

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

**SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986  
PROPOSITION 65**

**NOTICE**

**SECOND 15-DAY MODIFICATION TO PROPOSED AMENDMENTS TO  
TITLE 27, CALIFORNIA CODE OF REGULATIONS  
SECTIONS 25601, 25602, 25603, 25607.1, 25607.2  
ARTICLE 6, CLEAR AND REASONABLE WARNINGS - CONSUMER PRODUCTS**

**ADDENDUM TO THE INITIAL STATEMENT OF REASONS**

**April 5, 2022**

Public Availability Date: April 5, 2022

Deadline for Public Comment: April 20, 2022

As required by Government Code section 11346.8(c), and Title 1, section 44 of the California Code of Regulations, the Office of Environmental Health Hazard Assessment (OEHHA) is providing notice of changes to the proposed regulatory action to amend California Code of Regulations, Title 27, Sections<sup>1</sup> 25601, 25602, 25603, 25607.1, and 25607.2. Also included in this notice is an addendum to the Initial Statement of Reasons.

This notice initiates a public comment period beginning April 5, 2022, that will close on April 20, 2022. Details on how to comment are given below.

**Process to Date**

The Notice of Proposed Rulemaking was published on January 8, 2021, in the California Regulatory Notice Register (Register No. Z2020-1229-01). This initiated a comment period that was extended and closed on March 29, 2021. A public hearing was held on March 11, 2021, where OEHHA received 21 oral comments. Comments were submitted from 160 individuals or organizations. After considering public comments, a Notice of Modification of Text was published in the California Regulatory

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<sup>1</sup> All references to Sections are to sections in Title 27, California Code of Regulations, unless otherwise noted.

Notice Register (Register 2021, Number 51-Z) on December 17, 2021. This initiated a public comment period that was extended and closed on January 21, 2022. Comments were received from 36 individuals or organizations.

### Clarification of Regulatory Text in First 15-Day Modification

The first modification, published on December 17, 2021, had regulation text that did not show some language that had been stricken from the proposed amendment. These changes are being provided in this document for public comment.

The omissions and corrections to the first modified regulation text – with the omitted characters and text *italicized* - are as follows:

- In subsection 25602(a)(4)(A) the minimum label size of “5” which was replaced with “12”. While the “12” was shown in double underline, the “5” was not shown in double strikeout. 25602(a)(4)(A) is deleted in its entirety in the second modification, making this a moot issue.
- “[name of chemical]” was shown instead of
  - “[Name of ~~one or more chemicals known to cause cancer~~]” in 25603(b)(2)(A)(1) and 25607.2(b)(1)(A)(1) (current numbering),
  - “[Name of ~~one or more chemicals known to cause reproductive toxicity~~]” in 25603(b)(2)(B)(1) and 25607.2(b)(1)(B)(1) (current numbering)
  - “[Name of ~~one or more chemicals known to cause cancer~~]” in 25603(b)(2)(C)(1) and 25607.2(b)(1)(C)(1) (current numbering),
  - “[Name of ~~one or more chemicals known to cause reproductive toxicity~~]” in 25603(b)(2)(D)(1) and 25607.2(b)(1)(D)(1) (current numbering),
  - “[Name of ~~one or more chemicals known to cause cancer and reproductive toxicity~~]” in 25603(b)(2)(E)(1) and 25607.2(b)(1)(E)(1) (current numbering)

The language indicates where businesses may insert the name of the chemical about which they were providing warning. The language in the modified text “[name of chemical]” makes clear that the name of only one chemical is required in each of the parentheticals. This was done in response to comments. The omitted text (in double strike out and italic) was inadvertent.

OEHHA notes that the option to use signal words **“CA WARNING:”** or **“CALIFORNIA WARNING:”** in addition to **“WARNING”** in the first 15-day modification of Subsections 25602(b), 25603(a)(2), 25603(c) and 25607.2(a)(1) also affect the full-length safe harbor warning for consumer products.

The full modified text, including the first and second 15-day modifications, is accurately displayed in Attachment 1.

## **Second 15-Day Modification to Proposed Amendments**

### ***Overview of Second Modification***

After reviewing the comments on the first modifications, dated, December 17, 2021, the proposed regulatory text is being further modified. The specific modifications to the proposed amendments are shown in the regulatory text (Attachment 1). The proposed changes are outlined below, followed by the rationale for the change.

- The label size and package shape limitations on the use of the short-form warning were removed in Section 25602(a)(4). This modification means that the short form can be used on product labels of any size, regardless of package size and shape.
- The requirement in Section 25602(a)(4) that the font type size must be the same as the largest type size providing consumer information was removed. The existing provision requiring a minimum of 6-point type size when using short-form warnings remains unchanged.
- The proposed amendments were modified in Section 25602(a)(4) to reference the Section 25601(c) to make clear the existing requirement “to render the warning likely to be seen, read, and understood by an ordinary individual under customary conditions of purchase or use”.
- The language “exposes you to” in subsections 25603(b) and 25607.2(b) has been changed to “can expose you to” and thus in this regard conforms with the general content language in the general consumer safe harbor warning (Section 25603).
- The date that the regulation becomes operative has been modified to be two years rather than one year after the effective date of the amendments in Subsections 25602(e) and 25607.2(c). This allows additional time for business to implement changes to the short form. This is the same time period between the effective and operational dates as the 2016 major changes to the Article 6 safe harbor warning regulations.
- Minor changes were made for consistency across sections, and to correct a typographical error in the regulatory text.

## **Rationale**

### *Subsection 25602(a)(4)*

In the original proposal, subsection (a)(4) was amended to add two conditions that would allow for the use of a short form warning on a consumer product: a restriction of the total surface area of the product available for labeling and the requirement that the package shape or size would not be able to accommodate the general consumer product full length warning described in Section 25603(a). The April 5, 2022, modifications remove these requirements and also remove one requirement regarding font size – that it must be the same as the largest type size providing consumer information. Thus, the short form warning can be used on any package regardless of whether it can accommodate the full-length warning or the short form.

A reference to existing subsection 25601(c) was added to subsection (a)(4) a to make clear the existing requirements for a short-form warning. That is, as before, the use of the warning is governed by the conditions in subsection 25601(c) that the warning “must be prominently displayed” and it “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 seen, read, and understood by an ordinary individual under customary conditions of purchase or use.”

OEHHA received a number of comments about the maximum label size for use of the short form warning (proposed in Subsection 25602(a)(4)(A)). Comments raised questions about the feasibility of using the long form Proposition 65 safe harbor warning on a variety of products with label sizes greater than 12 square inches, as well as about how label size was to be determined. The inclusion of Proposition 65 information on labels is an important method of informing consumers about chemical exposures and the size limitation could in some cases make the placement of warnings on labels unnecessarily difficult and complex. The proposed label size amendment was therefore modified to revert to the existing provision allowing the use of the short form on product labels of any size.

The proposed package shape limitation (subsection 25602(a)(4)(B)) was removed to address the difficulty in determining compliance with the provision because of lack of specificity in how to determine whether the package shape and label could or could not accommodate the full-length warning.

The existing requirement in Section 25602(a) that the font size must be the same as the largest type size providing consumer information was removed. OEHHA is making this change because recent federal requirements would in some cases result in oversized

short-form warnings, and provide a disincentive to adding Proposition 65 warnings to label, an important method for giving warning. For example, the Nutrition Facts Label final rule which recently became effective requires in some instances large font sizes on nutrition labels (e.g., 16 and 22 point font)<sup>2 3</sup> and this in some circumstances would result in the short form warning taking up a high percentage of the product label, dominating other important consumer information, and rendering its use infeasible.

*Subsections 25603(b) and 25607.2(b)*

The language “exposes you to” in subsections 25603(b) and 25607.2(b) has been changed to “can expose you to” and thus in this regard conforms with the general content language in the general consumer safe harbor warning (Section 25603).

One consideration in adopting this language in Section 25603 in 2016<sup>4</sup> was that some products might result in exposures requiring warning to some people but not others, depending on how they are used. Also, 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”.

The word “and” was added to subsections 25603(b)(2) and 25607.2(b)(1) to conform to structure of subsection 25603(a)(2). Similarly section 25607.2(b)(1) was renumbered to conform to the structure of 25603(a)(2). These changes were non-substantive.

*Subsections 25602(e), 25603(d) and 25607.2(c)*

The April 5, 2022 modification increases the operative date for these proposed amendments from one year to two years from the effective date of the amendments. Several comments were received raising concerns about the feasibility of being able to make changes in the one-year timeframe. The two-year timeframe between the effective and operative dates (being proposed in this modification) is the same as

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<sup>2</sup> See 21 CFR subpart 101.9(d) (1). Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=101.9>. Last accessed 4/4/2022.

<sup>3</sup> Example visual at: <https://www.fda.gov/media/97999/download>

<sup>4</sup> 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. July 19, 2016, page 111. Available at: <https://oehha.ca.gov/media/downloads/cnr/art6fsor090116.pdf>. Last accessed 4/4/2022.

provided in the 2016 warning regulation that made major changes to the safe harbor warnings. It covered a number of provisions in addition to the short form safe harbor warning provisions. Businesses were able to achieve that timeframe. Products manufactured prior to the operative date can still have safe-harbor short-form warnings that comply with the 2016 regulations. Such products do not need to be relabeled to have safe-harbor warnings.

As noted in the 2016 rulemaking, “While the safe harbor warnings are voluntary, many businesses using the current safe harbor warnings may wish to transition to the new warnings since they offer safe harbor against enforcement actions.”<sup>5</sup> The increase in timeframe by one year provides businesses two years (the same period of time for the more extensive 2016 warning regulations) to make this change should they choose to do so.

### **Addendum to the Initial Statement of Reasons**

Changes to the January 2021 proposed amendments were made based on public comments. In addition to the discussion above, this Addendum to the Initial Statement of Reasons (ISOR) provides further information on the necessity of the proposal. It also provides language in the summary that was inadvertently omitted.

#### ***Addition to the Summary***

In finalizing the ISOR, text was inadvertently deleted from the Summary on page 3<sup>6</sup>. The text deleted is provided in *italic* below. Therefore, OEHHA is modifying the ISOR on page 3 by adding the italicized text in the language below:


... “In August 2016, the Office of Environmental Health Hazard Assessment (OEHHA) adopted major changes to the “Clear and Reasonable” safe harbor warning regulations (Title 27 of the California Code of Regulations, Article 6), originally adopted more than 30 years ago. The primary purpose of the rulemaking was to provide consumers with more specific information about the chemicals they are exposed to, and to point them to a newly constructed OEHHA warnings website for further *information about the chemicals, common routes of exposure and simple ways to reduce or eliminate common exposures. The 2016 regulations replaced nearly all the previously existing Proposition 65 warning regulations. These regulations became fully effective in August 2018.*

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<sup>5</sup> Ibid, page 17.

<sup>6</sup> Available at: <https://oehha.ca.gov/media/downloads/cmr/p65shortformisorf2021.pdf> or from Monet Vela as indicated in this notice.

*“The 2016 safe-harbor warnings require the name of at least one chemical for which the warning is being given and a link to the OEHHA warnings website where the consumer can find more information on the chemical and how to reduce exposures to it:*

*“ **WARNING:** This product can expose you to chemicals including formaldehyde and toluene which are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).*

*“During the development of the 2016 regulations, several stakeholders raised a concern that a full-length safe-harbor warning would not fit on small products or containers. In response to those concerns, OEHHA included the option to provide a “short-form” warning on a product label.”*

### ***Necessity***

The proposed regulation is necessary to ensure that California consumers receive information in safe harbor short form warnings that is comparable to the content contained in the general safe-harbor warnings for consumer products (Section 25603(a), but in a more compressed form. The naming of a carcinogen and reproductive toxicant can inform consumers in their decisions about their use of a product. OEHHA’s Proposition 65 Warnings Website (with a URL of [www.P65warnings.ca.gov](http://www.P65warnings.ca.gov) that must be included in safe-harbor warnings) has information on chemicals frequently named in warnings, including advice to consumers who wish to minimize their exposures to those chemicals. In addition, by requiring safe-harbor short-form warnings to name a chemical, the proposed regulation may discourage some businesses from providing prophylactic warnings that confuse consumers and dilute the overall value of Proposition 65 warnings. The inclusion of terms such as “Cancer risk from exposure to [chemical]”, or the alternative option “Can expose you to [chemical], a carcinogen” and similar language for reproductive toxicants provides a more specific explanation to consumers about why the warning is being given.

In providing for a short-form warning in its 2016 warning regulations, OEHHA did not intend to provide a widely used exception to its general safe-harbor requirement for warnings to name the chemical or the potential for the product to require exposure to that chemical. Instead, OEHHA envisioned limited use of the short-form warning on very small packages that could not accommodate a longer warning. The changes to the modified regulation text preserve flexibility for businesses to use short-form warnings on any consumer product, regardless of the size and shape of the package, as well as for internet and catalog sales, while ensuring the quality of information in short-form

warnings is comparable to those in the general consumer product safe-harbor warning. This will provide consumers with meaningful information and may discourage over-warning while furthering the consumer right-to know purpose of Proposition 65.

***Technical, Theoretical, and/or Empirical Study, Reports, or Documents Relied Upon***

The following is an additional technical, theoretical, and/or empirical studies, reports, or documents that OEHHA has relied upon during this rulemaking process. This is in addition to those documents that have already been listed in the Initial Statement of Reasons.

- [21 CFR Part 101, subpart 101.9\(d\)](#)

**Accessing the Modified Regulatory Text**

The full regulatory text, with the original proposed amendment and subsequent two modifications shown, is available on the OEHHA website at [www.oehha.ca.gov](http://www.oehha.ca.gov) or on request from Monet Vela in the OEHHA Legal Office at [monet.vela@oehha.ca.gov](mailto:monet.vela@oehha.ca.gov) or (916) 323-2517. It is also attached to this notice as **Attachment 1**.

**Submission of Comments**

The public may comment on the Clarification of Regulatory Text in First 15-Day Modification, the Second 15-Day Modifications to Proposed Amendments (the rationale and Attachment 1), and the Addendum to the Initial Statement of Reasons.

All written comments must be submitted to OEHHA by electronic submission, mail, or hand-delivery, by **April 20, 2022**, as indicated below. OEHHA strongly recommends that comments be submitted electronically through our website at <https://oehha.ca.gov/comments>, rather than in paper form. Alternatively, comments can be submitted in paper form, by either mail or delivered in person.

Electronic Submission (preferred):

Though OEHHA website at: <https://oehha.ca.gov/comments>

Mailed Submission:

Attention: Monet Vela  
Office of Environmental Health Hazard Assessment  
P. O. Box 4010  
Sacramento, California 95812-4010

In-person delivery submission:



Attention: Monet Vela  
Office of Environmental Health Hazard Assessment  
1001 I Street, 23rd Floor  
Sacramento, California 95814

OEHHA encourages all commenters to submit their comments in a format compliant with Section 508 of the federal Rehabilitation Act, Web Content Accessibility Guidelines 2.0<sup>7</sup> and California Government Code sections 7405 and 11135, so that they can be read using screen reader technology and those with visual impairments are able to listen to them.

Inquiries concerning the action described in this notice may be directed to [Monet Vela](#), in writing, at the address given above, or by telephone at (916) 323-2517.

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<sup>7</sup> <https://www.w3.org/WAI/standards-guidelines/wcag/>