Final Statement of Reasons
Title 27, California Code of Regulations

Proposed Amendments to Article 6
Clear and Reasonable Warnings

California Environmental Protection Agency
Office of Environmental Health Hazard Assessment

Contents

General

Subsequent to the adoption of the August 2016 amendments to the Article 6 Clear and Reasonable Warnings regulations, the Office of Environmental Health Hazard Assessment (OEHHA) received numerous inquiries related to the interpretation and application of several provisions of the amended regulations. OEHHA therefore determined that clarification of certain provisions of the new regulations would be beneficial to the regulated community. The proposed amendments are intended to further clarify the guidance OEHHA provides to businesses to better understand how to comply with the warning requirements.

OEHHA published the Notice of Proposed Rulemaking and Initial Statement of Reasons (ISOR) for this action on July 21, 2017. No public hearing was requested for this regulatory proposal. The 45-day comment period closed on September 7, 2017 and OEHHA received six comments.

Following careful consideration of the comments received during the comment period, OEHHA determined no substantive modifications to the proposed amendments were necessary. OEHHA has withdrawn proposed modifications to Sections 25602(d), 25607.14(a), 25607.15(a), 25607.16(a), and 25607.17(a) in response to comments received during this rulemaking. OEHHA's responses to the comments received during the comment period are incorporated within this Final Statement of Reasons (FSOR).

Summary and response to comments on the July 2017 proposed amendments

The following organizations submitted comments on the proposed amendments to OEHHA during the comment period (July 21, 2017 to September 7, 2017):

Association of Global Automakers, Inc. and
Alliance of Automobile Manufacturers (AGA/AAM)

California Chamber of Commerce et al. (CalChamber)[1]

Environmental Research Center, Inc. (ERC)

[1] CalChamber, et al. includes the following organizations: Advanced Medical Technology Association, American Beverage Association, Association of Home Appliance Manufacturers, Automotive Specialty Products Alliance, California League of Food Producers, California Manufacturers & Technology Association, Consumer Specialty Products Association, Grocery Manufacturers Association, National Shooting Sports Foundation, Personal Care Products Council, Plumbing Manufacturers International, Sporting Arms & Ammunition Manufacturers' Institute, and West Coast Lumber & Building Material Association.

Hach Company (Hach)

Seymour of Sycamore (Seymour)

Sporting Arms and Ammunition Manufacturers' Institute, Inc. (SAAMI)

Section 25600.1 Definitions

Section 25600.1(c) Consumer Information

1. Comment (SAAMI): Commenter suggests that the Section 25600.1(c) definition of "consumer information" be amended to exclude "hazard communication" mandated by the European Union (EU) in the Directive on Classification, Labeling, and Packaging and/or eliminate need to reproduce requirements of other countries.

Response: This comment is not directed at the proposed amendments. No modifications were made to the regulatory text based on this comment.

Section 25600.1(i) Label

2. Comment (Hach): Commenter suggests adding to the definition of "label" the phrase "included with" before "printed on or affixed to". The addition would make the definition more clear and consistent with the definition of "labeling" which allows a package insert that accompanies the product.

Response: "Label" and "labeling" are distinct definitions. OEHHA received similar comments during the 2016 Article 6 rulemaking requesting that package inserts, owner's manuals, and other information that accompanies a product be included as a standalone safe harbor warning method. In the FSOR for the 2016 Article 6 rulemaking OEHHA noted:

> "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." (FSOR September 2016, p. 77)."

With the exception of warnings contained in federally approved prescription drug labeling,[2] OEHHA's position continues to be that owner's manuals and package inserts are not sufficient standalone safe harbor warning methods for consumer products. However, a business is free to use such a method if it can show that the warning provided is clear and reasonable under the circumstances. No modifications to the regulatory text were made based on this comment.

Section 25600.1(j) Labeling

3. Comment (CalChamber): The commenter disagrees with the reasoning for striking "including tags at the point of sale or display of a product" within the definition of "labeling". The commenter also disagrees with OEHHA's position in the ISOR that tags at the point of sale or display would not be "a clear and reasonable warning method for most product exposures as such tags would be unlikely to be associated with the products they are referring to." Such tags would have to meet the definition of "sign", and therefore be "associated with the exposure" under Section 25600.1(m). Point of

[2] See Section 25607.7. This provision was carried over from the 2008 and earlier versions of the regulations.

sale and point of display warnings are important elements of clear and reasonable warning programs and court-approved settlements.

Response: As explained in the ISOR for this regulatory proposal, the definition of "labeling" in subsection (j) was modified by adding a "package insert" as an example of "labeling." The phrase "including tags at the point of sale or display of a product" was removed from the definition primarily because it lacked clarity and did not conform to OEHHA's intent in adopting the regulations. OEHHA considers shelf tags to be a form of signage, not labeling. For a consumer product safe harbor warning, a shelf tag ("sign") may be used at the point of display where it is clearly associated with the product. OEHHA agrees with the commenter that point of display warnings are important elements of some clear and reasonable warning programs and court-approved settlements.

Point of sale warnings are fundamentally different, since such a warning may or may not be clearly associated with a specific product. If retailers were to post multiple product-specific warnings at the point of sale, it is less likely that the consumer would see the warning for any specific product, and therefore OEHHA cannot deem most point of sale warnings for specific products as clear and reasonable. Point of sale signage is considered clear and reasonable in certain safe harbor warnings (see, e.g., Alcoholic Beverage Exposure Warnings (Section 25607.3(a)(2)), and Food and Beverage Exposure Warnings for Restaurants (Section 25607.5(a)(2)), this is for very narrow circumstances that are explained in the Initial and Final statement of reasons for those provisions.[3] Outside these circumstances, a business would not receive safe harbor protection for a point of sale warning, but could use such a warning if they can show that it is clear and reasonable.

Businesses are not required to follow the safe harbor warning methods in Article 6, Subarticle 2, and may provide their own "clear and reasonable" warning *as long as it complies with Health and Safety Code section 25249.6*. Additionally, a party to a court-ordered settlement or final judgment that establishes warning methods and content is deemed to be providing a clear and reasonable warning for that exposure if the warning complies with that order or judgment.[4]

No changes to the regulatory text were made based on this comment.

[3] Available at: https://oehha.ca.gov/proposition-65/crnr/notice-adoption-article-6-clear-and-reasonable-warnings
[4] Section 25600(e).

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

Section 25601(c)

4. Comment (ERC): Commenter strongly supports the addition of the word "seen" to Section 25601(c). The commenter emphasizes that in order for a warning to be "read" and thus "understood" it must first be able to be located by consumers in order to qualify as "clear and reasonable."

Response: Comment noted. No response is required.

Section 25602 Consumer Product Exposure Warnings – Methods of Transmission

Section 25602(b)

5. Comment (SAAMI): Commenter suggests that subsection (b) should be modified to allow any warning affixed to a product to be reproduced in a catalog or on the internet. This would allow retailers to simply look at a product without contacting multiple manufacturers. As currently written, the amendment limits the validity of this practice to only short-form warnings and would not apply to other safe harbor or non-safe harbor warnings.

Response: Subsection (b) already requires a business to use the standard warning content in Section 25603(a), and allows a business to use the short-form warning content on the website if the short-form content is provided on the product. Non-safe harbor warning content used for a product may be reproduced on the website, but would not meet the safe harbor warning requirements. It may still be considered clear and reasonable under the law. No changes to the regulatory text were made based on this comment.

Section 25602(d)

6. Comment (SAAMI): Commenter suggests that subsection (d) should be amended to state the subsection does not apply to short-form warnings.

Response: This comment is not directed at the proposed amendments. No changes to the regulatory text were made based on this comment.

7. Comment (SAAMI): Commenter supports the elimination of the term "on-product warning" and the clarification that a label may be "printed on or affixed to a product or its immediate container or wrapper." The revision enables practical use of the short-form safe harbor warning.

Response: Comment noted. No response is required.

8. Comment (CalChamber): Striking the word "warning" would contradict OEHHA's earlier modification to include language that addressed concerns of manufacturers, and others in the stream of commerce that the downstream use of another language could create upstream liability. The proposed amendment would broaden the requirement so that any sign or label related to the product with consumer information in a foreign language will trigger the requirement for warnings to be provided in that language. It would increase ambiguity and spur litigation. OEHHA should either keep this language unchanged or specifically define "consumer information" rather than defining it by examples of what is included and excluded, and OEHHA should make clear that liability should rest with the entity that made the non-English communication.

Response: The intent of the modifications to this subsection is to clarify situations in which alternative language warnings must be provided. The changes were not intended to expand upon the circumstances that would trigger the requirement for a language other than English. The proposed deletion of the phrase "a warning includes" and the proposed addition of the phrase "is provided" are therefore withdrawn. The text will remain unchanged.

Section 25607.16 Vehicle Exposure Warnings – Methods of Transmission

9. Comment (AGA/AAM): While making specific reference to pickup trucks and vans may provide some clarity and consistency with respect to the application of this tailored warning to vehicles, it does not warrant OEHHA's reversal of position in terms of the owner's manual language previously finalized and relied upon by manufacturers.

Response: OEHHA disagrees with the characterization of the proposed modification of text as a "reversal of position." The modifications to the vehicle warnings provisions were proposed because this commenter requested that OEHHA provide more specificity regarding the applicability of the vehicle exposure warnings to the commenter's product lines. The changes were intended to clarify that the warning methods and content in this section can be used to provide warnings for pick-up trucks and vans as well as other passenger vehicles. However, based on this comment and as discussed further below, OEHHA has withdrawn the proposed addition of the terms "pickup truck" and "van" to Sections 25607.14, 25607.15, 25607.16, and 25607.17.

10. Comment (AGA/AAM): In light of the specific reference to "pickup truck" and "van" in Section 25607.16, the associations believe that further clarification of the definition of those terms is important for the regulated and enforcement community to understand what type of vehicles are included. Commenter suggests including definitions in the FSOR: "A "pickup truck" is a motor truck with a manufacturer's gross vehicle weight rating of less than 16,001 pounds and which is equipped with an open box-type bed not exceeding 9 feet in length. "Pickup truck" does not include a motor vehicle otherwise

meeting the above definition, that is equipped with a bedmounted storage compartment unit commony called a “utility body.””

Response: In the ISOR for this rulemaking, OEHHA explained that “commercial” and “larger” vehicles were not included within the definition of “passenger vehicle”.This comment clarifies the scope of the terms “pick-up trucks and vans” in language familiar to the automotive industry. OEHHA has, however, withdrawn all specific instances of the terms “pickup truck” and “van” in the regulatory text, making definitions for those terms in this FSOR unnecessary. No changes to the regulatory text were made based on this comment.

11. Comment (AGA/AAM): The regulation should be clarified that it applies to vehicles that are “complete”, i.e., a fully assembled vehicle. Including the word “complete” will clarify to what vehicle categories the warning applies. This is especially important for the terms, “pickup truck” and “van” for which there are no statutory definitions.

Response: This comment is not directed at the proposed amendments. Further, the regulation is intended to cover various types of passenger vehicles based on their usual and customary meaning. Including the term “complete vehicle” in the regulation would not increase clarity. No response is required.

12. Comment (AGA/AAM): Commenter renews request that OEHHA either clarify that replacement parts are covered by the safe harbor language in Sections 25607.16 and 25607.17 or provide some other regulatory relief for replacement parts. Without the inclusion of replacement parts, automakers and parts manufacturers may have to separately label hundreds of thousands of replacement parts that are substantially identical to the original parts covered by the vehicle safe harbor warning.

Response: This comment is not directed at the modification of text. A response to this request was provided in the FSOR for the original regulation (September 2016 at page 154). No response is required.

Section 25607.17 Vehicle Exposure Warnings – Content

13. Comment (AGA/AAM): Commenter states that due to the long development cycle for products and owner’s manuals, most of its members already have printed manuals with the warning text as it appeared in the January 9, 2017 version of the regulations. Companies are now faced with disposing of and reprinting hundreds of thousands of printed manuals to comply with the proposed revised safe harbor warning text for no measurable benefit. To penalize manufacturers’ good faith compliance efforts, which were based on OEHHA’s assurance of the finality of this language, would undermine both compliance with the regulations and with OEHHA’s own rulemaking process. Commenter suggests several options to address their concerns. Option 1 would be to withdraw the proposed revision to the warning text in Section 25607.17 so it would not

require the reference to pickup trucks and vans. The commenter now takes the position that the definition of "passenger vehicle" in Vehicle Code Section 465 includes pickup trucks and vans, so even with "pickup trucks and vans" stricken from the regulatory language, consumers will understand the warning applies to pickup trucks and vans. Option 2 would be to place "pickup truck, van" in brackets and add a new subsection (a)(4) which states: "The bracketed phrase 'pickup truck, van' may, but is not required to, be included in the warning content in order to meet the requirements of this section with respect to pickup trucks and vans." Option 3 would be to add a new subsection (a)(4) which states: "A warning for a motor vehicle manufactured prior to August 30, 2020 is deemed to be clear and reasonable if it complies with the content in Section 25607.17(a)(3), even if the warning does not contain the phrase 'pickup truck, van'. A warning for a motor vehicle manufactured on or after August 30, 2020, is deemed to be clear and reasonable if it fully complies with the content in Section 25607.17(a)(3)."

Response: The terms "pickup truck" and "van" were proposed in response to a request from this commenter to clarify the scope of vehicles to which the tailored warning applies. OEHHA agrees with the commenter's statement that even with this phrase stricken, consumers will understand that the warning applies to the pickup truck or van they are purchasing and driving. No additional clarification is needed as the existing definition encompasses pick-up trucks and vans. The proposed modifications to Sections 25607.16 and 25607.17 are therefore withdrawn. Similarly, the related proposed addition of the terms "pickup truck" and van" in Sections 25607.14 and 25607.15 are withdrawn.

Miscellaneous

14. Comment (Seymour): Commenter requests that the operative date be extended six months to allow for compliance with additional changes because the commenter has already started modifying their warning labels.

Response: The modified Article 6 regulations are operative August 30, 2018. Extending the operative date for an additional six months would unnecessarily delay the implementation of the regulation. Section 25600(b) provides that a person may provide a warning prior to the operative date, but this is not mandatory and within the discretion of the business. No changes to the regulatory text were made as a result of this comment.

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.

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 action. OEHHA has determined that no alternative considered would be more cost-effective, or as effective in implementing the statutory policy or other provision of law. The amendments further clarify the guidance OEHHA provides to businesses to better understand how to comply with the warning requirements.