

**Final Statement of Reasons
Title 27, California Code of Regulations**

**Amendments to
Clear and Reasonable Warnings
Sections 25602, 25607, 25607.1 and 25607.3
Related to Consumer Product, Food and Alcoholic Beverage
Exposure Warnings**



**California Environmental Protection Agency
Office of Environmental Health Hazard Assessment**

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Summary

The Office of Environmental Health Hazard Assessment (OEHHA) published the Notice of Proposed Rulemaking and Initial Statement of Reasons (ISOR) for this action on January 31, 2020, initiating a public comment period that was to close on March 16, 2020. On March 13, 2020, OEHHA augmented the record and thereby extended the comment period until March 31, 2020. No public hearing was requested for the regulatory proposal.

One written comment letter was received from a coalition of groups including the Consumer Brands Association, California Chamber of Commerce, and others¹ (“the Coalition”). Following careful consideration of the relevant comments, OEHHA modified the text of the rulemaking proposal, including the withdrawal of several initially proposed substantive modifications to the existing regulation. OEHHA announced the withdrawal of these proposed modifications in a public notice published on September 18, 2020, initiating a 15-day comment period that closed on October 5, 2020. No comments were received during the 15-day public comment period.

OEHHA is providing responses to relevant comments submitted during this rulemaking in this Final Statement of Reasons (FSOR). Some written comments submitted during the regulatory process included observations about these regulations that do not constitute an objection or recommendation directed at the proposed action or the procedures followed in this rulemaking action. In addition, some remarks consist of the commenter’s interpretation of these regulations, which does not constitute an objection or recommendation directed at changing the proposed action or the procedures followed in this rulemaking process. OEHHA is not required under the Administrative Procedure Act (APA) to respond to such remarks in the rulemaking and therefore is not providing responses to all of these comments in this FSOR. However, the absence of

¹ Other signatories to the comments submitted by the Coalition include: Almond Alliance of California, American Beverage Association, American Chemistry Council, American Coatings Association, American Bakers Association, California Attractions and Parks Association, California Building Industry Association, California Farm Bureau Federation, California Grain and Feed Association, California League of Food Processors, California Seed Association, California Manufacturers & Technology Association, California Warehouse Association, California Business Properties Association, Council for Responsible Nutrition, National Association of Music Merchants, National Confectioners Association, Personal Care & Products Council, Plumbing Manufacturers International, Industrial Environmental Association, West Coast Lumber & Building Material Association, Western Independent Refiners Association, Western Wood Preservers Institute, and The Vision Council.

responses to such comments should not be construed to mean that OEHHA in any way agrees with them.

Update of Initial Statement of Reasons

In the Notice of Augmentation of Record published on March 13, 2020, OEHHA announced that a copy of the Consent Judgment in *People v. 1800Flowers.com et al.*, San Diego County Superior Court case No. 37-2020-00009417-CU-TT-CTL, regarding warnings for exposures to alcoholic beverages referred to in the ISOR was being added to the record. OEHHA's proposed amendments conform the safe harbor regulations to the provisions of the Attorney General's settlement, which will allow businesses that may not be parties to the settlement to use the same processes for providing Proposition 65 warnings.

Summary and response to comments received during the public comment period

The Consumer Brands Association, California Chamber of Commerce, and others ("the Coalition") submitted joint comments regarding Sections 25602 and 25607. No other comments were received.

Sections 25602 and 25607 Comments

Comment 1: The commenters stated that the proposed amendments would alter the existing safe harbor warning for almost every consumer product, including food and beverages sold over the internet or through mobile applications to require a Proposition 65 warning not only at the time of the online purchase, but also on the label of the product. The commenters stated that this would essentially eliminate stand-alone online warnings as a safe harbor warning method. The commenters requested that the proposed amendments to Sections 25602 and 25607 be withdrawn.

Response: OEHHA disagrees with the commenters' characterization of the existing safe harbor warning method. However, after carefully reviewing the comments, OEHHA withdrew the proposed substantive amendments to Sections 25602 subsections (a)(2), (b), and (c); the renumbering of existing Section 25607 subsection (b); and the addition of new subsections (b), (c), and (d). OEHHA will consider proposing these or other related amendments in a future rulemaking.

Comment 2: The commenters stated that the current safe harbor regulations do not require businesses selling online to provide both a website warning and a warning on or with the same product. The commenters interpreted Section 25602(a)(2) to allow a standalone internet warning as a safe harbor warning method. The commenters also

characterized the proposed amendments as altering Section 25602(a)(2) by limiting it to warnings provided via any electronic device or process “at the physical retail location” and eliminating standalone website and mobile application warnings as safe harbor warning methods.

Response: OEHHA disagrees with the commenters’ characterization of the existing regulations. However, the proposed amendments to Section 25602(a)(2) have been withdrawn. No further response is required.

Comment 3: The commenters stated that the elimination of stand-alone online warnings as a safe harbor warning method would have wide-ranging practical effects that are highly detrimental to online retailing in California. The commenters stated that following the adoption of the regulations in 2016, many companies relied upon the plain language of the regulations to create and implement their Proposition 65 warning programs. The commenters also stated that the proposed amendments would cause businesses to have to invest significant time and resources into changing their Proposition 65 warning programs.

Response: OEHHA disagrees with the commenters’ characterization of the existing safe harbor regulations as they apply to warnings for internet purchases and their speculation on the practical effects on businesses from the previously proposed regulatory changes. This comment is based on proposed changes to the regulations that have since been withdrawn. No response is required or given. Lack of a response should not be taken as an agreement with the comment.

Comment 4: The commenters stated that Subsection (a)(2) is not a clarifying change, but rather a “wholesale change” by OEHHA to the requirements of the August 2016 Article 6 safe harbor warning regulations. The commenters stated that the 2016 FSOR indicated that websites and smart phone applications are safe harbor methods, and that OEHHA made other statements that website warnings are safe harbor warnings.

Response: OEHHA disagrees with the commenters’ characterization of the FSOR for the existing regulations. Websites and smart phones can be a part of a safe harbor warning method, but neither are a standalone safe harbor warning method. This comment is based on proposed changes to the regulations that have since been withdrawn. No response is required or given. Lack of a response should not be taken as an agreement with the comment.

Comment 5: The Coalition stated that the safe harbor regulations seek to provide warnings prior to purchase, rather than prior to exposure. The commenters also stated that if a manufacturer puts a warning on the product label and it is sold over the internet, the purchaser will receive both an internet warning and a label warning, because for

online sales an internet warning is the only way a person can get a warning prior to purchase. The commenters opined that the amendments would not further OEHHA's objective that customers receive the warning prior to purchase, and instead treat website and mobile application sales differently by requiring two different types of warnings for those purchases: online warnings and warnings on or with the product.

Response: OEHHA disagrees with the commenters' characterization of the intent of the existing regulations. This comment is based on proposed changes to the regulations that have since been withdrawn. No response is required or given. Lack of a response should not be taken as an agreement with the comment.

Comment 6: The commenters questioned OEHHA's description of the amendments as clarifications of current safe harbor requirements, and stated that OEHHA did not attempt to explain, analyze, or justify the substantive change they encompass. The commenters asserted that there is no policy-based reason why a consumer who purchases a product online should need a warning at the time of purchase and a warning on the label of the product that is shipped to the consumer. The commenters stated that consumers at brick-and-mortar stores could receive a single warning, either at the point of purchase like a shelf sign or on the label of the product, and that there is no reason to treat online purchasers any differently. The commenters further stated that OEHHA's justification for requiring point of purchase warnings, instead of warnings before exposure as required by the statute, is that the consumer is making the purchase decision at the point of purchase, and is more likely to consider and heed a warning at that point rather than once the product is already purchased and in the consumer's home. The commenters stated that for products sold online, the point of purchase is online, and that by OEHHA's reasoning, that is the point at which the warning should be provided. The commenters opined that a warning on the label of the product itself would be superfluous.

Response: OEHHA disagrees with the commenters' characterization of the proposed amendments to Section 25602. This comment is based on proposed changes to the regulations that have since been withdrawn. No response is required or given. Lack of a response should not be taken as an agreement with the comment.

Comment 7: The commenters stated that adding a requirement for on-label warnings will impact production, distribution, and manufacturing costs. The commenters also claimed that unless a business is willing to provide an on-label warning to consumers outside of California, which the law does not require and which may cause confusion or alarm among those consumers, the business will need to create two lines of products with separate stock keeping unit (SKU) designations so that online retailers will know

which are destined for California and which for other jurisdictions. The commenters opined that this would increase expenses and complexity in the supply chain and could add to consumer costs.

Response: This portion of the comment consisting of the commenters' opinion of the potential impact of the proposed changes to Section 25602 is no longer relevant. This comment is based on proposed changes to the regulations that have since been withdrawn. No response is required or given. Lack of a response should not be taken as an agreement with the comment.

Comment 8: The commenters stated that the proposed amendments would spur frivolous litigation with respect to warnings that are "clear and reasonable" under the statute and that are therefore compliant with the law, but that do not comport with the proposed two-warning approach for online sales. The commenters claimed that if a company only warns online but does not put a warning on the product label, it risks receiving a notice of violation alleging that the online warning was insufficient, because a stand-alone online warning is not a safe harbor method.

Response: OEHHA disagrees with the commenters' speculation as to increased litigation arising from the proposed changes to Section 25602. This comment is based on proposed changes to the regulations that have since been withdrawn. No response is required or given. Lack of a response should not be taken as an agreement with the comment.

Comment 9: The commenters stated that the proposed amendments would have a significant adverse economic impact on businesses selling products online and through mobile applications. The commenters also stated that those businesses would now be required to provide a second warning on the product label to fall within the safe harbor.

Response: OEHHA disagrees with the commenters' statement that a non-mandatory, safe harbor regulation will increase costs to businesses. However, the proposed changes to Section 25602 have been withdrawn. No further response to the comment is required.

General Comments

Comment 10: The commenters alleged that the proposed amendments were "tainted by a clear violation of the APA." The commenter claimed that "non-substantive changes" to the safe harbor warning regulations under section 100 of Title 1 adopted in 2017 included a change to subsection 25602(b) that was substantive. Specifically, the commenter alleged that the addition of the word "also" was substantive and therefore adopting it through Section 100 violated the APA.

Response: OEHHA strongly disagrees with the commenters' allegation that the 2017 "Section 100" addition of the word "also" in Subsections 25602(b) and (c) was adopted in violation of the APA. Throughout the prior Article 6 rulemaking process, several of the Coalition members were aware of and commented on the original regulatory action that put in place the existing requirement for two warnings when a product is sold over the internet.

In the Explanatory Statement for the non-substantive changes filed with the Office of Administrative Law (OAL) in 2017, OEHHA discussed how a combination of methods was required including website warnings to claim safe harbor protection under the existing regulations.

"Section 25602

In subsections (b) and (c) add 'also' to emphasize the safe harbor warning method requirement to provide a warning for internet and catalog sales, respectively. ***The regulations require a business wishing to provide a safe harbor warning to use a combination of warning methods for internet and catalog sales, including the method described in subsection (a) and one of the specific warning method[s] for internet or catalog sales described in Sections 25602(b) or (c).*** On p. 77 of the Final Statement of Reasons (FSR), we noted:

'...[f]or 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 additionally modified the regulatory text in response to comments about the requirement to provide an additional warning on a website or in a catalog. In the FSOR for the 2016 rulemaking, OEHHA discussed the modifications that were made in response to comments about a second warning requirement in section 25602 for internet sales. [Fn. omitted] [2016 FSOR, p. 116.] Specifically, OEHHA modified Section 25600.2(b) and (d) to require that the manufacturer pass internet warning materials along to the retailer, and in Section 25602(b) and (c) OEHHA added the ability for a business to use the 'short-form' warning on the internet and catalogs in lieu of the longer warning, in addition to including it on the product label. Section 25602(b) expressly states that 'If an on-product warning is provided pursuant to Section 25602(a)(4) the warning provided on the website may use the same content as the on-product warning.'

Similarly, 25602(c) provides, 'If an on-product warning is being provided pursuant to Section 25602(a)(4), the warning provided in the catalog may use the same

content as the on-product warning.’ These changes are consistent with the existing safe harbor warning requirement in the regulatory text; as such, the changes do not materially alter any requirement, right, responsibility, condition, prescription or other regulatory element of any California Code of Regulations provision.”²

The commenters’ reframed argument presents a novel approach to challenge the existing “two warning” requirement. This does not, however, alter or diminish the fact that the changes were properly submitted to OAL and were reviewed and approved by OAL, in full compliance with the APA.³ The extensive rulemaking record for the 2016 Article 6 rulemaking demonstrates that many of the same stakeholders raised the same issue of “second warnings” for consumer products sold on the internet, albeit in the reverse. OEHHA thoroughly considered and responded to comments, modified proposed regulatory text in response to comments, repeatedly stated that two warnings for products sold on the internet are required to claim safe harbor protection and explained the reasons for adopting the existing regulatory language. Therefore, the addition or deletion of the word “also” had no significant regulatory effect upon the regulations as adopted in 2016, and businesses that wish to take advantage of the safe harbor warning provision are still responsible for providing warnings both on or with the product *and* on the website for products sold online, regardless of the addition of the word “also” to the existing regulation.

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

Comment 11: The Coalition further alleged that OEHHA’s proposed amendments were an attempt to “shore-up its illegal amendment” to subsection 25602(b) and to correct the alleged error that OEHHA made earlier in adding the word “also”.

Response: The commenters clearly mischaracterized the original 2016 rulemaking that adopted Section 25602 as erroneous and the subsequent amendments as illegal. As explained in response to Comment 10 above, one must only review the extensive record for these regulations to determine these allegations are false.

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

² Explanatory Statement, Change without regulatory effect amending subsections (b) and (c) filed on Jan. 1, 2017 pursuant to section 100, title 1, California Code of Regulations (Register 2017, No. 2), available at <https://oehha.ca.gov/media/downloads/crnr/sec100final.pdf> (last accessed Apr. 27, 2020).

³ Office of Administrative Law, Notice of Approval of Changes without Regulatory Effect Jan. 9, 2017, available at <https://oehha.ca.gov/media/downloads/crnr/oalapproval010917.pdf> (last accessed Apr. 27, 2020).

Comment 12: The commenters claimed that OEHHA failed to analyze the economic impact of the proposed amendments in accordance with Cal. Gov. Code § 11346.3. The commenters opined that OEHHA was wrong when it claimed that “[t]he action does not impose any new requirements on private persons or businesses.”

Response: OEHHA completed an Economic Impact Assessment (EIA) in accordance with Cal. Gov. Code § 11346.3, subsection (b). The EIA was included in the ISOR⁴ for this proposed rulemaking and was made available for public comment by publication in the California Regulatory Notice Register and on the OEHHA website. The commenters are correct to the extent that in the current rulemaking, OEHHA stated that the action would not impose any new requirements upon private persons or businesses. OEHHA further explained that the action simply clarifies existing provisions of the regulations. The proposed modifications are to non-mandatory safe-harbor provisions that a business may opt to use to provide a Proposition 65 warning. If a business determines the safe harbor methods and content are too costly, they are free to provide a warning via any method they choose that complies with the Act.⁵ Further, the proposed changes to Section 25602 have been withdrawn. No further response to the comment is required.

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

Comment 13: The commenters stated that the proposed amendments cannot be justified as a policy change and therefore should be withdrawn. The commenters also requested an additional opportunity to comment in the event OEHHA decides to adopt the amendments as proposed.

Response: The comment is based on proposed changes to the regulations that have since been withdrawn. As OEHHA has withdrawn the modifications initially proposed that are addressed in this comment, there is no need to provide an additional opportunity to comment on those provisions. OEHHA provided a total of 60 days for public comment on the amendments as initially proposed, and an additional 17 days for public comment on the modified regulatory text. OEHHA is not required by the APA to consider comments submitted outside of the prescribed comment period and therefore declines to accept further comments on this proposal.

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

⁴ Initial Statement of Reasons, p. 8.

⁵ Title 27, Cal. Code of Regs., section 25600(f).

Modification of Text of Proposed Regulation 15-day Comment Period

After carefully weighing the comments received during the initial public comment period, OEHHA decided to withdraw certain proposed amendments to the regulations. OEHHA announced it was withdrawing portions of these proposed amendments in a public notice published on September 18, 2020, initiating a 15-day comment period that closed on October 5, 2020. No comments were received. The following proposed amendments to Section 25602(a)(2) which specifies warnings “at the physical retail location”; Section 25602(b) that refers to internet purchases “including purchases through mobile device applications” and hyperlink “to the warning”; and Section 25602(c) that refers to catalog purchases “in addition to any other warning provided under this subarticle” were withdrawn. Also, the renumbering of existing Section 25607(b) to Section 25607(d) was withdrawn because the addition of a new Section 25607(b) that states an on-product warning is required in addition to an online or catalog warning for those types of purchases, and a new subsection (c) that imposed an alternative language requirement were withdrawn. OEHHA may propose these or other amendments in a future rulemaking. All other proposed amendments remained.

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 considered taking no action but finds that taking no action is inconsistent with the intent of the Act and its implementing regulations and would not provide all businesses that sell alcoholic beverages on the internet or through apps the opportunity to use the

methods set out in the Attorney General's settlement whether they were parties to that settlement or not. Therefore, 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.