subsection (e)(5) conflicts with Proposition 65. It excuses the retailer from the warning requirement even if the retailer continues to sell products without a warning even after receiving a 60-day notice identifying the product causing the unwarned exposure.

Response: This comment is not related to the modification of text. This issue is addressed in responses to similar comments received during the first comment period for the regulations.

377. Comment (Mateel): Section 25600.2(e)(5) does not specify if the enforcer or the alleged violator has the burden to establish the two factors listed in subparagraphs (e)(5)(A) and (e)(5)(B). The provision should be deleted or if included should specify that the retail seller has the burden to show there is a manufacturer, producer, packager, importer, supplier or distributor who is a "person in the course of doing business" and has designated an agent for service. A private enforcer would not know in advance of an enforcement action who each entity is in the chain of distribution.

Response: This comment is not related to the modification of text.

Subsection 25600.2(f)

378. Comment (RKratz): The proposed regulations do not minimize the burden on retail sellers of consumer products as required by HSC section 25249.11. If knowledge of a potential exposure requiring a warning does not come from the manufacturer, producer, packager, importer, supplier, or distributor of product, then it must come from "specific knowledge of the consumer product exposure received by the retail seller from any reliable source." Unless the source of this "specific knowledge" is a 60-day notice, then the "specific knowledge" is not defined. The term, "any reliable source" in subsection (f) needs to be defined or eliminated.

Response: This comment is not related to the modification of text. This issue is addressed in responses to similar comments received during the first comment period for the regulations.

379. Comment (ABA): Five days is not enough time to evaluate whether an exposure is occurring in response to a 60-day notice. The full 60-day notice period should be available for this evaluation.

Response: As noted in response to similar comments regarding this provision, OEHHA extended the timeframe for “actual knowledge” in subsection 25600.2(f) from two business days to five days after receipt of a 60-day notice based on comments received that 2 business days was not sufficient. Five business days should be enough time for a retail seller to contact a manufacturer to determine whether a warning is required, provide its own warning, or pull the product from the shelves to avoid liability. OEHHA declines to make the change recommended by the commenter.

380. Comment (AHPA): A retailer should not be deemed to have "actual knowledge" unless the notice includes detailed information to support the allegation. Five business days is too short. A retailer should be able to confirm the accuracy and validity of the allegation which may take several weeks. If a Proposition 65 warning is legitimately required, a delay of several weeks or months will have no discernible public health effect. Businesses have the constitutional right not to be forced to cease distribution of a lawful product or to disseminate government-mandated information that is incorrect, inaccurate, or misleading which would be the case if the notice is determined to be invalid. Request a revision to 30 days and a requirement that detailed data be provided to support the allegation.

Response: Subsection 25600.2(f), as proposed in November 2015, provided for a period of two business days from the date the retail seller receives notice served pursuant to subsection 25249.7(d)(1) of the Act before the retail seller is deemed to have actual knowledge. OEHHA extended this period for actual knowledge to five business days in response to requests from several stakeholders noting that the period was too short for a retail seller to respond. Other commenters stated that actual

knowledge occurs when notice is served and that there should be no additional period. OEHHA has determined that a period of five business days is sufficient time for a business to evaluate and take corrective action if it wishes to do so. Therefore, OEHHA declines to make the change requested by the commenter.

381. Comment (CA Retailers): The five business days specified in subsection (f) is too short, given the logistics in processing and understanding a 60-day notice, communication with the supplier, and providing the warning or pulling the product from the shelf. In order to allow for more efficient handling of notices, CA Retailers proposes a change to subsection 25600.1(b) that allows a retailer to designate more than one authorized agent if it wishes: change "the person or entity" to "a person or entity". In addition, request an explanation in the FSOR that the phrase, "sufficient specificity for the retail seller to readily identify the product in accordance with Article 9, section 25903(b)(2)(D)" is not met by a notice that identifies one product by name, SKU or other identifier, but attempts to provide notice for a broader specific type of product.

Response: As noted in response to the previous comment, OEHHA has determined that five business days is a sufficient time for a business to evaluate and take corrective action if it wishes to do so. The comment concerning the designation of more than one authorized agent is not related to the modification of text.

382. Comment (Environmental Coalition): In subsection (f) the problem is compounded by OEHHA using the warning regulations to indirectly and incompletely address a separate issue of knowledge. OEHHA's intent in these regulations is to address the clear and reasonable warning requirement. Knowledge is a separate issue deserving its own proceeding. Doing so here creates uncertainty and will likely lead to litigation over whether a retailer had knowledge of a particular exposure.

Response: This comment is not related to the modification of text. This issue is addressed in responses to similar comments received during the first comment period for the regulations.

Subsection 25600.2(g)

383. Comment (Environmental Coalition and Mateel): Subsection (g) obligates the retailer to provide supplier information, but there are no consequences for refusing or failing to do so. The commenters suggest revisions stating the retail seller is responsible for providing the warning when the retail seller refuses to provide supplier information for the product. The regulations should state the specific time period within which the retail seller must provide the name and contact information for the manufacturer, producer, packager, importer, supplier, and distributor of the product.

Response: This comment is not related to the modification of text.

384. Comment (CA Retailers): Clarify that the retailer's obligation to provide information to a private person who served a 60-day notice is similarly limited to the products specifically identified in the notice.

Response: This comment is not related to the modification of text.

385. Comment (ABA): In subsection (g), shifting the plaintiff's obligation to research appropriate enforcement targets to the retailers places an undue burden on retailers. This requirement is not adequately justified in the ISOR. ABA is not aware of any circumstance where it would be impossible to enforce Proposition 65 in the absence of this provision.

Response: This comment is not related to the modification of text.

Subsection 25600.2(i)

386. Comment (CA Retailers): Subsection (i) allows retailers and suppliers to enter into written agreements to supersede the allocation of responsibilities specified in subsections (b), (c), (d), and (e). Subsection (i) is a hollow provision because it gives all the contractual leverage in negotiation to suppliers. It violates the intent of the statute, incurs substantial costs and burdens on retailers, and may cause a proliferation of signs in stores that are impossible to manage effectively.

Response: This comment is not related to the modification of text. This issue is addressed in responses to similar comments received during the first comment period for the regulations.

387. Comment (Mateel): Subsection (i) is unjust and contrary to the intent of HSC section 25249.11(f). It allows a party with the most market power in the chain of distribution to force smaller businesses to be responsible for providing the warning. The regulations should specify any agreement between the retail seller and any manufacturer, importer, or distributor is null and void and unenforceable to the extent it shifts legal responsibility for providing a warning from the manufacturer to the retail seller.

Response: This comment is not related to the modification of text.

Section 25601 Safe Harbor Clear and Reasonable Warnings – Methods and Content

388. Comment (CalChamber and CRN): Businesses are not provided with guidance regarding what constitutes a "clear and reasonable" warning and businesses are therefore forced to use the safe harbor warning methods and content. OEHHA should maintain the existing description of “clear and reasonable warning” for businesses seeking to use a fully compliant alternative warning.

Response: This comment is not related to the modification of text. This issue is addressed in responses to similar comments received during the first comment period for the regulations.

Subsection 25601(c) (now 25601(b))

389. Comment (ACC): Subsection 25601(c) creates an illegal burden shift outside OEHHA's statutory authority.

Response: OEHHA disagrees that the requirement to name a listed chemical for each endpoint for which the warning is being provided is outside the scope of its authority. As stated in the ISOR, Subsection (c) provides that unless otherwise provided in the "short-form warning" provision of Section 25603(c), all warnings must include the name of one or more of the listed chemicals for which a warning is being provided. If a business is already providing a warning for a listed chemical, the identity of the chemical should already be known. If the warning is being provided with no knowledge of exposure to a listed chemical, then no warning is required and "over-warning" is occurring.

During the pre-regulatory process, many commenters expressed concern regarding the inclusion of chemical names in warnings. In order to fully evaluate the effectiveness of the inclusion of chemical names, OEHHA requested that the Warning Regulations Study conducted by UC Davis assess the inclusion of chemical names on the warning signs in relation to the existing warning signs with no chemical names. The results demonstrated that 66% of the people surveyed selected the sign with the specific chemical names as being more helpful than the sign that generally referred to chemicals. The survey also asked for respondents' reactions to inclusion of the specific chemical(s) in the sign. The most frequent reaction was that the inclusion of the chemical names made people feel better able to make an informed choice. In addition, participants' familiarity with specific chemicals (such as lead, mercury, and carbon monoxide) did not relate to their preference for the inclusion of chemical names on the signs. OEHHA has therefore determined that providing the name of a listed chemical in all warnings is consistent with and furthers the "right-to-know" purposes of the statute and provides more specificity regarding the content of safe harbor warnings.

Including the name of one chemical for each endpoint for which the warning is being provided is consistent with this purpose. No change to the regulation was made based on this comment.

"For which a warning is required"

390. Comment (CalChamber and Auto Alliance et al.): OEHHA recently used language similar to "for which a warning has been provided" in the BPA emergency regulation. Also the lead agency website regulation uses the term "for which a warning

is being provided". OEHHA should eliminate "for which the person has determined a warning is required" in subsection (c). The phrase infers that a business must make a determination that the exposure from listed chemicals will cause cancer or reproductive harm at the risk level defined in statute. It appears to require exposure testing and risk modeling prior to providing a warning which exceeds statutory authority. Businesses need the ability to warn in the absence of such definitive data. The commenters urge OEHHA to remove language as it is contrary to the statute, costly and unworkable and will likely lead to increased litigation.

Response: Based on this and other comments, OEHHA struck the phrase “for which the person has determined a warning is required” and replaced it with “for which the warning is being provided”.

391. Comment (CAPA): It is impossible to assess and quantify every possible exposure to nearly 900 listed chemicals. The statute gives two options; attempt to conduct an on-going scientific assessment or post prophylactic warning. Many businesses choose to give prophylactic warnings even though legally a warning is not required. Businesses should be free to make that choice without conducting an exposure assessment. Subsection (c) is problematic because it requires the name of the chemical for each outcome, cancer and reproductive toxicity, unless the one chemical named causes both. Agrees with CalChamber’s comment that this provision creates potential for more litigation predicated on 'bad warnings'. CAPA urges OEHHA to simplify subsection (c) and strike the last sentence.

Response: OEHHA disagrees that an exposure assessment is required to achieve the protections of the safe harbor methods and content. A business should be aware of the name of at least one listed chemical for which it is providing a warning. Further, OEHHA does not encourage the practice of “over-warning” and discourages businesses from providing prophylactic warnings when no warning may actually be required. In the ISOR for this rulemaking, OEHHA stated:

“Requiring that the warnings include more specific, relevant information will further the right-to-know purposes of the law and reduce the likelihood that businesses will provide unnecessary warnings for non-existent or insignificant exposures.”[50]

OEHHA declines to modify the regulatory text as requested by commenter.

392. Comment (ACA, ACC, CalChamber, CAPA, CCEEB, CRN, and RMA): The proposal requires a person to choose the chemical to be listed without providing detail regarding what information is required to show a warning for a product. It incurs the

[50] Initial Statement of Reasons, Title 27, California Code of Regulations, Proposed Repeal of Article 6 and Adoption of New Article 6 Regulations for Clear and Reasonable Warnings, Nov. 27, 2015.

burden to test for chemicals or do an exposure assessment to affirmatively demonstrate that a warning is required, which is a departure from current Proposition 65 law. The requirement is unnecessary and inconsistent with the statute. The commenters urge that OEHHA clarify what information is necessary to determine that a warning is required or abandon the chemical specific warning requirement altogether. Commenters support CalChamber's recommendation to make chemical specific warnings less burdensome and ambiguous. The phrase "to the extent that an exposure is at a level that requires a warning" was an unlawful burden shift as a defendant's only statutory burden is to demonstrate that no warning is required. The current proposal requires businesses to demonstrate that an exposure to that chemical or chemicals is at a level that requires a warning. OEHHA deleted the phrase but now requires warnings to name "one or more of the listed chemicals for which the person has determined a warning is required" which is substantively identical. Additionally, this deprives a business a legal defense as this requires a business to make an admission which cannot be later avoided by proving the exposure is below the safe harbor level. Further, converting a warning to an admission may increase liability to toxic tort claims from creative plaintiffs. The commenters urge that OEHHA delete, "for which the person has determined a warning is required" and insert "for which the warning is being provided." To name a chemical is to admit that individuals are exposed to carcinogens or reproductive toxicants at level above the No Significant Risk Level (NSRL) and Maximum Allowable Dose Level (MADL), a level that could be harmful. The proposed language is inconsistent with the recently adopted regulations for the Lead Agency website and BPA in canned foods and beverages. Both regulations use "for which the warning is being provided".

Response: Subsequent to this comment, OEHHA struck the phrase “for which the person has determined a warning is required” and replaced it with “for which the warning is being provided” which is consistent with the alternative proposed by the commenters. OEHHA has determined that including a chemical name in the warning content improves safe harbor warnings by providing more information to a person regarding exposures to listed chemicals. Businesses that provide a warning will know the chemical or chemicals for which the warning is being provided. OEHHA declines to abandon the chemical-specific warning requirement altogether as requested. This issue is also addressed in responses to similar comments received during the first comment period for the regulations.

“Include the name of one or more chemical for each endpoint”

393. Comment (ACC): The new language in subsection (c) [now subsection (b)] turns the "single chemical" specification into a "dual chemical" proposal. If a product contains a chemical known to cause cancer and a different chemical known to cause reproductive toxicity, the warning now should include at least two chemical names, one

for each endpoint. The requirement will make the warning less meaningful and effective. It adds ambiguity regarding the compliance obligation and increases litigation. The current safe harbor language is at least consistent and predictable.

Response: The commenter is correct that the names of two listed chemicals would be required in a warning if the product contains a chemical known to cause cancer and a different chemical known to cause reproductive toxicity. OEHHA has determined that this change would add clarity to the warning and is consistent with the purposes of the Act because it provides more information to a person regarding exposure to the listed chemicals based on the endpoint of concern. OEHHA disagrees with the commenter's characterization that the requirement will add ambiguity; rather, the requirement is clear with respect to compliance, and will lead to more effective warnings.

394. Comment (ACA): The proposed chemical-specific warnings will go against the goals of Proposition 65 reform. Requiring businesses to choose one or more chemicals to include in the warning will confuse consumers since there is no criteria for how to select what chemicals to include. It creates potentially misleading and unfair market advantages if only certain chemicals are warned about. Warnings are not helpful if different businesses choose different chemicals to include. Listing the names will not provide a meaningful warning because the consumer still would not know anything else about the chemical or its use in the product. Consumers are led to believe certain chemicals on the product warning are predominant, present at a higher level or present a higher risk of exposure or harm.

Response: This comment is not related to the modification of text. This issue is addressed in responses to similar comments received during the first comment period for the regulations.

395. Comment (AASA, CalChamber, and NMMA): The phrase, "one or more" is problematic because it could be interpreted to mean that the warning must specify all chemicals for which the warning is provided. The commenters request that the phrase be clarified that only one chemical must be specified, not all. The phrase "one or more" is ambiguous and must be clarified in the regulatory language. The phrase suggests that businesses may have to specify all of the chemicals for which a warning is being provided. Because of this, businesses that specify only one chemical when warning for multiple listed chemicals may be targeted for private enforcement actions and be required to defend such litigation in court at significant expense. The commenters recommend adding, "If a warning is being provided for more than one listed chemical, the warning meets the requirements of this article if the name of at least one of the listed chemicals for which the warning is being provided is included in the text of the warning."

Response: As discussed in response to similar comments, OEHHA disagrees that the use of the phrase “one or more” chemicals in subsection 25601(b) is unclear. Where a warning is being provided for more than one endpoint (cancer and reproductive toxicity) the warning must include the name of one or more chemicals for each endpoint unless the chemical is listed as known to cause both cancer and reproductive toxicity and this is stated in the warning. As an example, if a warning is being provided for Proposition 65-listed carcinogens A and B and Proposition 65-listed reproductive toxicants C and D, the warning may specify either carcinogen A or B, or both; and must include either reproductive toxicant C or D, or both. OEHHA disagrees that the phrase “at least one” is clearer than “one or more”. OEHHA declines to modify the regulatory text as requested by commenter.

396. Comment (CalChamber and CCEEB): Requiring the name of the chemical for each endpoint creates a new category of "bad warning" litigation and promotes over warning. It will make "safe harbor" warnings unsafe in practice. The commenters recommend striking the provision in subsection (c) [now subsection (b)] in its entirety and replacing it with, "This product can expose you to chemicals, including [name of one or more chemicals], known to the State of California to cause cancer, and/or birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/product." A second and less preferred option is to restore the November 2015 language.

Response: OEHHA has determined that requiring the name of a chemical for each endpoint is consistent with the purposes of the Act and does not believe the change will contribute to increased litigation and over warning. OEHHA declines to strike subsection (b) in its entirety as recommended by the commenter.

397. Comment (CRN): The regulations still lack clarity on how a business should select the one or more listed chemicals, thus creating another source of litigation. OEHHA must explicitly state its intent in the regulations and FSOR or a private enforcer could challenge the selection decision. OEHHA should provide detailed selection criteria based on sound scientific reasoning subject to public comment. CRN recommends adding to subsection (c) [now subsection (b)]: "If a warning is being provided for more than one listed chemical, the warning meets the requirements of this article if the name of at least one of the listed chemicals for which the warning is being provided is included in the text of the warning."

Response: This comment is not related to the modification of text. This issue is addressed in responses to similar comments received during the first comment period.

398. Comment (NAIMA): NAIMA objects to the requirement that a warning contain the specific chemical name because such a warning gives a consumer no perspective as to the risk. Listing the presence of a chemical is meaningless if the risk or exposure is

minimal or non-existent. NAIMA urges OEHHA to remove the requirement to identify the chemical.

Response: This comment is not related to the modification of text. This issue is addressed in responses to similar comments received during the first comment period for the regulations.

399. Comment (RKratz): If a retail seller does not have knowledge of a potential consumer product exposure requiring a warning, then it cannot include the name of one or more of the listed chemicals in the warning. Current warnings are non-specific; however, OEHHA wants to place the burden of identifying the listed chemicals in a product on the retail seller under all circumstances even if the retail seller has no knowledge of the potential consumer product exposure requiring a warning.

Response: This comment is not related to the modification of text. The commenter correctly notes that current warnings are non-specific; OEHHA proposed the current rulemaking to provide more information to a person being exposed to a listed chemical, prior to that exposure. The statement that OEHHA wishes to place the burden on the retail seller under all circumstances is erroneous. The regulations implement the statutory requirement to minimize burdens on retailers by placing responsibility on the manufacturer and others in the distribution chain to either provide the warning on the product label or notify and provide warning materials at no charge to retailers. [51] If a retailer does not have actual knowledge of an exposure, then it is not required to provide a warning under the Act, and is therefore not required to include the name of one or more chemicals in the warning.

400. Comment (RMA): The phrase "one or more" may create confusion whether a warning needs to include all of the chemicals for which the warning is being provided. RMA recommends that OEHHA edit subsection (c) [now subsection (b)] to clarify that to meet the safe harbor requirements only one chemical name is required on a warning for each endpoint in which a warning is being provided.

Response: OEHHA disagrees that the regulatory text in subsection (b) is confusing regarding the phrase “one or more”. The commenter is correct that in subsection (b) only one chemical name is required on a warning for each endpoint, however, a business may elect to provide additional chemical names in the text of the warning for each endpoint for which a warning is being provided. This issue is also addressed in responses to similar comments received during the first comment period for the regulations.

401. Comment (WSPA): WSPA is pleased that the chemical naming requirement is streamlined; however, naming any individual chemical is not likely to make the warning

[51] Health and Safety Code section 25249.11(f)

any more meaningful or informative to the public. WSPA is not aware of any general demand from the public that Proposition 65 warnings contain specific chemical information and does not typically receive requests for chemical information. This only makes warnings more cumbersome. The correct approach would be to not require chemical names for all product and environmental warnings as is the case with the on-label warnings in the proposed regulation.

Response: This comment is not related to the modification of text.

402. Comment (ACC): ACC objects to the provision of warnings under Proposition 65 and disagrees with the results of the UC Davis Study.

Response: This comment is not related to the modification of text. This issue is addressed in responses to similar comments received during the first comment period for the regulations.

Subsection 25601(d)(now 25601(c))

403. Comment (CRN): The language in subsection (d) [now subsection (c)] is ambiguous and likely to be challenged. Simplify the language by deleting “and must be displayed with such conspicuousness as compared with other words, statements, designs or devices on the label, labeling, or sign, as to render the warning likely to be read and understood by an ordinary individual under customary conditions of purchase or use."

Response: The language in subsection (d) [now subsection (c)] is provided as an alternative to minimum type size requirements in safe harbor warning content, which were deleted from several but not all subsections in the regulations in response to other comments. By striking this language, there would be no minimum type size requirements for several exposure scenarios and no adequate guidance concerning the visibility of a safe harbor warning. This would be contrary to the purposes of the Act. OEHHA declines to make the change requested by the commenter.

404. Comment (NAIMA): NAIMA appreciates that the specific font size requirements have been changed to a broader more feasible requirement that language be 'conspicuous' compared with other words and designs on package.

Response: Comment noted, no response required.

405. Comment (Auto Alliance et al.): The commenters recommend a modification to subsection (c) by adding the sentence, "Any label that satisfies the applicable subsections of Section 25607 shall be deemed as satisfying the requirements of this section."

Response: This comment is not related to the modification of text.

406. Comment (CalChamber): It is unclear as to whether warnings may be provided using package inserts, pamphlets, or owner's manuals. The term "labeling" is used throughout the regulations in subsections 25601(d), 25603(a)(1), and 25602(d). CalChamber recommends adding " labeling or sign" in subsection 25603(a)".

Response: These issues of providing warnings using package inserts, pamphlets and owner's manuals are addressed in responses to similar comments received during the first comment period for the regulations.

Subsection 25601(f) (now 25601(e))

407. Comment (ACC): Subsection (f) [now subsection (e)] prohibits businesses from adding truthful, accurate, helpful, relevant, meaningful, and complete information in or near warnings except for the limited information specified in the regulation. It is not clear if it would allow businesses to offer safe use and handling information about the product. It is also unclear if a business would be allowed to explain that for example, 99% of the daily exposure to a listed chemical comes from other sources, or to offer information about how to reduce exposure from those other sources, or that its product offers the lowest levels of a listed chemical amongst its competitors.

Response: The provision only applies to the content of the safe harbor warning. Other information that may be provided for the product separate and apart from the warning is not affected by this provision. Further, if the safe use and handling information provides information on the source of exposure and/or how to avoid or reduce exposure to the listed chemical or chemicals identified in the warning, it would be permissible under subsection 25601(e).

408. Comment (ACC): The science of warnings and risk communication indicate including additional information by manufacturers can improve consumer decision making. To the extent that a warning is needed, it can improve the effectiveness of warning. USFDA has explained the value of balanced risk information in the warnings they require such that important risk information not be omitted, nor unsupported information not be included. ACC urges OEHHA not to get into the business of policing commercial speech and suppressing truthful information that manufacturers want to communicate. Businesses are already accountable for the truthfulness of commercial claims and disparaging claims about competitors under other California laws. Tort laws provide an effective foundation for ensuring adequacy of warnings against significant risks. Consumer products subject to the Federal Hazardous Substances Act must deliver compliant warnings for hazardous substances.

Response: OEHHA agrees with the commenter to the extent that increased information available to consumers can lead to better informed decision making. Indeed, this is an important underlying premise for the modification of the Clear and Reasonable

Warnings regulations. However, as the lead agency for implementing the Act, OEHHA is obligated to ensure that warnings are meaningful and informative. Extraneous supplemental information has the potential to detract from or controvert a warning; this would be inconsistent with the intent of the Act. OEHHA has determined that providing more information that identifies the source of exposure or how a person can avoid or reduce exposure is beneficial information that is consistent with the purposes of the Act, and that this information can be included in a safe harbor warning, as provided under subsection (e). A business may provide warnings with additional information that otherwise comply with the Act, as is expressly provided in subsection 25600(f). There were no changes made in response to this comment.

409. Comment (ACC, AHPA, CalChamber, CRN, and Wine et al.): As subsection (f) [now subsection (e)] is currently drafted, it is easy for a bounty hunter to argue that any on-package communication, advertising and marketing material, or even website claims or social media claims triggers the supplemental speech prohibition. It is unclear whether website audio or video streaming next to a warning, product testimonials, endorsements, consumer ratings or feedback would trigger the prohibition. This provision violates the First Amendment of commercial free speech. The subsection currently prohibits all warnings, including supplemental warnings from containing supplemental information other than the two substantive restrictions OEHHA has identified. The term “Supplemental information” is so vague and overbroad that businesses will not reasonably know whether their conduct falls within bounds of the regulations. It is unclear what "warning" means. If it is the content itself, the entire label, package, or sign, then it is an unconstitutional chilling of free speech. CalChamber proposes to relocate subsection (f) to Subarticle 1 "General" Section 25600 and add, "The warning content required by this subarticle may contain information that is supplemental to the warning content...Such supplemental information may not be substituted for the warning content required by this subarticle." Wine et al. questions how these restrictions "square" with OEHHA's statement in the BPA documents that BPA is approved by the USFDA for use in food-contact applications even though BPA is subject to the Proposition 65 listing. Wine et al. and ACC urge the subsection be removed. AHPA requests the phrase, “explains the source of the exposure or provides information on how to avoid or reduce exposure to the identified chemical or chemicals” be removed and replaced with “truthful and not misleading”.

Response: The provision in subsection (e) was initially proposed in the general provisions of Subarticle 1. Some commenters indicated that it might implicate the First Amendment. Other commenters urged OEHHA to relocate the provision to the safe harbor provisions of Subarticle 2. OEHHA has the discretion to implement regulations to carry out the purposes of the Act including the development of safe harbor methods and content which in OEHHA’s opinion meet the clear and reasonable requirements of the Act. A business is not, however, required to follow the safe harbor warning

provisions. Subsection 25600(f) in the general provisions of Article 1 permits a person to provide a warning using methods and content other than those in Subarticle 2 as long as it complies with the Act. In terms of the meaning of "warning", it is defined in statute in HSC section 25249.11(f) in part as;

"…need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable."

OEHHA has determined that information regarding the identification of the source of exposure and ways to minimize or reduce exposure to the listed chemical is beneficial supplemental information that is consistent with the purposes of the Act. OEHHA deems warnings containing information on the source of exposure and ways to minimize or reduce exposure to be clear and reasonable. Additional kinds of supplemental information, including the types of information described in stakeholder comments, offer a near-endless range of possibilities affecting the content and reasonableness of warnings. The statement on BPA cited by the commenters is from the Notice of Emergency Rulemaking for that action and is factually correct. Whether or not a chemical is approved for use in food contact material has no bearing on whether a warning is required under Proposition 65 for that chemical, or whether supplemental information may be provided with safe harbor warnings. While warnings containing such additional information might still meet the statute's requirement for being clear and reasonable, OEHHA cannot pre-determine that such warnings are clear and reasonable and therefore qualify as safe harbor warnings. OEHHA declines to further modify the safe harbor provision.

410. Comment (CCEEB): CCEEB agrees with CalChamber's comments regarding commercial speech and adds that under current California law, Section 17200 Business and Professions Code, OEHHA can pursue enforcement action for deceptive business practices.

Response: As noted in the response to CalChamber and other commenters, OEHHA disagrees with the characterization of subsection 25601(e) as an infringement of commercial speech. OEHHA has no enforcement authority under Business and Professions Code section 17200 or Proposition 65. No change was made based on this comment.

411. Comment (DRoe): The overly broad definition of "supplemental information" has been successfully corrected and is properly located in the safe harbor context only.

Response: Comment noted, no response required.

412. Comment (Environmental Coalition): OEHHA deleted earlier provisions that prevented businesses from contradicting a Proposition 65 warning while still receiving

the benefit of the safe harbor. If the latest proposed revision is adopted, OEHHA can expect businesses to "*explain* the source of the exposure" in ways that dilute, diminish and contradict the effect of the warning and still take advantage of safe harbor warning. Companies may now be permitted to place contradictory information right next to the warning while still taking advantage of the safe harbor. This must not be allowed as it subverts the purpose of having a safe harbor. Revise subsection (f) [now subsection (e)] to make it clear that a business can only use the safe harbor warning if it does not dilute, diminish or contradict that warning; and replace "explains the source of the exposure" with "identifies the source" which aligns more closely with purpose of warning. Reinsert language in Section 25600 that makes it clear that contradictory, diluted or diminished warnings are not “clear and reasonable” even when a business chooses not to use the safe harbor language.

Response: Based on this and other comments, OEHHA has revised the text in subsection (e) by replacing “*explains* the source of exposure” with “*identifies* the source of exposure”. This change should prevent irrelevant information from being provided in the warning. The change to “identifies” obviates the need for the suggested “reinsertion” of the phrase “dilute, diminish or contradict” as the supplemental information being provided in subsection (e) is sufficiently narrow in scope. OEHHA declines to further modify Section 25600 as requested by the commenter.

413. Comment (Environmental Coalition): The First Amendment objections cannot hold water. The proposed language is constitutional. There can be no objection to restrictions on language that is by its nature optional, there is no issue of compelled speech.

Response: Comment noted, no response required.

414. Comment (NAIMA): NAIMA appreciates that supplemental information may be provided so long as such information does not contradict the warning. NAIMA urges OEHHA to allow transmission of full and complete and meaningful risk information.

Response: OEHHA has determined that the supplemental information included in the warning described in in subsection 25601(e) will improve the quality of information provided to consumers. It should be noted that the provision only applies to the content of the safe harbor warning. Other information that may be provided for the product separate and apart from the warning is not affected by this provision. No change was made based on this comment.

Section 25602 Consumer Product Exposure Warnings – Methods of Transmission

415. Comment (Environmental Coalition): The Coalition supports that methods be limited to posted signs, shelf signs, and shelf tags. To prevent confusion and improve

clarity, suggest eliminating the "labeling" definition as there is no circumstance where "labeling" is used in a manner distinct from "label".

Response: This comment is not related to the modification of text.

416. Comment (JAgliozzo): Many Proposition 65 warnings on consumer products are provided in font sizes so small as to be illegible for the ordinary consumer. Warnings are also printed in a non-contrasting color that makes it even more difficult to find or read. Consider an 8-point minimum and require a contrast color similar to black type on a white background.

Response: Based on this and other comments, OEHHA modified the general requirements of the regulations by adding subsection 25601(c) to require consumer product warnings to be provided with such conspicuousness as compared with other words, statements, designs or devices as to render the warning likely to be seen, read, and understood by an ordinary individual in the course of normal activity. Similarly, environmental exposure warnings require warnings to be provided in a conspicuous manner and under such conditions as to make the warning likely to be seen, read, and understood by an ordinary individual in the course of normal daily activity. Generally speaking, a warning printed in a non-contrasting color or in a very small type size would likely impair the ability of an ordinary person to see, read, and understand the warning and would therefore not meet the requirements for safe harbor protection. These changes should address the concerns expressed by the commenter. No additional changes were made based on this comment.

Subsection 25602(a)

417. Comment (RMA): In subsection (a)(1), the term "at each point of display of the product" is not defined and is confusing. In the case for tires that are sold in retail stores where only a small number of actual tires available for sale in the store are on display and for tires that are not on display in a retail store, requests that OEHHA specify that only products which can come into contact with the consumer require a shelf-tag, shelf-sign or label.

Response: This comment is not related to the modification of text. This issue is addressed in responses to similar comments received during the first comment period for the regulations.

Electronic or Automatic Warnings Prior To or During Purchase

418. Comment (CalChamber): The phrase "without requiring the purchaser to seek out the warning" in subsection (a)(2) is unworkable and subject to legal challenge because electronic devices and processes by definition require a consumer to take some affirmative steps thus leading to litigation over whether the consumer had to "seek out the warning". This creates uncertainty for businesses and will lead to litigation.

Strongly urge OEHHA to eliminate the phrase and alternatively identify the affirmative steps beyond those ordinarily associated with obtaining information via electronic devices or processes.

Response: This comment is not related to the modification of text. This issue is addressed in responses to similar comments received during the first comment period for the regulations.

419. Comment (RMA): The requirement to provide a product-specific warning via an electronic device or process may not be feasible for small tire stores or automotive centers that do not have internet access. Subsection (a)(2) does not provide a level of detail that would trigger "seeking out a warning" contrary to the provision. RMA recommends that OEHHA provide clarification about what levels of actions a purchaser must take to be considered "seeking a warning".

Response: The regulations do not require that a product-specific warning be provided via an electronic device or process; instead that is just one option laid out in the regulations that would satisfy the safe harbor. Other, non-electronic options are also available. This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

420. Comment (DRoe): The phrase, "during the purchase" in subsection (a)(2) is not clear. "During" in this context might mean that cash register receipts and the like would be authorized. OEHHA should use the same wording as in subsection 25602(b), that a warning must be displayed to the purchaser "prior to completing the purchase". Alternatively, OEHHA should require warnings be given "prior to tendering of payment." OEHHA cannot intend to give safe harbor status to post-purchase warnings. The term "during" should be eliminated.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

421. Comment (JAgliozzo): If electronic signage at the point of display is allowed for consumer products, it is not clear how public and private enforcers will be able to ensure the electronic warning was displayed at all times. A retailer could turn a display off at their convenience or turn it on after receiving a notice and claim the display was present at all times. Hard copy warnings on packaging would be clearer and more reliable for all consumers.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

Label and On-Product Warning Requirements

422. Comment (AHAM): Subsection (a)(3) is unclear and worse it eliminates the ability to place a warning in the owner's manual or use and care guide. The regulation needs substantial revision to better align with the Governor's stated reform goals. AHAM urges OEHHA to modify the subsection to retain the option of furnishing a warning via "other labeling" that accompanies product. This is a sensible method and for small products, the only method. A warning in the owner's manual is a good option because the manual has other health and safety warnings and cautions with proper use instructions, is generally kept longer than immediate packaging or immediate packaging that may never be seen by the consumer, is more likely to be kept intact while the package is discarded, is usually accessible online long after the purchase or resale, and provides manufacturer's contact information so consumer can obtain additional information. OEHHA should add "or other labeling" to subsection (a)(3).

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

423. Comment (CCEEB): It is not clear if the safe harbor consumer product warning can be conveyed via some form of "labeling" in addition to a label. CCEEB urges OEHHA to add, "or labeling" to subsection (a)(3).

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period and in the ISOR for the regulations.

424. Comment (ACA): The proposed language in subsection (a)(4) will increase confusion because of the vague parameters of being no smaller than the "largest type size used for other consumer information". ACA recommends that the font size be no smaller than the font used for the precautionary statements rather than consumer information. Alternatively, OEHHA can require the font size to be no smaller than 6 point font without referencing other consumer information.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

425. Comment (RMA): Subsection 25602(a)(4) does not include "labeling". OEHHA should modify subsection 25602(a)(4) to include "other labeling".

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

426. Comment (CalChamber): The term "on-product" is undefined and ambiguous. The regulations would benefit from clarifying that the "on-product" warning need not appear on the product itself but can instead appear on its label or exterior packaging. This can be accomplished by adding the term "on-package" after the term "on-product" in subsections 25602(a)(4) and 25603(b).

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

Subsection 25602(b)

Warnings for Internet Purchases

427. Comment (CA Retailers): The Act requires a warning before exposure and is not properly construed to always require a warning before purchase. There is no precedent for such construction of law regulating health and safety aspects of consumer products where the online retailer makes no affirmative representation regarding the product. Subsection (b) would require each retailer to manually review labels of thousands of products sold online to determine if a warning is required. Suppliers could force retailers to provide warnings for products sold in California although the retailer did not want to put the warning on their website. Even if the retailer was not forced by suppliers to provide an online warning in lieu of labeling or other warnings, OEHHA would require the retailer to provide an online warning even if the product label carried a warning.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

428. Comment (Environmental Coalition): The Coalition supports that the warning be included on the product display page for internet purchases. However, the Coalition continues to believe that the option of hyperlinking to a different page even with the word "WARNING" is not sufficient.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

429. Comment (ACA): OEHHA does not have the authority to require warnings for products sold online or in a catalog when the product already has an on-product warning. However, if OEHHA chooses to require internet and catalog warnings, ACA supports the most recent amendments to the provisions. Consumers and businesses benefit from the amendments and they reduce the burden on manufacturers to provide two warnings on the same product.

Response: OEHHA disagrees with the commenter's assertion that it does not have authority to require warnings for products sold via the Internet or in a catalog. As the lead agency for implementation of Proposition 65, OEHHA "may adopt and modify regulations, standards, and permits as necessary to conform with and implement this chapter and to further its purposes."[52] Because of the unique nature of internet and catalog sales, a consumer may purchase a product and potentially be exposed to the product before receiving a warning required under the Act. Further, a purchaser may not be able to easily return the consumer product and may incur additional costs that may result in a consumer risking exposure because of the inconvenience imposed on the consumer. OEHHA has determined that in order to qualify for safe harbor protection, vendors of consumer products sold online will need to provide a warning prior to completing the purchase. In order to alleviate the potential burden on businesses selling consumer products on the internet, if a consumer product bears a warning using the truncated warning content of subsection 25603(b), the business may also use the content of subsection 25603(b) rather than the full warning content of subsection 25603(a). The portion of the comment supporting these changes is noted and requires no additional response.

430. Comment (RMA): Subsection 25602(b) can be interpreted to require online retailers to provide a second warning even if the product they are selling contains an on-product warning. RMA recommends that OEHHA clarify that online warnings are not required for products that already contain an on-product warning.

Response: As noted in the comment above, OEHHA has determined that in order to qualify for safe harbor protection, consumer products sold online will need to provide a warning prior to completing the purchase. No change to the regulatory text has been made in response to this comment.

431. Comment (NAIMA): NAIMA appreciates the amendment that allows internet and catalog warnings to be the same as on-product warnings.

Response: Comment noted, no response required.

Subsection 25602(c)

Warnings for Catalog Purchases

432. Comment (AHPA): There is no clear definition for "catalog" in subsection (c). AHPA strongly objects to the possible interpretation that all forms of sale literature are required to bear a warning. AHPA requests a definition of "catalog" in Section 25600.1

[52] Health and Safety Code section 25249.12(a)

as a printed pamphlet, booklet or similar document identifying products offered for sale along with pricing or ordering information.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

Subsection 25602(d)

Foreign Language Requirement

433. Comment (CalChamber): Subsection 25602(d) is tied to the definition of "consumer information" in subsection 25600.1(c), however, "consumer information" uses the phrase "including but not limited to" which has the effect of requiring a foreign language if any other information is in a foreign language. This is contrasted with the approach in subsection 25607.1(c) that triggers a foreign language only if any consumer information about a specific food product is provided in a language or languages other than English. CalChamber recommends changing the phrase to, "If any consumer information on a label, labeling or sign for a product is provided in a language..."

Response: OEHHA has modified the definition of “consumer information” in subsection 25600.1(c). This change addresses the concerns expressed by the commenter and requires no additional response.

434. Comment (NAIMA and WSPA): Eliminate the foreign language requirement in subsection (d) because there is only so much room on a package label. Mandatory pictograms are intended to communicate a warning in a universal language and alleviate the need for a warning to also be written in a foreign language. The foreign language requirement is fraught with ambiguity.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first comment period for the regulations.

435. Comment (AHPA): Subsection 25602(d) implies that the manufacturer, producer, packager, or distributor is required to have advance knowledge about all of the languages in which retailers selling its products may choose to provide labeling or signage about the product. This is an infeasible requirement because there is no way for manufacturers, packagers, producers or distributors to anticipate all the languages used by a retailer and the inherent space limitations of a label. The proposed text implies all warnings for a product must be provided in precisely the same printed material, which is unnecessary. The requirements can be fulfilled if a warning is delivered via labeling or signs printed in the necessary additional languages or by other

means such as electronic or verbal communications in the additional languages. Request adding, "or by other electronic, written or verbal means."

Response: This comment is not related to the modification of text. OEHHA agrees that where a product manufacturer or other business in the chain of commerce is not aware that a retail seller provides consumer information in other languages, the retail seller should be responsible for providing the warnings in those languages to the extent they are required. Further, to the extent resources are available, OEHHA plans to provide compliant Proposition 65 warnings in multiple languages on its website for use by businesses, including retail sellers of consumer products. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

436. Comment (CalChamber): While the Proposal gives detailed and precise requirements for the language to be employed in the English-language warnings, it does not give an indication of how these warnings are to be properly translated. As the safe harbor warnings have been replaced by these provisions, businesses do not have guidance on the content that must be included in the non-English warnings. Allegedly improperly translated warnings may further prompt suits, defense of which will require engaging linguistic experts to prevail, making a forced settlement inevitable. Accordingly, OEHHA should specify precisely what the foreign language warnings must say. At the very least it should be limited by the "rule of reason" to limit frivolous translation lawsuits. The foreign language requirement should be limited to only one language other than English.

Response: This comment is not related to the modification of text. However, OEHHA agrees that there could be minor differences between various translations of Proposition 65 warnings. Rarely if ever is there only one correct way to translate a communication into another language. Even relatively simple translations require the translator to make decisions regarding word choices and restructuring translated sentences in ways that are clear to readers of the other language. It is not OEHHA's intent to stipulate only one way to translate a warning or prevent translators from using their professional judgment. As long as the translation is reasonable and is sufficiently clear to the reader, it would comply with the requirements of the regulations. To assist businesses seeking to provide foreign language warnings, to the extent resources are available, OEHHA will post translations of warnings on its warnings website at https://www.p65warnings.ca.gov/. OEHHA declines to limit the foreign language requirement to one language for the reasons noted in previous responses to comments and the ISOR for the regulations.

437. Comment (CalChamber): With respect to the foreign language requirement, it can be eliminated by including translated warnings on OEHHA's website in multiple languages in lieu of requiring businesses to provide them whenever another language is

present on label. OEHHA should clarify in either the regulations or the FSOR that if the warning is being provided in multiple languages that it does not mean multiple pictograms are also required to accompany each foreign language Proposition 65 warning.

Response: This comment is not related to the modification of text. As stated in previous responses to similar comments, whether or not two pictograms should be included will depend on the circumstances. Where the English and alternative language warnings are provided together, a second warning symbol would not be necessary. However, if the alternative language warning is not co-located with the English version, it would be appropriate to include the symbol with the warning message.

438. Comment (ACA): Subsection 25602(d) will burden manufacturers by requiring more information in a finite section of labels. The requirement will likely confuse consumers that are not in the US and are not affected by Proposition 65. It creates a new risk for being sued for not properly translating the warnings in a foreign language in a clear and reasonable way. When online translations from several different translation websites were sought out, each provided a slightly different version of the warning text. ACA urges OEHHA not to apply the foreign language requirement for warnings particularly for on-product warnings on small packages. OEHHA can satisfy the language requirement by supplying translations on its website. If OEHHA adopts the language requirement, ACA encourages OEHHA to adopt the recommendations submitted by CalChamber that only require one pictogram per warning if English and other languages are required.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

439. Comment (ACA): The regulation should clarify that if a warning is provided in multiple languages, multiple pictograms are not required. In the April 2016 discussions with OEHHA, OEHHA stated that if English and a foreign language are provided close to each other, one pictogram would be required. However, if English and a foreign language are on opposing sides of the label, two pictograms would be required. This should be clarified in the FSOR or in the regulatory text.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

Other Comments on Section 25602

440. Comment (ICC): When a non-California manufacturer wants to sell goods nationwide, Proposition 65 warnings have to be added as an extra sticker or new labels

need to be printed for California customers. Any extra hazard warning can be a deterrent to non-California customers who do not understand Proposition 65 labeling and may be considered over-labeling. The additional labeling creates an undue burden on California employers.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

Section 25603 Consumer Product Exposure Warnings – Content

441. Comment (Environmental Coalition): The phrase, "such as" used throughout subsection 25603(a) introduces ambiguity about whether the product will cause exposure to the named chemical. Combined with the phrase, "can expose" a person has no way to know whether an exposure will occur or to what chemical. The phrase "such as" should be replaced with "including" as in the November 2015 version of regulations which was clearer than this new language.

Response: Subsequent to this comment, OEHHA modified the regulatory text by replacing “such as” with “including” throughout the regulations.

442. Comment (AHPA): Warnings for exposures to Proposition 65 listed reproductive toxicants in subsections 25603(a)(2)(B), (a)(2)(C), and (a)(2)(D) would be much more informative if they had instructions that the product should not be used by those populations who could be negatively affected by exposure, rather than requiring a declaration of the presence of the chemical. Suggest alternative warning language.

Response: This comment is not related to the modification of text. A similar comment by the commenter was responded to during the first comment period.

443. Comment (ICC): When analytical methods easily detect parts per trillion of specified chemicals in mixtures, when more attributed health concerns can be verified, and when the Proposition 65 list is expanded, then the Proposition 65 warning statements in subsection 25603(a)(2) may have to end up covering a wide range of chemicals by revising the statements to read as "WARNING: This product may expose you to Proposition 65 chemicals which are known to the State of California to cause one or more of the following: cancer, birth defects or other reproductive harm..." Users should be advised to read Section 15 of the SDS for chemical identification and to go to the Proposition 65 warnings website for further information. This statement should be posted in a location where it can be readily seen, read or identified.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

444. Comment (Mateel): The information and practicality requirements expressed in the Proposition 65 Preamble and Ballot Pamphlet are not met because proposed Section 25603 does not require the warning to identify each chemical or relevant route of exposure for which the warning is being given. Section 25603 fails to conform to the requirements of the Act.

Response: This comment is not related to the modification of text. OEHHA disagrees with the commenter that the Preamble and Ballot Pamphlet require that warning content must include the name of each and every individual chemical for which a warning is given.

445. Comment (ACC): The Proposition 65 website may be illegal and outside OEHHA's authority. It is the regulated entity responsible for the exposure that has the obligation to issue a warning. OEHHA has no authority to do so and cannot assume the role. ACC objects to the inclusion of the URL on safe harbor warnings. The sufficiency of a warning cannot rest on the requirement that the label include an URL to the agency website. It presents a potential compelled speech problem under the First Amendment. OEHHA is simultaneously prohibiting businesses from offering supplemental information about product use, risks, and benefits while forcing businesses to tell its customers about OEHHA's website. The regulation presumably precludes a business from making a statement that the URL is required by law and does not constitute the business's endorsement of the information provided. An internet retailer that wanted to post a notice that there is incorrect information on the website and requests a correction could open itself up to a lawsuit for an 'inadequate' warning. ACC urges that the URL requirement be withdrawn.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

Warning Symbol

446. Comment (ACC): ACC asks OEHHA to not misuse the ANSI safety alert symbol consisting of a black exclamation point in a yellow equilateral triangle with a bold black outline. The Proposition 65 warning is not a safety warning and should not be misunderstood to be one. It is inappropriate and likely will confuse consumers. Urge OEHHA to remove it.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

447. Comment (ACA and CalChamber): The commenters believe the requirement of the ANSI symbol (pictogram) will confuse consumers because the symbol is commonly used in other contexts unrelated to Proposition 65. If OEHHA intends to use a

pictogram, then create a Proposition 65 specific black and white pictogram. Participants in OEHHA's UC Davis Study did not express a preference for yellow and were not confused by a black and white symbol, thus the yellow color is not a necessary component of warning. Urge OEHHA to eliminate the mandate that the symbol be in yellow color and allow printing in black and white; as an alternative allow businesses subject to Hazard Communication Standard (HCS) to provide a black exclamation point.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

448. Comment (ICC): The Proposition 65 symbol may cause confusion and be misleading to employees familiar with the current use of similar symbols. OSHA Hazard Communication Standard uses an exclamation mark within a diamond shaped box to denote irritant, skin sensitizer, and other acute toxic effects and uses a silhouette [with the exploding chest] within diamond shaped box and the signal word "Warning" to categorize a chemical as "suspected of causing cancer". The signal word "Danger" is used to categorize a chemical as "may cause cancer".

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

449. Comment (ICC): It would be helpful to eliminate additional warning symbols and statements because bar codes, QR codes, pictograms and other symbols already take up considerable space and attention on a label. Consumers and employees are already directed to the Proposition 65 Warning website for additional information. It is not necessary to confuse the labeling further with Proposition 65 warning symbols and statements.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

450. Comment (ICC): ICC proposes that Safety Data Sheets (SDSs) with an appropriate Proposition 65 symbol, warning and statement in Section 15 be readily accessible at all locations where Proposition 65 chemicals need to be considered and that no Proposition 65 warning or symbol be used on the label.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

451. Comment (NAIMA): NAIMA objects to the inclusion of a yellow ANSI pictogram that would cause consumer confusion and create technical challenges for companies.

There would be significant costs to reconfigure printing apparatus to add yellow color. No consumer research has been shown to support the need for such an expensive and burdensome undertaking. NAIMA urges OEHHA to allow the ANSI pictogram to be in black and white in all circumstances.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

452. Comment (PCBP): Requiring yellow for the pictogram will be costly and unnecessary because red is already required by HCS and having red and yellow pictograms will be confusing. There is an internal inconsistency with occupational warnings in Section 25606 because products that are sold for both occupational and consumer use will be in a conflict between the yellow and red pictograms. PCBP urges OEHHA to eliminate the color yellow from subsection 25603(a)(1). OEHHA should also clarify that a red border may be used on either or both consumer and occupational warning exclamation point pictograms.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

453. Comment (ICC): ICC offers six alternative symbol and warning statements. Variations include: Triangled silhouette with white background using either "WARNING" or "DANGER", Triangled silhouette with yellow background using either "WARNING" or "DANGER", or Diamonded silhouette with white background using either "WARNING" or "DANGER". Also proposed revising warning statement to read, "This product can expose you to chemicals [name of one or more chemicals] which are known to the State of California to cause one or more of the following: cancer, birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov." The broad coverage of the phrase, "to cause one or more of the following" allows for a standard statement format to be used for all Proposition 65 chemicals and eliminates the need for multiple "Content" and "Methods of Transmission" tailored warnings. Reference to the P65Warning website automatically allows users to find more detailed information from OEHHA's Proposition 65 Warning website.

Response: This comment is not related to the modification of text. Issues concerning the selection of the warning symbol are addressed in responses to similar comments received during the first comment period for the regulations.

On-Product Short-Form Warning

454. Comment (ACA): ACA appreciates that the abbreviated on-product warnings were maintained.

Response: Comment noted, no response required.

Section 25604 Environmental Exposure Warnings – Methods of Transmission

455. Comment (WSPA): The term "clearly defined entrances" is not defined and this forces regulated businesses to guess at the phrase's meaning and where "all" such "public entrances" are for purposes of posting required warnings. This regulation places a burden on businesses and increases likelihood of litigation.

Response: OEHHA disagrees that a “clearly defined entrance” should be a defined term. An example of a “clearly defined entrance” could be a public entrance to a facility such as the entrance to a construction area, theme park, sports facility or other building. On the other hand, the entrance to an open space like a smoking area may not have a “clearly defined” entrance.

456. Comment (DRoe): Although identification of the source of exposure is explicit for mailed notices and published notices, it is not explicit for posted notices. The three elements of Section 25604 should be drafted in parallel so all three methods for posted notices, mailed notices and published notices include the same requirement of "clearly identify the source of the exposure".

Response: OEHHA agrees with the commenter that the safe harbor warning methods for environmental exposures should be drafted in parallel. Based on this and other comments, OEHHA modified Section 25604, subsections (a)(1)(A), (a)(2)(A), and (a)(3)(A) to include the phrase “Clearly identify one or more sources of exposure”.

457. Comment (WSPA): Warning notices for environmental exposures "delivered to each occupant in the affected area" is directly at odds with HSC section 25249.11 that provides that warning notices "need not be provided separately to each exposed individual and may be provided by general methods". WSPA urges OEHHA to remove the requirement for individual delivery of warnings and instead require warnings be transmitted in a way that is designed to fairly convey a "clear and reasonable" warning to exposed individuals.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

458. Comment (WSPA): The phrases "source of the exposure" and "map that identifies the affected area" are not defined and subject to expansive interpretation by opportunistic plaintiffs. For locations with diffuse and intermittent environmental exposures it may be difficult to create a map that can accurately identify the exact location of exposures. The requirement clutters an understandable warning and results in further costs for the regulated businesses.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

459. Comment (CalChamber): Subsection 25604(a)(2)(A) is an entirely new concept that is not "sufficiently related to the original text that the public was adequately placed on notice that the change could result" as specified in Government Code section 11346.8(c). The name of the exposure source is unnecessary because OEHHA has the express ability to request this type of information in the Lead Agency website regulation subsection 25205(b)(4) from businesses providing environmental exposure warnings. OEHHA also does not require source information for consumer products and it should treat environmental exposures similarly by eliminating the new source identification requirement and instead reserve such information for the Lead Agency website. Recommend OEHHA revert to the prior proposal.

Response: The changes were made in response to comment received during the prior comment periods that expressed concerns that the regulations lacked clarity. OEHHA disagrees with the commenter that the identification of the “source of exposure” in subsection 25604(a)(2)(A) is not “sufficiently related” to the text as specified in Government Code section 11346.8(c). This regulation is focused on warnings for exposures to listed chemicals. Identifying the source of those exposures is directly related to the intent expressed in the documents that were made available to the public as part of the initial rulemaking.

In the Notice of Proposed Rulemaking published on November 27, 2015 OEHHA stated that:

> “These new regulations would further the “right-to-know” purposes of the statute and *provide more specific guidance on the content of safe harbor warnings for a variety of exposure situations, and corresponding methods for providing those warnings* [emphasis added].”

OEHHA further expressed its intent in proposing the changes to Article 6:

> “In proposing this regulatory action, OEHHA intends to address many of the issues that have surfaced since the original regulation was adopted in 1988 by clarifying the relative responsibilities of manufacturers and others in the chain of distribution for providing warnings for products that are eventually sold at retail. The proposed regulations would also make needed changes to the current requirements for a “safe harbor” warning by integrating new technology, *providing more useful information to Californians about their exposures to listed chemicals* and by providing more compliance assistance for affected businesses, thereby furthering the purposes of the Act [emphasis added].”

Finally, we noted the following benefits to the people of California:

> "The proposed regulation will benefit the health and welfare of California residents and improve worker safety *by providing more information to the public and facilitating businesses' compliance with the Act. More informative warnings will further the purposes of Proposition 65 by helping the public to make informed decisions regarding the products they choose to purchase and the places they frequent based on information about their exposures to chemicals that cause cancer or reproductive effects* [emphasis added]."

Because of this OEHHA has determined that the public was put on notice of the types of modifications OEHHA was considering, namely providing more informative warnings prior to exposure to a listed chemical; the identification of an exposure source in subsection 25604(a)(2)(A) is consistent and "sufficiently related" to the Notice of Proposed Rulemaking.

OEHHA further disagrees that the concept of identifying the source of an environmental exposure is an "entirely new concept". The warning method described in subsection 25604(a)(1)(A) expressly referred to clearly identifying the area for which the warning is provided, "including the location and source of the exposure". Subsection 25604(a)(2)(A) was modified for consistency within the environmental methods section.

As OEHHA noted in the ISOR when this rulemaking was proposed:

> "Specifically, subsection (a)(1) requires signage to be posted at all public entrances to the affected area in no smaller than 72-point type that clearly identifies the area for which a warning is being provided. The warning must be provided in a conspicuous manner to ensure the warning is seen, read, and understood. The warning must clearly identify the area for which the warning is being provided and the location and *source of the exposure* [emphasis added]. The warning must be provided in English and in any other language used in signage in the affected area."[53]

OEHHA fully complied with Government Code section 11346.8(c) as the change was sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action. OEHHA published a Notice of Modification of Text in the California Regulatory Notice Register and posted the Notice of Modification of Text and the full text of the resulting adoption with clearly indicated changes on the OEHHA website available to the public for a 15-day comment period and OEHHA is responding to those written comments in this FSOR.

460. Comment (CalChamber and CCEEB): The requirement to identify the exposure source is unworkable because it may be interpreted to require exposure assessments.

[53] Initial Statement of Reasons, p. 32.

It will also result in expensive litigation to resolve the ambiguity of the term "exposure source". It is unnecessary and duplicative as OEHHA can request and provide such information through its Lead Agency website regulation. If OEHHA intends for businesses to perform exposure assessments then the Administrative Procedure Act requires that an economic impact analysis be conducted.

Response: OEHHA does not believe this provision imposes a requirement upon a business to perform an exposure assessment, and OEHHA does not intend to impose such a requirement here. The business providing a warning should know at least one source of exposure for which they are providing a warning in the same way they should know at least one chemical for which they are providing a warning. If this is not the case, then by definition no warning should be provided since there is no “knowing and intentional” exposure to a listed chemical.

The fact that OEHHA can request information from a business under a separate provision of the regulations does not relieve businesses of the requirement to provide a clear and reasonable warning. OEHHA also has no reason to believe this section will result in expensive litigation. The regulations simply require a business to disclose information it already possesses about the source of the chemical exposure. No additional analysis is required. It should be noted that the regulations provide non-mandatory safe harbor methods and content for warnings. A business may choose to provide the warnings in any other manner that is clear and reasonable (subsection 25600(f)).

461. Comment (DRoe): Adding the phrase, "Clearly identify the source of exposure" to subsections (a)(2)(A) and (a)(3)(A) makes environmental exposure warnings meaningful.

Response: As noted previously, the regulations were modified to specifically address this issue.

462. Comment (WSPA): The foreign language requirement in subsection (a)(2)(D) is fraught with ambiguity. Businesses will revise warnings to reflect potentially multiple languages and then will wonder which languages the businesses will "ordinarily use". It will result in increased litigation and in longer warnings that are less likely to be read and understood by the public. WSPA urges OEHHA to consider dropping the multiple language requirement in favor of directing the public to OEHHA's Proposition 65 Warnings website where further information can be provided in any and all languages desired by OEHHA.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

463. Comment (Environmental Coalition, DRoe): The revisions in Sections 25604 and 25605 convey specific useful information to persons affected by the exposure. It is far better and more informative to say, "[Name of one or more exposure source(s)]..." Given the vast number of possible exposure scenarios, OEHHA should provide examples in the FSOR of the various environmental exposure scenarios and what 'the source' of exposure might be so businesses may know what level of generality they must use to locate the source of exposure and then by reason of analogy know how to do so in a given situation. David Roe commented that identification of the source of environmental exposures is a major and necessary improvement. Proposition 65 warnings are given only for "knowing and intentional" exposures and the responsible party already knows what the source of exposure is; therefore, it is reasonable to expect that such parties can name one or more of the relevant exposure sources. If needed, illustrative examples for different types of environmental exposures could be explained in the FSOR (e.g., "touching [this object]", "breathing downwind of [this smokestack]", "wading in [this lake or stream]", etc.

Response: OEHHA agrees that there are a large number of possible exposure scenarios and of possible exposure sources. The intent of this provision is to accommodate a variety of ways to properly identify an exposure source. When a business is providing a warning via mail, email or newspaper advertisements concerning exposures to individuals outside of its facility, the source would appropriately be identified as the name of the facility (e.g., “Joe’s Auto Body Shop” or “Corporation X chemical processing plant”). In other words, for most warnings delivered to individuals by mail or email, or for newspaper warnings, the name of the business providing the warning and the “source of exposure” would generally be the same. In contrast, when the business is providing a warning to individuals who incur the exposure on the business’s premises, such as inside a building or a facility, the source would need to be identified with more precision. For example, if a business is providing a warning for lead, and is posting the warning in the affected area, the source of the exposure might be identified as paint or as dust. A warning indoors for formaldehyde might appropriately identify the source as carpet, furniture, wall-board, particle-board, or even indoor air – any of these identifications would serve the purpose of providing some information to people about where the exposure is emanating from, or about how they might be exposed. Although a business may name more than one source, they are only required to name one source in the affected area, even if multiple sources are involved.

Section 25605 Environmental Exposure Warnings – Content

464. Comment (Environmental Coalition): The phrase, "such as" in subsection 25605(a) introduces ambiguity about whether the product will cause an exposure to the named chemical. Combined with the phrase, "can expose" a person has no way to know whether exposure will occur or to what chemical. The phrase, "such as" should be replaced with "including" as was in the November 2015 version of regulations which was clearer than this new language.

Response: Based on this comment, OEHHA replaced the phrase “such as” with “including” throughout the regulation.

465. Comment (CalChamber): The phrase "Name of one or more exposure source(s)" can be interpreted to suggest that an environmental exposure warning requires all sources of exposures to be identified in the warning. However, it is understood that OEHHA‘s intent is to allow businesses to specify one exposure source in the warning, even if the warning is being provided for multiple exposures. CalChamber recommends adding a new subsection with the following language: “If a warning is being provided for more than one exposure, the warning meets the requirements of this article if the name of at least one exposure source for which the warning is being provided is included in the text of the warning".

Response: OEHHA has replaced the phrase “name of one or more exposure source(s)” with “name of one or more sources of exposure”; however, OEHHA does not agree that the previous phrase, or the phrase as modified, is ambiguous. The commenter is correct that OEHHA intends to allow businesses to specify one exposure source for each chemical identified in the warning, even if the warning is being provided for multiple exposures in the affected area. A business has the option of identifying additional sources of exposure. OEHHA does not believe that the addition of a separate subsection with the phrase “for which the warning is being provided” is necessary, and declines to make the change recommended by commenter.

466. Comment (Mateel): The information and practicality requirements expressed in the Proposition 65 Preamble and Ballot Pamphlet are not met because proposed Section 25605 does not require the warning to identify each chemical or relevant route of exposure for which warning is being given. It fails to conform to the information content requirements under the Act.

Response: This comment is not related to the modification of text. As OEHHA stated in response to an identical comment from the same commenter regarding Section 25603, OEHHA disagrees with the commenter that the Preamble and Ballot Pamphlet require that warning content must include the name of each and every individual chemical for which a warning is given.

Section 25606 Occupational Exposure Warnings

467. Comment (ACA): It is unclear if occupational exposure warnings can be used for exposures coming from an occupational area as well as industrial products. ACA urges OEHHA to clarify its intent so products that already have warnings that comply with OSHA's HCS can fall under the occupational warning safe harbor. ACA suggests the section be expanded to “Occupational Exposure and Industrial Product Warnings”.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

468. Comment (ICC): ICC recommends that the Proposition 65 warning statement be placed in Section 15 of the OSHA Hazard Communication Standard 2012 Safety Data Sheets (SDS) for applicable chemicals. Federal OSHA does not regulate the Section 15 regulatory Information of a SDS, therefore, supplemental Proposition 65 information can conveniently be included for the benefit of all concerned.

Response: This comment is not related to the modification of text and is beyond the scope of the rulemaking.

469. Comment (ICC): The Hazard Communication Standard requires maintaining Safety Data Sheets (SDS) as 'readily accessible' and to list carcinogens that are at 0.1% or more by weight. OEHHA should adopt the same de minimis concentration for Proposition 65 chemicals or adopt a lower level at 0.01%. The SDS would become the base logistic to provide the initial 'clear and reasonable warning' to employees and the general public who could have access to the SDS which could give reference to more detailed information via product-specific shelf signs, electronic notice before purchase, internet warning before purchase, product-specific catalog warning, or Proposition 65 website. Disclosure of Proposition 65 information in the SDS may reduce the anxiety of “clear and reasonable”, “reasonably conspicuous”, “truthful” and "readily accessible" into a harmonized acceptance.

Response: This comment is not related to the modification of text and is beyond the scope of the rulemaking.

470. Comment (Mateel): Section 25606 is circular and nonsensical because 8 CCR Section 5194(b)(6)(c) provides that an employer may provide a workplace Proposition 65 warning that is "in compliance with California Code of Regulations Title 22 (22CCR) Section 12601(c) in effect on May 9, 1991." Why propose Section 25606 when this rulemaking repeals Title 22 Section 12601(c)?

Response: The reference is to Title 8, Cal. Code of Reg., section 5194, which discusses how to comply with the provisions of the California occupational standard and Proposition 65. The intent of the provisions of subsection 25606(a) is to carry over the

existing regulations that allow an employer to provide a clear and reasonable warning by complying with the federal and state Hazard Communication Standards. OEHHA has no authority to modify Title 8 to update the cross references. Based on this and other comments, OEHHA modified the occupational exposure warning provisions by adding subsection (b), which provides that if a listed chemical is not covered by subsection (a), warnings may be provided consistent with the safe harbor methods and content in Subarticle 2.

471. Comment (NAIMA): It is not clear that the requirements apply not only to occupational exposure area warnings but also to industrial product exposure warnings provided by manufacturers to downstream users. NAIMA requests clarification on what warnings are required for non-consumer products and employees.

Response: Subsection (b), added in response to comments, provides that if a listed chemical is not covered by subsection (a), warnings may be provided consistent with the safe harbor methods and content in Subarticle 2. Subarticle 2 covers both consumer product warnings and environmental warnings. The regulations allows for the use of these methods and content provisions for industrial product exposures not already covered by subsection (a).

472. Comment (ILMA): The proposed harmonization of Proposition 65 and the Occupational Safety and Health Administration's Hazard Communication Standard 2012 ("HCS 2012") is problematic. HCS 2012 does not explicitly require a company to provide Proposition 65 warnings in its SDSs. The location for including that information, Section 15, is non-mandatory per Appendix D of HCS 2012. Businesses who comply with HCS 2012 may but are not under obligation to notify anyone that a product may contain a Proposition 65 listed chemical. The stipulation that "a warning to an exposed employee about a listed chemical meets the requirements of this article if it fully complies with all warning information, training and labeling requirements of the federal Hazard Communication Standard..." is incongruent with what HCS 2012 and Proposition 65 require. ILMA fails to understand how compliance with HCS 2012 would prove sufficient for Proposition 65 warnings. Therefore, this section requires revisions to address those lingering issues.

Response: Based on this and other comments, OEHHA added subsection 25606(b) under which a business may provide a warning consistent with the consumer product exposure and environmental provisions of this article if an exposure to listed chemicals is not covered under subsection (a). This would include an exposure to a listed chemical that is not covered by the HCS which is listed in subsection (a).

473. Comment (ACA): ACA requests adding a new subsection to Section 25606 that would allow those that do not meet the requirements of subsection (a) to still comply with the provisions of Sections 25602 and 25603.

Response: Based on this and other comments, OEHHA modified the occupational exposure warnings by adding subsection (b), which provides that if a listed chemical is not covered by subsection (a) warnings may be provided consistent with the safe harbor methods and content in Subarticle 2.

Section 25607 Specific Product, Chemical and Area Exposure Warnings

474. Comment (AHFA): AHFA requests once again that the second sentence of subsection 25607(a) be deleted or modified.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

475. Comment (CRN): Subsection 25607(b) is confusing and seems to suggest, as in subsection 25601(c), that a business has the burden of proving a warning is required. Subsection (b) is unnecessary and should be eliminated. Alternatively, it should be modified as suggested for Section 25601(c).

Response: This comment is not related to the modification of text.

476. Comment (ICC): With the anticipated expansion of additional tailored warnings into Section 25607, the regulatory subsection numbering would become unwieldy. A standard warning system would be better. OEHHA should simplify some of the requirements for better understanding and ease of utilizing the safe harbor warnings.

Response: This comment is not related to the modification of text.

Section 25607.1 Food Exposure Warnings – Methods of Transmission

Subsection 25607.1(a)

477. Comment (CRN): CRN appreciates the removal of type size and font size in subsection (a) and elsewhere throughout the regulation.

Response: Comment noted, no response required.

478. Comment (CRN): Modify subsection (a) to state, "…is provided using at least one of the following methods." OEHHA should explicitly state either in the regulation or the FSOR that a business has sole discretion to determine which warning method to use.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

Subsection 25607.1(b)

479. Comment (ABA): The requirement for an enclosed box as specified in subsection (b) remains problematic. It may confuse and mislead consumers by signaling a more significant or acute level of risk than is being presented by the exposure. Some consumers may think that other product information related to health, such as cooking or storage instructions, which are not enclosed in the box, is less significant than the Proposition 65 warning. OEHHA has provided no evidence or rationale to support the emphasis. Request removal of the in-box requirement.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

480. Comment (CRN): The words, "other labeling" should be included so the regulation continues to allow warnings in package inserts and related methods. The phrases, "set off from other surrounding information" and "enclosed in a box" are unnecessary and will likely cause alarm and confusion among consumers. USFDA reserves boxed warnings for medications with significant risk of serious or life-threatening effects and it is not warranted by Proposition 65 warnings. Dietary supplements and food products are subject to numerous product labeling requirements that address size and placement of information on labels. There is limited space available for a boxed warning. Using larger containers to accommodate product label adds to environmental wastes and additional, unnecessary costs. A warning is adequately conveyed without it being in a box.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

Subsection 25607.1(c)

481. Comment (CGA): It is not clear as to what "any consumer information about a specific food product" in subsection (c) means in terms of the warning translation requirement. It is not clear if a product promoted in association with a religious or ethnic holiday must provide a translated warning.

Response: The definition for “consumer information” in subsection 25600.1(c) limits the information to warnings, directions for use, ingredient lists, and nutritional information; and specifically excludes the brand name, product name, company name, location of manufacture, or product advertising. Based on this definition, information pertaining *only* to a religious or ethnic holiday would not fall under the definition of consumer information that would trigger the need for a warning in a language other than English to meet the requirements for a safe harbor warning.

482. Comment (CRN): Federal labeling requirements already address foreign language requirements for product labeling. For example, if any foreign language is on the label, all product information must be translated to that language. Even if OEHHA gives flexibility in the translation requirement, dietary supplement companies must follow federal labeling laws without exception. CRN requests to eliminate the foreign language requirement for food exposures until OEHHA conducts a thorough review of the relevant federal labeling requirements for dietary supplements and food products, identifies potential conflicts, and explains how the proposed regulations should be reconciled with the federal requirements.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations. It should be noted that warnings need not be provided directly on product labels. There are other methods available in the event that the safe harbor provisions conflict in some way with federal requirements.

483. Comment (CGA): There are challenges present for food product warnings if manufacturers can force retailers to use shelf tags. In some cases, multiple shelf tags are already in use for individual products. For example, separate shelf tags are required to identify items authorized for purchase under California's Special Supplemental Food Program for Women, Infants, and Children (WIC) program and those tags have specific requirements. Pricing and product quantity information must be present. In addition, some companies voluntarily include additional shelf labels to identify products that are gluten-free, diabetic-friendly or lower-sodium. CGA requests clarification regarding products that already have more than one shelf tag; which tag prevails in determining largest font size and where should the various tags be placed?

Response: Regarding the commenter's contention that manufacturers can "force" retailers to provide warnings on shelf tags, under subsection 25600.2(i), retailers can enter into an agreement with manufacturers regarding the type of warning materials being provided. In terms of the largest type size, OEHHA struck the type size requirements of Section 25607.1 and added subsection 25601(c), which provides that consumer product exposure warnings must be prominently displayed with such conspicuousness as compared with other words, statements, designs or devices on the label, labeling or sign as to render the warning likely to be read and understood by an ordinary individual under customary conditions of purchase or use. Both type size and placement of the warning would therefore be guided by whether the contemplated location would be conspicuous to the extent that the warning would be likely to be read and understood under customary conditions of use.

Section 25607.2 Food Exposure Warnings – Content

484. Comment (CRN): CRN requests the restoration of the original safe harbor language for food exposures that reflect the nature of dietary supplements and food products. The current safe harbor language "may contain" reflects variability of the presence and levels of certain chemicals found naturally in food products. The phrase, "consuming this product can expose you to..." is unnecessarily alarming and inconsistent with federal regulations. The proposed language will likely confuse consumers by elevating the level of risk of consuming products and presents a conflicting message about product safety. The current safe harbor language appropriately conveys the required information to consumers.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

485. Comment (ABA): Although the March 25, 2016 Notice states both subsections 25603(a)(2)(C) and 25607.2(a)(4) have been "modified to clarify situations in which a warning is required for multiple chemicals that each cause a different toxicity endpoint, subsection 25607.2(a)(4) remains unchanged. Request that it be modified.

Response: The commenter is correct that subsection 25607.2(a)(4) was unchanged in the March 2016 notice of modification of text. The suggested changes were made in the modification of text in May 2016.

486. Comment (ABA): The same concerns exist for food and beverage products as for other consumer goods in small packaging. There is limited available space, effectively eliminating the on-product warning option especially considering the foreign language requirement. Since OEHHA believes its shortened language "will provide useful information to individuals while avoiding unwieldy on-product warnings" (ISOR p. 29), ABA requests that new subsections (b) and (c) [as in Section 25603(b) and (c)] be added to Section 25607.2.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

Section 25607.5 Food and Non-Alcoholic Beverage Exposure Warnings for Restaurants – Methods of Transmission

487. Comment (CGA): Food offered for sale in restaurants is substantially similar to that offered in the grocery setting. The main difference is when the food will be consumed. There is no logical rationale to provide a different warning scheme for similar foods based on the business model alone. CGA objects to holding different food vendors to different standards. The warning method and content for restaurants are

equally appropriate and valid for the grocery setting. CGA requests that the regulations apply equally to all types of food vendors not just restaurants.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

488. Comment (CGA): Rather than mandating that restaurants provide individual food product warnings, a generalized signage has been the preference and requirement, with additional information available if the consumer wants it. There is no rational basis to treat the grocery setting differently than the restaurant setting. The proposed regulations provide numerous instances outside of the food setting where generalized warnings are deemed appropriate.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

489. Comment (CA Restaurant): Subsection (a) does not clearly apply to take-away, delivery or drive-thru services. CA Restaurant proposes that the phrase, "immediate consumption on or off premises" be added. The phrase is used in statute in HSC section 25249.7(k)(1)(B). OEHHA should harmonize the terms in regulation with the statute.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

490. Comment (CA Restaurant): Many food facilities have more than one public entrance, and some have no discernible entrances. It is not clear what constitutes "public". In line with the statute that warnings need not be provided separately to each individual, customers frequent many restaurants with great regularity and it seems unnecessary to have to provide a warning to every customer on every visit. CA Restaurant proposes to require that a sign be placed so it is readable and conspicuous to "most" customers and permit flexibility such that the sign is available either as they "enter the restaurant" or "before they place an order".

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

491. Comment (CA Restaurant): The regulations are unnecessarily restrictive with respect to the dimensions of the sign. Existing Proposition 65 signs are 10 x 10 inches and businesses should have the flexibility to provide either size, 8 1/2 x 11 inches or 10 x 10 inches.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

492. Comment (CA Restaurant): Subsection (a)(2) is unnecessarily burdensome. It is not clear what "each point of sale" means. CA Restaurant proposes allowing the sign to be placed on or adjacent to a counter where food is ordered as long as the sign is conspicuous and readable and based on the language in court-approved consent judgments filed by Attorney General.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

493. Comment (CA Restaurant): Subsection (b) creates uncertainty and litigation risk. OEHHA should limit the circumstances in which the use of other languages is required. Because of the range of cuisine popular throughout California, many restaurants use non-English words to communicate with customers who are primarily English speaking. Oftentimes restaurants identify menu items in foreign language and provide item descriptions in English. It would be unduly burdensome to require warnings to be provided in both languages. The requirement should be triggered by clearly defined criteria so restaurants have certainty they have complied and should not impose unnecessary burdens on restaurants that result in the littering of walls and menus with warnings in multiple languages when English is understood by most customers.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

Section 25607.6 Food and Non-Alcoholic Beverage Exposure Warnings for Restaurants – Content

494. Comment (Environmental Coalition): By referring to "certain foods and beverages sold or served here…" and giving examples "such as acrylamide…and mercury…" the warning will not provide sufficient specificity for consumers to determine which foods and beverages are subject to the warning. Similarly amusement park warnings will likely lead to general meaningless warning signs that do not allow consumers to make informed choices about exposure. A better approach would be to require warnings to identify each source and location affected, or at least the common characteristics of the sources that cause the exposure.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

Section 25607.7 Prescription Drug Exposure and Emergency Medical and Dental Care Exposure Warnings

495. Comment (Environmental Coalition): The existing regulation states, "…under federal law *and* the prescriber's accepted practice" while the proposed regulation states "…under federal law *or* the prescriber's accepted practice". OEHHA should retain the existing regulation and reinstate "and".

Response: This comment is not related to the modification of text.

Sections 25607.8 and 25607.9 Dental Care Exposure Warnings – Methods of Transmission and Content

496. Comment (CDA): Support the language provided in the dental care exposure warnings.

Response: Comment noted, no response required.

Section 25607.13 Furniture Product Exposure Warnings – Content

497. Comment (Mateel): Subsection 25607.13(a)(2) does not conform to the information content requirements for warnings under the Act. It fails to require that furniture warnings provide each chemical name and route of exposure sufficient for an about-to-be-exposed person to make an informed decision about whether or how to avoid exposure. Such information is critical as noted by OEHHA for a public enforcer to make a decision about whether to prosecute a violation and is equally critical for an about-to-be-exposed person to make an informed decision.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

Section 25607.15 Diesel Engine Exposure Warnings (Except Passenger Vehicle Engines) – Content

498. Comment (Auto Alliance et al.): Warnings must now include the statement, "do not idle the engine except as necessary," which exceeds the authority under the statute that only requires warnings for certain exposures to listed chemicals. The statement goes beyond a warning, it urges an action. The commenters request that OEHHA not include this or any other additional text in the label.

Response: The phrase “do not idle the engine except as necessary” was added to provide an additional caution for a person to minimize exposure to diesel engine exhaust and is consistent with the advice given in other warnings to help people

minimize exposure to exhaust. No change to the regulation was made based on this comment.

Section 25607.16 Vehicle Exposure Warnings – Methods of Transmission

499. Comment (Auto Alliance et al.): The definition for “passenger vehicle” is overly broad and can create significant uncertainty as responsible parties work to identify appropriate warnings for appropriate vehicles. Subsection (a) should be amended to include in addition to passenger cars, light-duty trucks, medium-duty vehicles and heavy-duty vehicles. Separate categories could lead to different labels on different types of vehicles making it confusing for consumers and difficult for manufacturers to comply.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

500. Comment (Auto Alliance et al.): By requiring warnings both in the owner's manual and driver's window, there would be two warnings for one product. OEHHA should provide flexibility by requiring either method by changing "and" to "or". Also ensure that the requirements do not limit the owner's manual to a printed version. In some cases, the owner’s manual is in electronic format. Therefore, it should not explicitly use "printed" or "print" in regulation. Alternatively, clarify in the FSOR that both printed and electronic versions are allowed.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

501. Comment (Auto Alliance et al.): Recommend a modification to subsection (a)(2) as follows: "…or off-road vehicle, in on smaller than 8-point type…"

Response: This issue is addressed in responses to similar comments received during the first comment period for the regulations.

Section 25607.17 Vehicle Exposure Warnings – Content

502. Comment (AASA): If OEHHA does not provide a replacement part exemption, AASA urges OEHHA to include language for replacement parts in the vehicle-specific warning language in subsection 25607.17(a) as follows: "…off-road vehicle, and use of replacement parts for vehicles" and in subsection 25607.17(a)(3) as follows: "…can expose you to chemicals from the vehicle and/or replacement parts such as..." OEHHA should include the recommended language as it would provide a much more practical way to provide a warning to consumers servicing their own vehicles rather than provide individual warnings for every replacement part.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period.

503. Comment (Auto Alliance et al.): Replacement parts often contain the same Proposition 65 chemicals as in an original part, which is covered by the existing vehicle warning label. Warnings provided to consumers via print or electronic means should warn that parts for servicing or maintaining their vehicles could cause exposures. Request a revision as follows: "(a)...or off-road vehicle, and use of replacement parts for vehicles..." and "(a)(3)...expose you to chemicals from the vehicle and/or replacement parts such as..." Alternatively, OEHHA should provide further clarification in the FSOR.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period.

504. Comment (ACC): ACC objects to the inclusion of specific chemical references in the warnings, such as carbon monoxide, phthalates and lead in Sections 25607.17 and 25607.19. "Phthalates" is not on the Proposition 65 list and as a generic truncated category it is over inclusive. It is factually inaccurate and misleading and should be removed.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

Section 25607.18 Recreational Vessel Exposure Warnings – Method of Transmission

505. Comment (NMMA): Subsection 25601(d) enables any consumer product warning to be displayed on or with the product as long as it meets the requirements outlined in subsection 25600.1(j), the definition for “labeling”. As such, subsection 25607.18(a)(1) should be amended to better reflect the multitude of display options.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period.

506. Comment (NMMA): The tailored warning for recreational vessels limits the manufacturer to only three locations for a warning label in an owner's manual, contradicting the definition of "label" and "labeling" in Section 25600.1 and the label requirements in Section 25602. In Sections 25600.1 and 25602 the manufacturer should have the flexibility to include a warning label in the owner's manual in any location, as an insert or as an addendum included in the owner's manual package. Subsection 25607.18(a)(1) requires the manufacturer to either produce a California specific owner's manual or change the universal owner's manual to comply with Proposition 65 at the expense of other needed language. NMMA requests that Section

25607.18 be amended to include "…in any appropriate warning section of the manual or as an insert included with the owner's manual, and;"

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period.

Section 25607.23 Amusement Park Exposure Warnings – Content

507. Comment (CAPA): The term, "exposure source" is ambiguous. It is difficult to implement and impossible to use in a way that will avoid lawsuits that claim the true source of exposure was not named. The requirement to name the exposure source creates enormous litigation opportunities. The requirement is inconsistent with the more than two years' effort of work on updating regulations. It imposes a confusing burden on amusement parks, subjects them to increased litigation, and is legally invalid because of the adoption process OEHHA is required to follow for adopting regulations. The two-year effort arrived at the decision to require businesses to provide a warning designed to attract attention and supplement the warning with OEHHA's Proposition 65 warning website.

Response: Subsequent to this comment, OEHHA modified the amusement park exposure warning content in Section 25607.23 to address exposure scenarios unique to amusement parks. The modified text reads, "Some areas or features in this amusement park can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer or birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/amusement-parks." In its June 6, 2016 comments, the commenter noted that the addition of the phrase "some areas or features" and the deletion of the phrase "name of one or more exposure source(s)" addresses the concerns voiced by the commenter.

508. Comment (Mateel): Section 25607.23 does not conform to the information content requirements for warnings under the Act. The amusement park exposure warning must identify sources and locations of all exposures for which warning pertains. The location of multiple sources of exposure need not be specified in a warning if the identifying, common characteristics of each type of exposure are stated in the warning. Such a warning must be provided in a manner sufficient to distinguish locations or sources to which no warning pertains. An amusement park exposure warning should also specify each listed chemical and the relevant route by which exposure occurs. OEHHA has noted that such information is critical to informed decision-making.

Response: OEHHA disagrees with the commenter that Proposition 65 requires amusement park warnings to name every exposure source and chemical. The statute is silent on whether a clear and reasonable warning should include chemical names and

exposure sources. The statute does empower the lead agency to promulgate regulations that implement and further the purpose of the Act.

As the lead agency tasked with adopting regulations that implement and further the purposes of the Act, OEHHA has determined that providing information regarding the identity of chemicals and routes of exposure is consistent with the Act and an important component of the "safe harbor" warnings that represent OEHHA's interpretation of what constitutes a "clear and reasonable" warning under the Act. OEHHA believes that the safe harbor warning methods and content proposed in this rulemaking will increase information provided in warnings as well as the meaningfulness or warnings provided to a person before exposure to a listed chemical. Requiring the name of every listed chemical in a warning, however, in many cases will not be practical for businesses providing warnings under the Act. OEHHA has modified the amusement park safe harbor warnings to require the name of one or more chemicals a person can be exposed to in the amusement park. The supplemental information on the OEHHA website will provide additional information regarding the listed chemicals that a person can be exposed to under various exposure scenarios. OEHHA believes that these changes are consistent with a person's right-to-know about exposures to listed chemicals and are a correct interpretation and application of the expressed intent of the California voters who passed Proposition 65.

Although Section 25607.23 does not require every source of exposure to be identified, Section 25607.22 requires warnings for exposures to chemicals in consumer products, alcoholic beverages, food, and enclosed parking facilities where such exposures occur on the premises of the amusement park. The OEHHA Proposition 65 warnings website will contain supplemental information regarding exposures that can occur at an amusement park.

Section 25607.24 Petroleum Products Warnings (Environmental Exposures) – Methods of Transmission

509. Comment (WSPA): The foreign language requirement provisions in subsection (b) are fraught with ambiguity.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

Section 25607.25 Petroleum Products Warnings (Environmental Exposures) – Content

510. Comment (ILMA): Both Sections 25607.24 and 25607.25 are misleading to workers and counter to the intent of Proposition 65 warnings. Subsection

25607.25(a)(3) is inappropriate in industrial operations where refined petroleum products are used because there is no crude oil in industrial facilities. Almost without exception, highly-refined petroleum oils used in machining and grinding applications do not contain any toluene or benzene. Therefore, employees in general manufacturing shops would be over-warned because they are warned of toluene and benzene that are absent and are likely not warned of other chemicals unless the employer voluntarily does so.

Response: This comment is not related to the modification of text. It should be noted that Section 25606 applies to occupational exposures.

Miscellaneous or General Comments

511. Comment (CH&LA): Plaintiffs typically equate 'presence' of a chemical equivalent to 'exposure' requiring a warning. To the extent that it can be mitigated by the proposed regulations, that would be a significant improvement.

Response: This comment is not related to the modification of text.

512. Comment (CH&LA): CH&LA requests that OEHHA convey in the FSOR that exposure to a consumer product other than food or alcohol that is present at a facility but not being sold by that facility should be considered an environmental exposure and not a consumer product exposure.

Response: This comment is not related to the modification of text. OEHHA is considering an informal request for the development of a “tailored warning” pursuant to Section 25607, *et seq.* for exposures to listed chemicals in hotels and apartments.

513. Comment (Environmental Coalition): The Coalition is disappointed by OEHHA's presentation of these modifications without an analysis or statement of reasons asserting that the modifications are “real, substantive changes”. The Administrative Procedure Act requires an agency to publish an Initial Statement of Reasons along with a proposed regulation detailing the proposal’s purpose, rationale, and intended benefits citing Gov. Code section 11346.2(b).) The Coalition opines that these revisions substantially change the proposed regulations, thereby invalidating the Initial Statement of Reasons (“ISOR”) published on November 27, 2015. OEHHA should revise it to explain the new changes.

Response: When considering each modification of text, OEHHA closely considers the Administrative Procedure Act requirements and whether the changes are properly submitted to the public as a modification of text or as a new rulemaking.

In the Notice of Proposed Rulemaking published on November 27, 2015 OEHHA stated that:

> "These new regulations would further the "right-to-know" purposes of the statute and provide more specific guidance on the content of safe harbor warnings for a variety of exposure situations, and corresponding methods for providing those warnings."

OEHHA further expressed its intent in proposing the changes to Article 6:

> "In proposing this regulatory action, OEHHA intends to address many of the issues that have surfaced since the original regulation was adopted in 1988 by clarifying the relative responsibilities of manufacturers and others in the chain of distribution for providing warnings for products that are eventually sold at retail. The proposed regulations would also make needed changes to the current requirements for a "safe harbor" warning by integrating new technology, providing more useful information to Californians about their exposures to listed chemicals and by providing more compliance assistance for affected businesses, thereby furthering the purposes of the Act [emphasis added]."

Finally, OEHHA noted the following benefits to the people of California:

> "The proposed regulation will benefit the health and welfare of California residents and improve worker safety by providing more information to the public and facilitating businesses' compliance with the Act. More informative warnings will further the purposes of Proposition 65 by helping the public to make informed decisions regarding the products they choose to purchase and the places they frequent based on information about their exposures to chemicals that cause cancer or reproductive effects."

Because of this, OEHHA has determined that the public was put on notice of the types of modifications OEHHA was considering, and the modifications of text are consistent and "sufficiently related" to the Notice of Proposed Rulemaking.

OEHHA fully complied with Government Code section 11346.8(c) as the modifications were sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action. OEHHA published a Notice of Modification of Text in the California Regulatory Notice Register and posted the Notice of Modification of Text and the full text of the resulting adoption with clearly indicated changes on the OEHHA website available. The notices were available to the public for a 15-day comment period and OEHHA is responding to those written comments in this FSOR, as required by the Administrative Procedure Act.

514. Comment (Environmental Coalition): With respect to the prohibition on contradicting the warning, OEHHA states it was deleted "based on stakeholder comments". Environmental Coalition advocated for keeping the prohibition and the public deserves to know why OEHHA ignored their suggestion and adopted industry's instead.

Response: Some stakeholders commented that prohibiting what businesses may say in their warning might raise issues relating to the First Amendment. OEHHA felt there was merit to a stakeholder suggestion to modify the regulation to say that the only supplemental information that could be incorporated into a safe harbor warning for consumer products would be the source of the exposure and ways to reduce or avoid the exposure. OEHHA believes such information is consistent with a clear and reasonable warning. Businesses are allowed to provide other kinds of supplemental information as long as the resulting warning meets the overall statutory requirement for a clear and reasonable warning. However, such warnings would not qualify for safe harbor protection against legal challenges that the warning is not clear and reasonable.

515. Comment (Auto Alliance et al.): Under the current proposal, since exposure information is not readily available manufacturers must resort to labeling products even if the chemical does not pose a significant risk. Over-labeling will confuse consumers. The commenters recommend that OEHHA establish a de minimis percent-by-weight level for Proposition 65 chemicals. Establishing de minimis levels will allow the automotive sector to use existing resources to expedite implementation and allow consumers to distinguish between small or insignificant risks from those that potentially pose a threat to human health and environment.

Response: This comment is not related to the modification of text and is beyond the scope of this rulemaking. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

516. Comment (Auto Alliance et al.): The commenters appreciate that OEHHA addressed some previous concerns about changing "purchaser" to "consumer" to provide clarity in a number of areas of nomenclature and clarifying the vehicle repair requirements.

Response: Comment noted, no response required.

517. Comment (ABA, Auto Alliance et al., and ILMA): The commenters support the comments submitted by CalChamber.

Response: Comment noted, no response required.

518. Comment (ABA): Including the name of one or more chemicals makes the warning cumbersome, lengthy and potentially unmanageable for some products. However, ABA appreciates the clarification that generally a warning need only identify one chemical even if the product contains multiple chemicals.

Response: These issues are addressed in responses to similar comments received during the first comment period for the regulations.

UC Davis Warnings Study

519. Comment (ACC): ACC previously submitted a review evaluating OEHHA's UC Davis Study and it appears OEHHA did not read or consider the review. OEHHA has no factual or legal basis to support the conclusion that the proposed regulation is "effective" at all or "more" effective than something else. ACC urges OEHHA to make significant additional modifications with an additional opportunity for public comment or withdraw the regulation in full.

Response: After reviewing the comment letter and attached study, OEHHA asked the UC Davis Extension Collaboration Center to also review the ACC-commissioned review. OEHHA overall concurs with the following response of the UC Davis Extension Collaboration Center, which concluded that the review of the UC Davis study mischaracterized the purpose of the study and is largely irrelevant:

> "The purpose of the Study was to assess people's opinions of the helpfulness of the current and proposed Proposition 65 warnings in California. The Study uses the term 'effective.' The term effective is defined as having an intended effect. In this case, the intended effect is to identify the warning that is perceived as most helpful. Effectiveness was defined this way, as helpfulness, on Page 7 of the report. In contrast, the Assessment defined effective as changing behavior. As such, the Assessment concludes that the Study's research question is 'a question of behavioral responses and not a question of mere opinion.' Viewed this way, the Assessment described the Study as a 'public health intervention' that requires a randomized-controlled trial to evaluate its effectiveness. We agree that if the goal of the study was to study behavioral change, several of the Assessment's criticisms would be relevant. However, when viewed as intended, as a study of the relative helpfulness of the current and proposed warnings, several of the criticisms in the Assessment are no longer relevant." [54]

Modifying safe harbor warning content is a key part of OEHHA's objective to increase the likelihood that a person will see, read and understand a warning prior to exposure to a listed chemical. To that end, OEHHA commissioned a study of the effectiveness of proposed safe harbor warnings, not the extent to which a proposed warning would effectuate behavioral change. The issue of behavioral change, while important, was not the focus of the study and OEHHA believes that a study focusing primarily on behavioral change is misleading and irrelevant. No changes were made based on this comment.

[54] "ACC/Evolving Strategies LLC's Assessment of the Proposition 65 Study", Memorandum from Kali Trzesniewski, Ph.D., University of California Davis Extension Collaboration Center to Carol J. Monahan Cummings, Chief Counsel, Office of Environmental Health Hazard Assessment, May 25, 2016.

520. Comment (ACC): The rulemaking record now makes it clear OEHHA cannot achieve its goal of making Proposition 65 warnings more "effective". Proposition 65 is not legislatively designed to support an effective warning system for consumer products. A legislative defect cannot be remedied with the good intentions of the executive branch and regulatory action. Experts in the field are clear that the need for a warning and the design of its content are a function of the severity of hazard and the likelihood the hazard will materialize. The statute only speaks to hazard. Proposition 65 is completely misaligned with the science of warnings and risk communication. The foundation cannot be improved or fixed by regulation, statutory changes are needed.

Response: This comment is not related to the modification of text addresses issues and is beyond the scope of the rulemaking.

General and Procedural Comments

521. Comment (CalChamber, ACA, and CRN): Given the significant issues remaining to be resolved, OEHHA should modify the current proposal and release a revised draft and revised statement of reasons for an additional round of public comment. ACA and CRN support CalChamber's recommendation.

Response: After reviewing the comments on the modification of text published on March 25, 2016, OEHHA made revisions to the proposed regulatory text that were included in a second modification of text published in the California Regulatory Notice Register on May 20, 2016. It was not necessary for OEHHA to issue a revised statement of reasons. The Notice of Proposed Rulemaking published on November 27, 2015 stated that:

> "These new regulations would further the "right-to-know" purposes of the statute and *provide more specific guidance on the content of safe harbor warnings for a variety of exposure situations, and corresponding methods for providing those warnings* [emphasis added]."

OEHHA further expressed its intent in proposing the changes to Article 6:

> "In proposing this regulatory action, OEHHA intends to address many of the issues that have surfaced since the original regulation was adopted in 1988 by clarifying the relative responsibilities of manufacturers and others in the chain of distribution for providing warnings for products that are eventually sold at retail. The proposed regulations would also make needed changes to the current requirements for a "safe harbor" warning by integrating new technology, *providing more useful information to Californians about their exposures to listed chemicals* and by providing more compliance assistance for affected businesses, thereby furthering the purposes of the Act [emphasis added]."

Finally, OEHHA noted the following benefits to the people of California:

> "The proposed regulation will benefit the health and welfare of California residents and improve worker safety *by providing more information to the public and facilitating businesses' compliance with the Act. More informative warnings will further the purposes of Proposition 65 by helping the public to make informed decisions regarding the products they choose to purchase and the places they frequent based on information about their exposures to chemicals that cause cancer or reproductive effects* [emphasis added]." Specifically OEHHA cited the following benefits:

Because of this OEHHA has determined that the public was put on notice of the types of modifications OEHHA was considering and the changes made were consistent with the Notice of Proposed Rulemaking. OEHHA additionally made several changes that addressed most of the concerns from the commenters. OEHHA has determined that the outstanding items potentially requiring modifications to the regulatory text have been addressed and has decided that no further rounds of additional comment are required for this rulemaking.

522. Comment (CCEEB, AHAM): The commenters endorse CalChamber's comments. The latest proposal is unworkable. It is suggested that this is a final proposal. This is concerning because there are new regulatory concepts that have not been discussed or vetted until now. The changes will result in compliance challenges, increased consumer confusion and increased litigation, contrary to the Governor's reform goals.

Response: As noted above in the response to CalChamber's comments, these changes are consistent with the established purpose and intent of the current rulemaking and could have been reasonably anticipated. Several modifications were made to the regulatory text subsequent to these comments; no additional changes have been made based on this comment.

523. Comment (AHAM): Far more information is available today than when Proposition 65 was enacted. Information overload, information in multiple places, and differing labels can be counter-productive and lead to poor decision making. Over-warning is counterproductive and can result in 'warning fatigue' and undermine the effectiveness of a Proposition 65 warning. The California Supreme Court recognized that over-warning dilutes the force of warning and is counterproductive (*Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910, 931-32 (Cal 2004).

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

524. Comment (CAPA): These modifications require a 45-day notice. The change to require the name of the exposure source is substantial and is not sufficiently related to the regulation noticed on November 27, 2015 to place anyone on notice that it could be

added and is contrary to Government Code section 11346.8. It was made explicit in the website regulations that OEHHA would provide exposure information on its website, eliminating any thought that businesses would have to add exposure source to warning. Request that the requirement to name one or more exposure sources in the warning regulation be struck.

Response: As noted in the response to comments from CalChamber above, OEHHA has fully complied with Government Code section 11346.8(c) as the modifications of text for this comment period were sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action. OEHHA published a Notice of Modification of Text in the California Regulatory Notice Register and posted the Notice of Modification of Text and the full text of the resulting adoption with clearly indicated changes on the OEHHA website available to the public for a 15-day comment period. OEHHA is responding to written comments from this comment period in this FSOR.

Subsequent to this comment, OEHHA modified the regulatory text for the amusement park warnings by striking the proposed phrase “Name of one more exposure source(s)” and replacing it with “Some areas or features”. This modification addresses the concerns stated by the commenter.

525. Comment (CAPA): In its January 2016 comments, CAPA expressed acceptance of the amusement park warning regulations and asked only that OEHHA confirm in the FSOR and regulation that only one chemical had to be named in the warning to be compliant. Instead OEHHA made two significant changes to the amusement park regulation that makes it unworkable and questions its legality. The two changes were made without notice to amusement park industry.

Response: OEHHA has modified the amusement park warning content in Section 25607.23 by striking “name of one exposure source” and replacing the phrase with “Some areas or features”. These modifications addressed the concerns expressed by the commenter.

526. Comment (PCBP): The regulations deviate from clarity and consistency and the Office of Administrative Law (OAL) can disapprove the regulation. Substantial changes were also made and affected parties did not have time for an industry-wide analysis and response. PCBP requests a longer time now or a follow-up comment period after further changes are made in response to the current comments.

Response: Several changes were made to the regulation for clarity and consistency during the May 2016 comment period for the second modification of text. As noted in the response to comments from CalChamber above, OEHHA has fully complied with Government Code section 11346.8(c) as the modifications of text for this comment period were sufficiently related to the original text that the public was adequately placed

on notice that the change could result from the originally proposed regulatory action. OEHHA published a Notice of Modification of Text in the California Regulatory Notice Register and posted the Notice of Modification of Text and the full text of the resulting adoption with clearly indicated changes on the OEHHA website available to the public for a 15-day comment period. OEHHA is responding to written comments from this comment period in this FSOR.

527. Comment (CAPA): Proposition 65 requires a business to give a warning before exposing a person to a listed chemical except under certain circumstances. A business is not prohibited from giving a warning even if it is not required. The proposed regulation converts a warning to an admission that a warning is required. At present, a business can assert its warning is clear and reasonable and that it had no obligation to provide any warning because exposure was below the NSRL or MADL. Under this proposal, the latter defense is precluded.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations.

528. Comment (CGA): CGA strongly cautions OEHHA to give deference to its own comments related to the emergency regulations adopted for bisphenol A (BPA) in canned food warnings that, "Placing point-of-display signs throughout a facility at each location where an affected product is displayed would be unworkable given the number of products affected." The statement was correct as it related to BPA warnings and even more so when multiplied across the thousands of products under the proposed regulation that would require individual point-of-display warnings.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period for the regulations. Point of display signs are just one option among others for providing warnings for consumer products including foods. The situation presented by bisphenol A is unique and has been addressed in a separate rulemaking action.

529. Comment (Mateel): Comparable standards of specificity and usefulness must apply to warning notices given by businesses to exposed individuals as it applies to notices from private enforcers to businesses before bringing an enforcement action.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period.

530. Comment (Mateel): As with a Notice of Violation, a warning must disclose all relevant routes of exposure. The standards for safe harbor warnings should require that a business identify the routes of exposure involved because a human body's ability to absorb different chemicals varies by the route of exposure. Route is important

information that an exposed-person needs to evaluate exposure intelligently to decide whether or how to avoid exposure.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period

531. Comment (Mateel): As with a Notice of Violation, a warning must identify the product or service that causes the exposure. Warnings are insufficient if they do not allow the person to distinguish between those product brands or models that cause exposure to listed chemicals and those that do not. To provide a compliant warning, one must include some description of the specific product, service, area or feature that causes exposure.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period.

532. Comment (Mateel): The warning provision of HSC section 25249.6 has an identical goal to how OEHHA interprets the Notice of Violation provisions of HSC section 25249.7. A business must provide sufficient notice of exposure to allow the person to be exposed to intelligently evaluate the potential exposure and avoid exposure if the person chooses. Proposition 65 intends that warnings facilitate informed decision-making about whether and how citizens protect themselves from exposure to listed chemicals. Information on content requirements set by the safe harbor warning regulations must provide notice of an exposure at least as useful to a potentially-exposed citizen as the Notice of Violation is required to be given to a business.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period.

533. Comment (Mateel): Mateel hired an expert to design, supervise and evaluate the survey of consumer memory and understanding of warnings provided at Disneyland. A copy of the survey and results were provided (300+ pages). The survey findings suggest that for a warning to be effective, it must be a relatively tight nexus between the warning, the source of exposure, and the information about how a person can be exposed.

Response: This comment is not related to the modification of text. OEHHA agrees there should be a nexus between the warning, source of exposure, and information about how a person can be exposed. Modifications made to the provisions for environmental exposure warnings are intended to strengthen the nexus in the warning between the source of the exposure and the chemical or chemicals involved.

534. Comment (NAIMA): OEHHA believes that the message is helping and protecting a consumer yet has never conducted any consumer research to determine if the new safe harbor language and graphics will have a significant benefit to consumers. There

is no consumer perception research that substantiates that consumers understand these warnings in a meaningful way. However there is evidence that the unintended consequence of warning labels is misperception and confusion. [NAIMA provided a link to an inoperative URL [http://oehha.ca.gov/prop65/public_meetings/pdf/MacInnis _Dart2.pdf; the referenced presentation is located on the OEHHA website at http://oehha.ca.gov/media/downloads/proposition-65/comment/macinnisdart2.pdf. "A Consumer Perspective on Warning Labels: Misconception and Confusion as Unintended Consequences of Warning Labels" by Deborah J. MacInnis, Ph.D., December 10, 2007 DART Meeting.] Urge OEHHA to document through consumer research that the current and amended warning system does not create confusion among consumers.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period. As discussed in earlier responses, UC Davis Extension Collaboration Center conducted a public survey for OEHHA of the current and proposed safe-harbor warnings. The survey found that 75 percent found the proposed safe harbor warnings to be more helpful.

535. Comment (WSPA): WSPA incorporates its April 2015 and June 2014 comments by reference.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period.

536. Comment (AASA): According to subsection 25600(b) a product manufactured prior to the effective date is in compliance as long as the warning complies with the September 2008 revision of article. However, as previously explained in their January 2016 comments, replacement parts must be available for several years and have extremely long shelf life. It is important for manufacturers, distributors, wholesalers, and retailers of replacement parts to avoid increased liability risks due to these regulatory changes. Request an exemption for replacement parts.

Response: This comment is not related to the modification of text. These issues are addressed in responses to similar comments received during the first comment period.

537. Comment (AASA): AASA supports the comments submitted by Auto Alliance et al.

Response: Comment noted, no response required.

538. Comment (Wine et al.): The commenters commend OEHHA for its "open door" and "listening ear" in considering substantive points made by stakeholders.

Response: Comment noted, no response required.

539. Comment (CH&LA): OEHHA agreed in a meeting that individually hotels and apartments should have their own safe harbor warning language for public entrance warnings to cover the majority of potential exposures that may be encountered, subject to the carve outs for alcohol, food and garages. CH&LA is hopeful that if OEHHA extends the current comment period past April 11, 2016 that these provisions can be included in regulatory text. The current proposal is impossible for hotels to comply with. It makes no sense, and would result in the posting of hundreds of thousands of warning signs and would be extremely expensive.

Response: OEHHA is considering an informal request for the development of a "tailored warning" pursuant to Section 25607, *et seq.* for exposures to listed chemicals in hotels and apartments, that will more specifically address the issues raised in this comment.

540. Comment (CH&LA): OEHHA informed CH&LA that procedurally there is insufficient time to insert a hotel-specific safe harbor warning. CH&LA states that OEHHA expects to finalize the proposed regulation and then address a hotel-specific warning before the two-year delayed effective date in Section 25600(b).

Response: This comment is not related to the modification of text. OEHHA is considering an informal request for the development of a "tailored warning" pursuant to Section 25607, *et seq.* for exposures to listed chemicals in hotels and apartments, that will more specifically address the issues raised in this comment.

Summary and response to comments on the May 2016 proposed regulations

OEHHA further modified the text of the proposed regulations based on comments received on the modified text published on March 25, 2016. A number of clarifying changes were made to the text of the regulations, most of which are non-substantive. All changes were highlighted in the text of the regulations.

The most significant changes are summarized below:

- In Section 25600(e) the term "fully" was removed. This provision is intended to be a statement of current law. Specifically, if a party to a court-ordered settlement or judgement complies with the order requiring a particular method or content for a warning, the warnings provided are clear and reasonable as a matter of law. Commenters asked that OEHHA clarify its intent that this provision is not intended to provide a new avenue for enforcement of the law through this provision.
- Section 25600(f) was moved from Section 25601(b) and slightly modified to clarify that businesses are free to provide a warning that is different from the safe harbor methods and content specified in Subarticle 2 as long as the warning complies with Section 25249.6 of the Act.
- Section 25600.1(c) was revised by removing the phrase, "but is not limited to" and adding the words, "company name, location of manufacture" as additional exceptions to the definition of "consumer information".
- In Section 25600.1(e) the word "consumer" was added to clarify the type of product intended to be included.
- In response to several comments, section 25600.1(f) was revised to delete the words "medium, including but not limited to", add the term "source, such as", and add the phrase "or objects", to better clarify the sources of exposure that should be identified in an environmental exposure warning.
- In Section 25600.2(a) the phrase, "to the extent practicable" was added to parallel the statutory requirement concerning adopting regulations concerning clear and reasonable warnings.
- Section 25601(b) (formerly numbered as subsection (c)) was revised to remove, "for which the person has determined a warning is required" and replaced with, "in the consumer product or affected area for which the warning is being provided" to clarify that the regulation does not impose any new testing or burden of proof requirements for a business. This regulation only applies where a business has already decided to provide a warning; it does not determine when a warning is required.
- Sections 25602(d) and 25607.1(c) were revised to better clarify the circumstances under which a warning must be provided in a language other than English.

- Based on several comments, clarifying changes were made for consistency throughout the regulation to terms that were being used inconsistently including "label", "warning labels", "warning materials" and "warning information".
- The uniform resource locators (URLs) for the general warning content were shortened to "WWW.P65Warnings.ca.gov" for simplicity and consistency with the existing structure of the warnings website.
- In Section 25603(a)(2) and throughout the regulations the term, "such as" was replaced with "including" for the warning content in response to comments suggesting the word is more clear.
- Section 25603(a)(2)(E) was added to allow a business to provide a consumer product warning for a single chemical exposure, by allowing the business to delete the words "chemicals including" from the safe harbor warning content.
- Section 25604(a) was revised to ensure consistency in the format, structure and requirements for environmental warnings.
- Section 25605(a) was revised for readability and clarity. An example of the text of a compliant warning is as follows:

> ⚠**WARNING**: Entering this area can expose you to chemicals known to the State of California to cause cancer, including asbestos, from construction debris. For more information go to www.P65Warnings.ca.gov.

- Section 25605(a) was modified to allow a business to provide an environmental warning for a single chemical exposure.
- Section 25606(b) was added to clarify that occupational exposure warnings for chemicals that are not covered under subsection (a) can be provided using the methods and content requirements set out in the regulations for consumer product or environmental exposures.
- Section 25607.2(a)(4) was revised for consistency with the other consumer product warnings.
- Section 25607.2(a)(6) was added to allow a business to provide a food product warning for a single chemical exposure, by allowing the business to delete the words "chemicals including" from the safe harbor warning content.
- Section 25607.23(a)(3) the warning content for the amusement park tailored warning was revised to replace "[Name of one or more exposure source(s)]" with "Some areas or features" in consideration of the unique characteristics of environmental exposure scenarios in amusement parks. OEHHA intends to develop more information for its website concerning the most common sources of exposures, the chemicals that are likely to be present at amusement parks, and ways patrons can reduce or avoid exposures in order to supplement this warning, just as OEHHA plans to provide more detailed website information for all of the tailored warnings.

The following organizations submitted comments on the modifications of text during this comment period (May 20, 2016 to June 6, 2016):

- Alliance of Automobile Manufacturers, Association of Global Automakers, Inc., and Motor & Equipment Manufacturers Association (Auto Alliance, et al.)
- American Chemistry Council (ACC)
- American Coatings Association (ACA)
- Asian Food Trade Association (AFTA)
- Automotive Aftermarket Suppliers Association (AASA)
- California Chamber of Commerce Coalition (CalChamber)
- California Attractions and Parks Association (CAPA)
- California Hotel & Lodging Association and California Association of Boutique and Breakfast Inns (CH&LA)
- Council for Responsible Nutrition (CRN)
- Flavor and Extract Manufacturers Association (FEMA)
- Frozen Potato Products Institute (FPPI)
- Intercontinental Chemical Corporation (ICC)
- National Marine Manufacturers Association (NMMA)
- Lucas Novak (LNovak)
- Nutraceutical Corporation (NC)
- Rubber Manufacturers Association (RMA)
- Schoenfeld Consulting (SC)

Section 25600 General

Subsection 25600(b)

541. Comment (ACA): Subsection 25600(b) states that the sell-through period applies to "consumer products." In light of OEHHA's new, narrow definition of "consumer products," the effectiveness of this sell-through provision has been limited because an entire class of products will not be allowed to utilize the sell-through period. ACA recommends that OEHHA make it clear in the FSOR that the sell-through period applies to all products and not only consumer products.

Response: This comment is not related to the modification of text. OEHHA agrees that the sell through period is intended to cover warnings for all types of product exposures.

542. Comment (Auto Alliance et al.): The commenters request to extend the implementation period an additional third year because any change to existing owner's manuals or labeling requires time for notification, redesign of materials, and application of any changes. A model year approach is also necessary for these same reasons. A three-year transition period will better align with engineering cycles and model change overs in the industry.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

543. Comment (CalChamber): The phrase, "such warning will be deemed to be clear and reasonable" in subsection (b) requires clarification. The FSOR must clarify that the provision allowing for compliance with the new regulations prior to the effective date

pertains to the proposed warning content, methods of transmission, and to the provisions pertaining to retailers in proposed Section 25600.2. CalChamber suggests an amendment to subsection (b) to provide a two-year deferral of the effective date during which businesses will have the option of using either (1) the old safe harbor warning content and methods pursuant to the September 2008 revisions, (2) the newly adopted safe harbor warning content and methods pursuant to the newly proposed regulations, or (3) alternative warnings that comply with either the requirements specified in Section 25601 of the current regulations or subsection 25600(f) of the new regulations.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

Section 25600.1 Definitions

544. Comment (CH&LA): Amend the definitions for “affected area” and “consumer product” since the terms remain vague and unclear and will lead to continued and increased frivolous litigation.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

545. Comment (FEMA): Food ingredients not sold to the public should not be directly subject to Proposition 65 warning requirement. Food ingredients sellers do not know: what products their ingredients are used in, how much of their ingredient is used in a particular final product, or how much of or how often a particular food is consumed. Therefore, food ingredient sellers are not in a position to analyze whether a warning is required. FEMA requests that the phrase “or component part thereof” be removed from definition of “consumer product”. No public comment has been identified that requests that "consumer product" be defined to include all of the separate component parts of consumer products. OEHHA was asked whether any such comment was submitted, and OEHHA has not identified one. The modifications were proposed with no ISOR and were not signaled by the November 2015 notice of the Article 6 amendments, therefore it violates the APA including Government Code section 11346.8.

Response: This comment is not related to the modification of text. This comment, including the portion alleging the violation of the APA, was responded to in a substantively similar comment from the same commenter during the second comment period.

Section 25600.2 Responsibility to Provide Consumer Product Exposure Warnings

546. Comment (ACA): OEHHA does not have the authority to require warnings on the internet or in catalogs for products sold online or in catalogs when the product already contains an on-product warning. If OEHHA intends to retain internet and catalog warning requirements for products, it must clearly state what is required to provide adequate notice to retail sellers and what retail sellers' responsibilities are in terms of posting warnings for products sold online and in catalogs once they have received notice. In the March 2016 proposal, OEHHA was clear that once a company affixes a label to the product bearing a compliant Prop 65 warning, then companies have satisfied their responsibility under Article 6 and the responsibility to post the Proposition 65 warning language on the internet when the product is sold online falls on the retail seller. While that language remains in this new draft, OEHHA has made changes in this new draft to subsection 25600.2(e)(4) that may be interpreted as conflicting with the text in subsection 25600.2(b). Subsection 25600.2(b) indicates that manufacturers, producers, packagers, importers, suppliers and distributors can comply with Article 6 by simply providing a compliant Proposition 65 warning on a product label, *or* by providing written notice to the retailer (with warning materials, including warning language for products sold on the internet, certain required statements, and confirmation of receipt of notice from retailer). However, revised subsection 25600.2(e)(4) seems to suggest that a retailer must receive not only notice but also "warning materials," which causes confusion because there is no description of the required notice in subsection 25600.2(e)(4), and under subsection 25600.2(b), warning materials are only required if a business is providing *written notice* to the retailer, not when a notice is provided to retailers by affixing a Proposition 65 label onto a product. ACA urges OEHHA to clarify that once a manufacturer has affixed a compliant Proposition 65 on-product label, they have satisfied their responsibilities to provide notice to the retailer under Article 6 and are not required to send the retailer additional "warning materials". ACA suggests an amendment in subsection (e)(4): "The retail seller has received written notice and warning materials or a label affixed to the product bearing a warning that satisfies Section 25249.6 of the Act pursuant to subsections (b) and (c) and..."

Response: Under subsection (b), where a product is sold on the internet, in order to take advantage of the safe harbor provided in the regulation, the warning must be provided on the product display page or be otherwise prominently displayed prior to the customer completing the purchase. The warning label used on the product may be reproduced or pictured on the internet website. Subsection 25600.2(b)(3) was modified in March 2016 to require product manufacturers, producers, packagers, importers, suppliers, and distributors to provide retail sellers with warning language to use on their websites for the product. Where the product manufacturer has included the warning on

a product label or labeling, the retail seller may use the same warning language on its website, or provide a picture of the label or labeling for the product to the extent that the warning is readable and legible in the picture. This should alleviate any significant cost burdens for retail sellers, while ensuring that consumers are warned prior to exposure to a listed chemical from products sold over the internet. OEHHA believes the regulatory text is clear regarding the responsibilities of the businesses in the chain of commerce to provide a warning for exposure to a listed chemical. Subsection 25600.2(b) provides a manufacturer with the option of affixing a warning on a product, or providing a notice with warnings materials to the retail seller. By either choice, the manufacturer will have satisfied its responsibility to comply with the warning requirement under the Act.

547. Comment (Auto Alliance et al.): The modifications to Section 25600.2 clarifying that there is no requirement for a retailer to affirmatively demonstrate that a warning is required improves the feasibility of the proposed requirements.

Response: Comment noted, no response required.

548. Comment (FPPI): FPPI is concerned that the specific language in subsection (b)(2), "Includes the exact name or description of the product or specific identifying information for the product such as Universal Product Code or other identifying designation," imposes an unnecessary administrative burden on manufacturers while providing no tangible benefits to consumers. FPPI proposes that the term 'exact' be removed because a general description would be sufficient.

Response: This comment is not related to the modification of text. OEHHA notes that the provision allows the product to be identified using "the exact name *or* description of the product *or* specific identifying information for the product such as a Universal Product Code *or* other identifying designation" (emphasis added). This should provide sufficient options for the business to identify the product without undue effort or cost. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

549. Comment (FPPI): Subsection (b)(3) places an undue burden on manufacturers to provide "all necessary warning materials such as labels, labeling, shelf signs or tags." Manufacturers have no control over the varied locations and designs of product shelves where their products may be sold. As such, manufacturers would not be able to offer appropriate warning materials without spending substantial time and resources in researching and designing appropriate warning materials that are appropriate for retailers' uses. Retailers are in a better position to prepare the appropriate warning materials. FPPI recommends that OEHHA provide manufacturers with an option to offer to provide warning materials at no cost to retailers or reimburse retailers of reasonable costs of such warning materials.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

550. Comment (FPPI): Subsection (b)(4) needs clarification regarding what constitutes electronic confirmation. For example, Microsoft Outlook has an optional function of confirming electronic delivery of e-mails automatically once the message is accessed by the receiver. FPPI requests that OEHHA deem such functionality to be considered as meeting the 'electronic confirmation' requirement.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

551. Comment (ACA): ACA recommends that OEHHA clarify in subsection (d) that once the retail seller receives written notice and warning materials or a product with a label bearing a compliant Proposition 65 warning, the retailer is responsible for placement and maintenance of warnings, including for internet sales. ACA suggests an amendment in subsection (d) that "... including warning language for products sold over the Internet, that the retailer receives on a product label, or from receiving written notice pursuant to subsections (b) and (c)."

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

552. Comment (FPPI): Subsection (e) does not include a provision for circumstances where a final, potentially smaller retailer not originally identified in the supply chain purchases products from another larger retailer. FPPI is concerned that manufacturers may be held liable when an owner of a corner store sells products without proper warning messages. Manufacturers would not be able to utilize their compliance with written notice provisions because identities of these small retail sellers are unknown to manufacturers. Manufacturers would have no choice but to put warning messages on their products and negate the purpose of having the written notice provision. This would be extremely burdensome for national companies. FPPI requests adding a provision to subsection (e)(5) that the manufacturer must have actual knowledge that the retail seller is engaging in selling the products to consumers.

Response: This comment is not related to the modification of text. Proposition 65 applies to all businesses with 10 or more employees. Thus, it is up to all the businesses in the chain of commerce to either label the product or pass along warning materials to the businesses to which they sell the products in order to ensure a clear and reasonable warning is provided to the consumer of the product.

553. Comment (LNovak): The proposed revisions in subsection (e) will allow manufacturers, distributors, and retailers to avoid reasonable warnings for internet sales. As an example, if a manufacturer or distributor places a Proposition 65 warning directly on the product and ships it to a retailer who sells it over the internet, but without a Proposition 65 warning on the internet page, the consumer is not warned until he receives product and sees the warning on product. The consumer has no choice but to keep the product or go through the time-consuming and sometimes costly process to return the product. This would not be a reasonable warning and contradicts "prior to completing the purchase" in subsection 25602(b). The responsibilities of the internet retailer are not clear. It appears an internet retailer is only responsible for internet warnings if the manufacturer or distributor complies with both subsection (b) [affixing a warning on product] and (c) [providing a notice] as opposed to subsection (b) only.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

554. Comment (AFTA): If the source of "actual knowledge" is not through a notice served pursuant to subsection 25249.7 (d)(1), then the term “any reliable source” is not defined. OEHHA needs to clearly define the term “any reliable source” as it is used in subsection (f). If OEHHA cannot or will not define it, then the term needs to be eliminated. Otherwise, it will have no clear meaning under Proposition 65, except as it will be interpreted in the future by Attorney General or Courts in subsequent litigation.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

Section 25601 Safe Harbor Clear and Reasonable Warnings – Methods and Content

555. Comment (CAPA, Auto Alliance et al., and RMA): In subsection (b) [formerly numbered as subsection (c)], the phrase, "person has determined a warning is required" was stricken and the phrase "... in the consumer product or affected area for which the warning is being provided" was added. The commenters support the change and believe it clarifies that exposure testing and risk modelling are not required to be conducted prior to providing a warning.

Response: Comment noted, no response required.

556. Comment (CalChamber and RMA): In subsection (b) [formerly numbered as subsection (c)], if OEHHA intends to allow businesses to identify any listed chemical the businesses select even if the businesses are providing the warning for multiple listings,

OEHHA should make a clear and unequivocal statement that a business has full discretion to do so. The phrase "one or more of the listed chemicals in the consumer product or affected area for which the warning is being provided" could suggest that if there is exposure to more than one listed chemical, the warning would have to specify every such chemical. The commenters suggest an amendment to subsection (b) to that effect.

Response: OEHHA does not agree with an interpretation that "one or more of the listed chemicals" means that every listed chemical for which a warning is being provided must be included in safe harbor warning content. OEHHA intends to allow a business to identify any one listed chemical the business selects, even if the business is providing the warning for multiple chemicals. If, however, the listed chemicals for which a warning is being provided cover both the cancer and reproductive toxicity endpoints, the name of one chemical for each endpoint must be included in the warning. (If one of those chemicals is listed for causing both cancer and reproductive toxicity, naming that one chemical in the warning will suffice.) In all cases, the warning must include the name of one chemical, and a business *may* include the name of additional chemicals at its discretion.

557. Comment (ACA): ACA objects to the inclusion of the chemical specific warning requirements under subsection 25601(c). The provision goes against the goals of Proposition 65 reform to reduce the flood of frivolous litigation from private parties, provide more certainty to businesses, and provide more meaningful warnings to the public. OEHHA should abandon the chemical specific warning requirements altogether. In the alternative, ACA supports the recommendations of CalChamber to make chemical specific warnings less burdensome and ambiguous.

Response: This comment is not directed to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

558. Comment (ACC): In subsection (e) (formerly numbered as subsection (f)), the proposal to suppress the delivery of truthful and accurate information by manufacturers made worse by OEHHA's omission of critical information on the agency website violates the First Amendment.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

Section 25602 Consumer Product Exposure Warnings – Methods of Transmission

Subsection 25602(a)

559. Comment (CalChamber and RMA): The phrase "without requiring the purchaser to seek out the warning in subsection (a)(2)," is ambiguous and needs clarification. The commenters urge OEHHA to incorporate a rule of reason around what this vague phrase is intended to mean and ensure that steps that consumers ordinarily associate with using an electronic device while shopping are permissible such as scanning a QR code with a smart phone and clicking on a hyperlink.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

560. Comment (CalChamber): Although the term "on-product" in subsection (a)(4) appears to refer to warnings that are on the exterior packaging or on the product itself, it would be beneficial if it were clarified in the FSOR that an "on product" warning need not appear on the product itself but can appear on its exterior packaging. The short-form warning option (in subsection 25603(b)) is intended to incentivize businesses to provide warnings that consumers will be able to see before they purchase a product. To ensure OEHHA's intent of incentivizing the use of on-product warnings is effectuated, the FSOR must make this clarification.

Response: The regulations provide several methods that may be used to provide consumer product warnings. Warning labels on the product or exterior container or packaging are just one option. To comply with the statute, the warning should be placed in such a manner as to ensure that it is seen and understood prior to exposure. For example, where a business provides the warning on a product label (as defined in subsection 25600.1(i)), if a person will be exposed to a listed chemical immediately upon opening a product's outer packaging through contact with the product, the warning should be placed on the outer container, package or wrapper.

The commenter incorrectly described the intent of the short-form warning option provided in subsection 25603(b). OEHHA's intent in proposing the short-form warning is to provide businesses with an on-product (or on-package) warning option that takes up less space than the standard safe harbor warning, which may be particularly helpful for small products and small packages.

561. Comment (CRN): Clarify that on-product warnings for food exposures, including dietary supplements, may use the shortened warning language provided in proposed subsection 25602(a)(4).

Response: The "short form" warning methods and content found in subsections 25602(a)(4) and 25603(b) respectively, may be used for food exposure warnings. "Dietary supplements" are included in the definition of "Food" in subsection 25600.1(g);

a business may use the short form warning methods in subsection 25603(b) for food exposures from dietary supplements. No changes were made to the regulatory text based on this comment.

Subsection 25602(b)

562. Comment (ACA): OEHHA does not have the authority to require warnings on the internet or in catalogs when the product already has an on-product warning. Because OEHHA appears intent on maintaining internet and catalog warning requirements, OEHHA must clearly state what is required to provide adequate notice to retail sellers and what retail sellers' responsibilities are in terms of posting warnings for products sold online and in catalogs once they have received notice.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

Subsection 25602(d)

563. Comment (CalChamber and ACA): Subsection (d) does not give an indication of how warnings are to be properly translated. Businesses do not have guidance on the content that must be included in non-English warnings. Improperly translated warnings may prompt lawsuits. The FSOR should state that precise verbiage of translated warnings is subject to liberal construction and a "rule of reason" so as to reduce likelihood of frivolous translation lawsuits.

Adding to the uncertainty is that the foreign language requirement applies to consumer product signs, labels or shelf tags, but makes no mention of on-product warnings even though on-product warnings are explicitly listed as a warning method under the same section of the proposed regulations. The commenters urge OEHHA to eliminate the foreign language requirement especially for on-product warnings or small packages. OEHHA can satisfy its interest in educating the public about warnings by supplying translations of warnings on its website. If OEHHA adopts the foreign language requirement, at the minimum encourage OEHHA to exempt on-product warnings, adopt the language recommendations of CalChamber, and only require one Proposition 65 pictogram per warning if both English and additional languages are required.

Response: To the extent feasible, OEHHA plans to post approved translations for commonly used warnings on its website. OEHHA has already done this for warnings for BPA exposures in foods.[55] Simply providing the alternative warning language on the OEHHA website, however, will not ensure that non-English readers will see it prior to

[55] See https://www.p65warnings.ca.gov/chemicals/bisphenol-bpa for translated warning in nine commonly-used languages.

exposure. Therefore, OEHHA declines to limit the regulation in the manner suggested by the commenters.

As stated in a response to an earlier comment, OEHHA understands that there rarely if ever is only one correct way to translate a statement into another language. Even a relatively simple translation can require the translator to make word choices and restructure sentences so that the translation is clear to readers of the alternative language. It is not OEHHA's intent to stipulate only one way to translate a warning or prevent translators from using their professional judgment. As long as the translation is reasonable and is sufficiently clear to the reader, it would comply with the requirements of the regulation.

Whether or not two pictograms should be included will depend on the circumstances. Where the English and alternative language warnings are provided together, a second warning symbol would not be necessary. However, if the alternative language warning is not co-located with the English version, the symbol should be included with the alternative language warning.

In the case of a "short-form" on-product warning, the regulation is clear that a short-form warning should be in any alternative languages used to provide consumer information on a label, sign or shelf tag. OEHHA believes it is reasonable that the shortened on-product warning can be provided in the relevant alternate language.

564. Comment (ACA): OEHHA must take a holistic view of the new proposal's impacts on the limited space on labels, particularly if OEHHA wants to encourage use of on-product warnings. It is important that OEHHA provide necessary flexibility, both in content and type size, to manufacturers who warn on product labels so that the new requirements are technically feasible, particularly for small packages.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

Section 25603 Consumer Product Exposure Warnings – Content

565. Comment (ACA): ACA objects to the use of the ANSI symbol. As recommended in the Cal Chamber's comments, if OEHHA intends to include a pictogram, ACA supports the creation of a Proposition 65-specific pictogram in black and white. ACA urges OEHHA to eliminate the mandate that the symbol be in yellow. For practical purposes businesses often have labels pre-printed on a contractual basis in large quantities to reduce the cost per label. On pre-printed labels, there is an area left blank for the product's specific hazard communication information, including Proposition 65 warnings. At the manufacturing facility, hazard communication information and

Proposition 65 warning is printed using one tone (black) or two tone (red and black) printers. The color requirement would essentially make printers that were specially purchased for the transition to HCS 2012 or Cal OSHA HCS obsolete in less than 2 years. Request to allow manufacturers to print pictogram in black and white.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

566. Comment (ICC): The exclamation point in a triangle symbol is already used in the marketplace and industry to indicate altogether different messages. Provided examples of other uses such as by Microsoft® in computer error messages, other consumer product warning statements, and ANSI standards (ANSI Z535). The Proposition 65 symbol is being discredited because its format is too common and its content would be conflicting with other multi-use warnings already long-established. Suggest adopting a more unique and informative symbol such as the triangle silhouette. It would be beneficial to actually provide a picture in the regulation of a more explanatory symbol in Section 25603(a)(1). Note that examples of the warning symbol will be provided on the OEHHA website prior to the effective date of the regulations.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

567. Comment (ICC): The vague and ambiguous symbol in subsection (a)(1) seems to attempt to impose its use nearly everywhere. The non-uniqueness of this symbol as well as its use in so many other common hazards signs and admonitions makes it ludicrous to introduce its use for Proposition 65 chemical warnings and totally ignores the possibility of an improved symbol. To continue to have selected, separate accompanying warning statements for nearly every possible different industry and facility in the State and not change to a standard, uniform warning is beyond comprehension and enforces an early dissolution of any further intelligent discussion.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

568. Comment (ICC): Instead of a sign that says “Welcome to California” there could be a Proposition 65 billboard as one enters by land with the warning statement: “There is a possibility as you experience California that you may encounter chemicals which may cause cancer and/or reproductive harm. Contact website www.P65Warnings.ca.gov for all locations in the State where such possibilities may

exist; such detailed listing is updated daily on our Prop65 App for your convenience and expediency to further enjoy beautiful California. Have a great day!"

Response: This comment appears to be rhetorical in nature and is not related to the modification of text. While OEHHA appreciates that Proposition 65 compliance can pose challenges to businesses, the law reflects the wishes of California's voters. For almost 30 years, Californians have asserted their right to be informed of exposures to chemicals that cause cancer, birth defects or reproductive harm. As the lead agency for Proposition 65, OEHHA remains committed to working with businesses, advocacy groups and other interested parties to ensure that Californians receive meaningful and informative warnings in ways that minimize burdens on businesses.

569. Comment (CRN): The ISOR states that the shortened warning is intended to "accommodate some product manufacturers' stated concern that a longer warning message will simply not fit on the labeling or packaging of some small products." (ISOR at p. 31) The ISOR further states that "all methods for transmitting the warning for other consumer products under Section 25602 are equally available to businesses that manufacture or sell foods." (ISOR at p. 34) CRN understands that warnings for dietary supplement products and other food exposure warnings may utilize shortened warning language provided in subsection 25603(b); however, the proposed regulation as currently written is ambiguous regarding this point. Clarify that on-product warnings for food exposures, including dietary supplements, may use the shortened warning language provided in proposed subsection 25603(b).

Response: As we noted in our response to a similar comment from the same commenter regarding subsection 25602(a), warnings for "food" as defined in subsection 25600.1(g), including "dietary supplements", may use the short form warning methods in subsection 25603(b). No changes were made to the regulatory text based on this comment.

Section 25605 Environmental Exposure Warnings – Content

570. Comment (CalChamber): The phrase "one or more sources of exposure" in subsection (a)(3) is ambiguous and can be interpreted that an environmental exposure warning must specify all sources of exposure if the business determines that exposures are occurring from multiple sources. CalChamber understands OEHHA's intent is to allow businesses to specify one source, even if exposures may be occurring from multiple sources; if this is the case, OEHHA should clarify its intent. CalChamber included recommended clarifying language for the FSOR:

> "Section 25605 subsection (a)(3) provides the safe harbor warning content for environmental exposure warnings. The safe harbor warnings require businesses to specify the name of "one or more sources of exposure" in their warnings. The phrase "one or more sources of exposure" is intended to mean that if a warning

is being provided for chemicals that are exposing individuals from more than one source within the affected area, then the person providing the warning may specify one source in the warning. The business may, but is not required to, specify more than one exposure source in the warning. Further, the business may elect to specify any source for which it is providing a warning in its warning. For example, if a warning is being provided for Proposition 65-listed carcinogen A, which is exposing individuals from sources X and Y, the warning may specify source X only, source Y only, or both sources X and Y."

Response: As stated in response to previous comments on this issue, OEHHA believes that the requested FSOR language accurately describes OEHHA's intent for this provision of the regulations.

Section 25606 Occupational Exposure Warnings

571. Comment (CalChamber): Section 25606 contains a similar ambiguity as previously contained in the grandfathering provision in proposed subsection 25600(e) relating to the phrase "if the warning fully complies with the order or judgment". The phrase "fully complies with all warning information, training and labeling requirements . . ." in subsection (a) may inadvertently lead private enforcers to believe that a new avenue for enforcement of Proposition 65 has been created. CalChamber requests that OEHHA clarify in the FSOR that it does not intend this proposed section to contravene existing law on federal preemption of occupational warning aspects of Proposition 65.

Response: The commenter is correct that OEHHA does not intend for the term "fully complies" in subsection 25606(a) to provide a "new avenue" for enforcement of the Act on the basis of this provision, or to contravene existing law on federal preemption of occupational warning aspects of Proposition 65. OEHHA does not believe this language is unclear.

572. Comment (ACA): If OEHHA does not adopt a policy so that all industrial products compliant with HCS 2012 are compliant with Article 6, OEHHA can build upon the amendments made in the occupational exposures section. While OEHHA's new subsection (b) of Section 25606 is appreciated, it does not clearly address exposure from industrial products.

Response: Responses to similar comments are provided in responses to comments received during the second comment period for the regulations.

573. Comment (ACA): The new subsection (b) references Section 25601, and that Section 25601(c) provides, "Consumer product exposure warnings must be prominently displayed on a label, labeling, or sign, and must be displayed with such conspicuousness as compared with other words, statements, designs or devices on the label, labeling, or sign…". Section 25606 does not make it clear that warnings are

allowed on Safety Data Sheets (SDSs). Industrial product manufacturers often warn on SDSs because downstream industrial users are properly trained on the nature of hazard communication. If OEHHA wants to allow industrial products that do not fall under the subsection 25606(a) occupational exposure safe harbor to use the consumer product safe harbor provisions, companies must have clarity that this provision covers industrial products and that a warning on an SDS is compliant with the safe harbor warning provisions. As an alternative, ACA encourages OEHHA to clarify its intent for industrial products in the FSOR.

Response: As noted in earlier comments, OEHHA believes that the addition of subsection (b) will address industrial exposures. If there is an occupational exposure to a listed chemical, the employer may provide a warning that complies with the warning information, training and labeling requirements of the federal Hazard Communication Standard, California Hazard Communication Standard or Pesticides Worker Safety requirements, as stated in subsection 25606(a). For exposures to listed chemicals from products not covered by subsection (a), subsection (b) allows an employer to provide warnings using the safe harbor warning methods and content for consumer product and environmental warnings. The portion of the comment recommending that OEHHA allow warnings to be provided on Safety Data Sheets is outside the scope of this rulemaking as OEHHA cannot prescribe the content of forms under the authority of a federal or other state agency.

574. Comment (ACA): OEHHA has stated a number of times that the safe harbor for occupational exposures is intended to cover both occupational exposure area warnings as well as industrial product exposure warnings. However, it is not clear by the current drafting of the regulations. The concerns can be addressed by allowing industrial products and occupational exposures to comply with Article 6 by fully complying with the Federal Hazard Communication Standard (HCS 2012) or the California Hazard Communication Standard.

Response: As noted in response to earlier comments, warnings for exposures to listed chemicals in industrial products and other occupational exposures that comply with the Federal Hazard Communication Standard or the California Hazard Communication Standard are deemed to comply with Proposition 65.

Section 25607.1 Food Exposure Warnings – Methods of Transmission

575. Comment (CRN and NC): Subsection 25607.1(a) states that a warning for food exposures, including dietary supplements, is compliant if it meets the content requirements of Section 25607.2 and uses a method provided in Section 25602. One of the permitted methods, under subsection 25602(a)(4), is an on-product label warning that complies with the content requirements of subsection 25603(b), which is the shortened warning. It is unclear whether food exposures may utilize the shortened

warning because the required content for food exposure warnings under Section 25607.2 does not include the shortened warning language. The commenters request that OEHHA clarify this in the FSOR by expressly stating that a warning for food exposures, including dietary supplements, may use the shortened warning indicated in subsection 25603(b) and that such a warning would be deemed compliant with the regulation.

Response: As we noted in our response to a similar comment from the same commenter regarding subsections 25602(a) and 25603(b), warnings for “food” as defined in subsection 25600.1(g), including “dietary supplements”, may use the short form warning methods in subsection 25603(b). No changes were made to the regulatory text based on this comment.

576. Comment (NC): OEHHA should make it clear that a warning is a safe harbor warning even if a business uses the phrase, "California Residents Only", or "For California Residents", or "For California Residents Only" either inside the boxed warning or before the boxed warning to indicate the warning is only intended for California consumers. This language has been approved in numerous consent judgments involving dietary supplements.

Response: This comment is not related to the modification of text..

577. Comment (NC): NC requests that OEHHA clarify in the FSOR that the Proposition 65 warning can be inside the same box as other caution or warning statements on dietary supplements and foods.

Response: This comment is not related to the modification of text. As a general matter, OEHHA does not object to the inclusion of the Proposition 65 warning with other warnings or cautionary statements, as long as the warning is likely to be seen prior to exposure.

Sections 25607.12 and 25607.13 Furniture Product Exposure Warnings – Methods of Transmission and Content

578. Comment (SC): SC expresses concern about the on-product warning requirement in subsection 25607.13(a)(1). An on-product furniture warning must contain the symbol described in subsection 25603(a)(1), namely, “a black exclamation point in a yellow equilateral triangle with a bold black outline.” Since October 2012 the commenter’s retail furniture stores have posted Proposition 65 warnings notices in three locations: at all store entrances in the form of a 8.5 x 11 inch sign, on the price tag attached to the furniture item in the form of a 2 x 2 inch yellow triangle with the words “PROP 65”, and at the sales counter in the form of a 8.5 x 11 inch sign. All locations provide the warning prior to purchase. The commenter provided copies of its marketing information,

fact sheet, and sample signage. The “exclamation point” is not as communicative to customers as the “PROP 65” sign. The “exclamation point” simply calls attention to a warning, whereas the “PROP 65” yellow triangle adds meaning to the warning. The on-product warning and cash register receipt statement are provided after purchase. The commenter does not oppose the after purchase warnings, however, the warning system is strengthened when customers are informed about potential chemical exposures related to furniture they intend to purchase.

Response: This comment is not related to the modification of text. The safe harbor provisions of the regulation are not mandatory, and the regulation expressly allows businesses to provide warnings in any manner that is “clear and reasonable” for purposes of the Act (subsection 26000(f)).

Sections 25607.14 and 25607.15 Diesel Engine Exposure Warnings (Except Passenger Vehicles) – Methods of Transmission and Content

579. Comment (NMMA): Due to the significant volume of aftermarket engine sales in California, Sections 26507.14 and 25607.15 should be amended to be more universally applicable to engines purchased by consumers separate from the vessel such as off-road vehicles, motorcycles, or generators. A standalone warning that encompasses diesel and non-diesel engines, simply by striking out “diesel,” would better protect the consumer.

Response: This comment is not related to the modification of text.

Section 25607.16 Vehicle Exposure Warnings – Methods of Transmission

580. Comment (Auto Alliance et al.): The definition for passenger vehicle is overly broad and creates uncertainty as responsible parties work to identify the appropriate warning for the appropriate vehicle. Because the definition of passenger vehicle does not include light-duty trucks, medium-duty trucks, or heavy-duty vehicles, warnings for these vehicles would need to follow the less specific methods of transmission and content in Sections 25602 and 25603 to secure safe harbor. The definition should be revised to read, “as defined in Vehicle Code Section 465 and/or Section 410”. The commenters encourage OEHHA to make it clear either in the regulations or in the FSOR that the intention is to include, in addition to passenger cars, light-duty trucks, medium-duty vehicles and heavy-duty vehicles.

Response: This comment is not related to the modification of text. OEHHA intends the provision to cover all passenger vehicles, which includes some trucks, but would not include many medium- or heavy-duty trucks. OEHHA used the Vehicle Code section suggested by the California auto retailers. OEHHA is considering an informal request

for the development of a "tailored warning" pursuant to Section 25607, et seq. for exposures to listed chemicals from other vehicles.

581. Comment (Auto Alliance et al.): This is the first and only instance where two warnings are required for a single product. OEHHA should provide flexibility to require labeling subsection 25607.16(a)(1) in the owner's manual or subsection 25607.16(a)(2) a label attached to the front window.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations. OEHHA notes that this is not the only instance where two warnings are required for a single product in the regulations.

582. Comment (Auto Alliance et al.): OEHHA should make sure that the regulations do not inadvertently limit the owner's manual to a printed version. In some cases, the owner's manual is provided in an electronic format. Alternatively, a statement in the regulations and/or the FSOR that provisions for the owner's manual warning apply to both printed and electronic versions would provide appropriate clarification.

Response: As discussed in previous comments, an owner's manual serves as an adjunct to other warning methods. For purposes of the safe harbor warning method in subsection (a)(1), OEHHA does not intend to restrict the owner's manual warning to only printed versions of the owner's manuals; rather an electronic version of the owner's manual may be provided in addition to the label or hang tag required under the safe harbor method described in subsection (a)(2) and the printed manual, if any, described in subsection (a)(1).

583. Comment (Auto Alliance et al.): The commenters recommend that OEHHA establish *de minimis*, percent-by-weight levels for the Proposition 65 chemicals. Establishing *de minimis* levels will not only allow the automotive sector to use existing resources to expedite implementation, but it will also allow consumers to distinguish between small or insignificant risks and those that potentially pose a threat to human health and the environment.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

584. Comment (Auto Alliance et al. and AASA): In their previous comments, the commenters requested an exemption for replacement parts, which included aftermarket and service parts. Such an exemption would eliminate any possible litigation against replacement part manufacturers. When the vehicle is first sold to the consumer, there are not separate warnings for each vehicle part; all vehicle parts on an original vehicle is covered by the passenger vehicle warning which must be provided as a window label

and in the owner's manual. If replacement part is used to replace the existing vehicle part, the safe harbor warning for the passenger vehicle should cover those replacement parts. To provide clarity, request OEHHA to state in the FSOR that replacement parts are covered by the passenger vehicle warning.

Response: This comment is not related to the modification of text**.** Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

Section 25607.18 Recreational Vessel Exposure Warnings – Method of Transmission

585. Comment (NMMA): Subsection 25607.18(a)(1) limits a manufacturer to only three locations for a warning label in the owner's manual. This limitation contradicts the definition of "label" and "labelling" in Section 25600.1 and the label requirements for consumer products found in Section 25602. Per Sections 25600.1 and 25602, a manufacturer should have flexibility to include the warning label in the owner's manual in any location, as an insert and/or as an addendum included in the owner's manual package. Limiting the manufacturer to just three locations forces the manufacturer to either produce a California-specific owner's manual, or change the universal owner's manual to comply with Proposition 65, at the expense of other needed language.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

586. Comment (NMMA): Subsection 25601(d) enables any consumer product warning to be displayed on or with the product as long as it meets the requirements outlined in subsection 25600.1(j), "written, printed, graphic, or electronically provided communication that accompanies a product including tags at the point of sale or display of a product." As such subsection 25607.18(a)(1), governing recreational vessels, should be amended to better reflect the multitude of display options.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

Section 25607.23 Amusement Park Exposure Warnings – Content

587. Comment (CAPA): The phrase, "identify the affected area and exposure source" was stricken and the phrase, "Some areas or features in this amusement park can expose you to chemicals...." was added to subsection 25607.23(a)(3). CAPA supports the changes.

Response: Comment noted, no response required.

Miscellaneous or General Comments

588. Comment (ACC): ACC has serious concerns with the current regulatory proposal. The concerns include the requirement to include specific chemical names in the warnings; the limitations on a business' right to include properly substantiated, truthful, and accurate information in the warning; the requirement to include an inappropriate pictogram in the warning; and the requirement to include a URL to the OEHHA website and the information posted on the website. The rulemaking record offers evidence why these changes will not improve the operation of the program or the meaning of warnings. The record is also clear that these modifications will undermine the statutory goals and increase bounty hunter litigation. ACC urges OEHHA to withdraw the proposed rule in its entirety.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

589. Comment (CalChamber): OEHHA has elected to retain some problematic provisions that would substantially increase litigation by creating a new breed of "bad warning"; impose an unworkable and costly requirement on those providing environmental exposure warnings; require for the first time two warnings for one product; and eliminate the long-accepted method of transmitting warnings via owner's manuals.

Response: This comment is not related to the modification of text. Responses to similar comments are provided in responses to comments received during the first and second comment periods for the regulations.

590. Comment (CH&LA): CH&LA is pleased that the Notice of Modification states, "OEHHA also intends to continue to adopt additional provisions in the Article that address specific exposure situations such as exposures that occur at hotels and apartments, which will supplement the existing regulatory proposal and become effective during the two-year phase-in period for the Article. Businesses are encouraged to work with OEHHA staff to develop such tailored warnings where they are needed."

Response: Comment noted, no response required.

591. Comment (CH&LA): CH&LA believes it is essential to adopt hotel-specific warning provisions. There has been longstanding confusion of what constitutes an "affected area" in the context of hotels. During the pre-regulatory phase, a tailored hotel, apartment and other lodging proposals were discussed; however when the formal

Notice of Proposed Rulemaking was released, the proposal was omitted. Subsequent to the commencement of the current rulemaking process, CH&LA submitted numerous comments advising OEHHA to adopt hotel-specific warning requirements. OEHHA stated that it agrees that hotels could have their own safe harbor warning; however, from a procedural standpoint under the APA, there was insufficient time to insert a hotel-specific warning in this proposal. OEHHA plans to first finalize the New Article 6 and a hotel-specific warning language can be considered as an amendment to the New Article 6 within the two-year effective date of the New Article 6.

Response: OEHHA is currently considering an informal request for the development of a "tailored warning" pursuant to Section 25607, et seq. for exposures to listed chemicals in hotels and apartments.

Technical, Theoretical, and/or Empirical Study, Reports, or Documents

Prior to this rulemaking, OEHHA received formal and informal feedback regarding the potential development of a regulatory proposal concerning the Article 6 Clear and Reasonable Warnings. Under the heading of "Technical, Theoretical, and/or Empirical Study, Reports, or Documents Relied Upon in the Initial Statement of Reasons" for this regulatory action, OEHHA indicated that it had reviewed but did not rely upon the oral and written public comments offered during the pre-regulatory process from interested parties.[56] OEHHA also reviewed and considered, but did not rely on, public records from cases filed under Proposition 65 including:

- *Ingredient Communication Council (ICC) v. Lungren* (1992) 2 Cal. App. 4th 1480.
- *Environmental Law Foundation v. Wykle Research, Inc.* (2005) 134 Cal. App. 4th 60.
- *Dowhal v. SmithKline Beecham Consumer Healthcare*, (2004) 32 Cal. App. 4th 910, 934-35.
- *Nicolle-Wagner v. Deukmejian*, (1991) 230 Cal. App. 3d 652.

In order to assess the effectiveness of the current and proposed warnings, OEHHA commissioned a study by researchers at the UC Davis Extension Collaboration Center.[57] The study is included as Appendix A to the ISOR for the regulations.

[56] Initial Statement of Reasons, Title 27, California Code of Regulations: Proposed Repeal of Article 6 and Adoption of Article 6, Sections 25600 - 25607.29, Clear and Reasonable Warnings, at 53.

[57] UC Davis Extension Collaboration Center, Proposition 65 Clear and Reasonable Warning Regulations Study: Survey results assessing the effectiveness of existing and proposed Proposition 65 warning signs (2015).

OEHHA further considered the economic impacts of the proposed regulations and prepared an assessment of the economic impact of this proposed regulatory action. This is included as Appendix B to the ISOR for these regulations.

OEHHA relied upon the US Census Bureau's 2007-2011 American Community Survey (ACS). OEHHA also relied upon Title 11, Cal. Code of Regs., Section 3202(d)(3), which is available at the Attorney General's website at https://oag.ca.gov/prop65/regulations.

The documents relied on are included in the rulemaking record and are available for public inspection by contacting Monet Vela of the OEHHA Legal Office at (916) 323-2517.

Local Mandate Determination

OEHHA has determined this regulatory action will not impose a mandate on local agencies or school districts nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. Local agencies and school districts are exempt from Proposition 65. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from this regulatory action. The regulations intend to clarify the relative responsibilities of manufacturers, retailers and others in the chain of distribution concerning providing clear and reasonable warnings. Additionally, the regulations will provide more opportunities for safe harbor guidance in specific exposure situations.

Alternatives Determination

In accordance with Government Code section 11346.9(a)(7), OEHHA has considered available alternatives to determine whether any alternative would be more effective in carrying out the purpose for which the regulations were proposed. OEHHA has also considered whether an alternative existed that would be as effective as, and less burdensome to, affected private persons than the proposed action. OEHHA has determined that no alternative considered would be more effective, or as effective and less burdensome to affected private persons, than the proposed regulations because the regulations will further the 'right-to-know" purposes of Proposition 65 by incorporating new technology in providing warnings that will give consumers more information about the potential exposure to listed chemicals and give businesses more compliance assistance in furtherance of the purposes of the Act.

Pursuant to Government Code section 11346.9(a)(4)&(5), OEHHA considered alternatives to the proposed regulations. One alternative considered was that OEHHA withdraw the entire regulatory proposal. OEHHA has determined that this is not a reasonable alternative because the existing regulations have become outdated and do not currently incorporate the changes in technology that have occurred in the 30 years

since Proposition 65 was passed and individuals who may be exposed to listed chemicals would not be provided useful, informative, and updated warnings.

Pursuant to Government Code section 11346.5(a)(13), OEHHA has initially determined that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to the attention of OEHHA, would be more effective in carrying out the purpose for which Proposition 65 is proposed, or would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The warning regulations proposal has been developed over the course of more than two years.

The now-withdrawn January 2015 regulatory proposal identified 12 listed chemicals or chemical groups that would have been required to be named in the warning if exposures to those chemicals were the reason for the warning. This alternative, it was argued, would result in costs for testing products or locations to determine if their warnings would need to name some of those chemicals. However, as modified, this regulation would require only that one or more chemicals for each endpoint covered by the warning be named in the warning. The choice of which chemical is named is left to the discretion of the business providing the warning. This should not trigger the need for any additional testing as businesses providing warnings have already ascertained that they are causing an exposure to at least one chemical and should know the identity of that chemical. There were no small-business specific alternatives submitted during the rulemaking process.

Attachment A

UC Davis Response to ACC Critique of Warning Study