Initial Statement of Reasons Title 27, California Code of Regulations Proposed Amendments to Article 6

## **Clear and Reasonable Warnings:**

**Short-Form Warnings for Consumer Product Exposures** 

January 2021



California Environmental Protection Agency Office of Environmental Health Hazard Assessment

## **Table of Contents**

Summary3	
Background/Problem to be Addressed by the Proposed Rulemaking4	
Proposed Amendments8	
§ 25601 Safe Harbor Clear and Reasonable Warnings – Methods and Content	
§ 25602. Consumer Product Exposure Warnings – Methods of Transmission	
§ 25603. Consumer Product Exposure Warnings – Content	
§ 25607.2. Food Exposure Warnings – Content	
Necessity15	
Benefits of the Proposed Regulation15	
Technical, Theoretical, and/or Empirical Study, Reports, or Documents Relied Upon .15	
Reasonable Alternatives to the Regulation and the Agency's Reasons for Rejecting Those Alternatives	
Reasonable Alternatives to the Proposed Regulatory Action that Would Lessen Any Adverse Impact on Small Business and the Agency's Reasons for Rejecting Those Alternatives	
Evidence Supporting Finding of No Significant Adverse Economic Impact on Business 16	
Efforts to Avoid Unnecessary Duplication or Conflicts with Federal Regulations Contained in the Code of Federal Regulations Addressing the Same Issues16	
Economic Impact Assessment Required by Gov. Code section 11346.3(b)17	
Creation or Elimination of Jobs within the State of California	

Benefits of the Proposed Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment	
Appendix A – Examples of Actual Short-Form Warnings	
Appendix B - Examples of Short-form Warnings Compliant with the Proposed Amended Regulations on 5 sq. in Product Surface Area*	21
Short-form warning on 5" x 1" product surface area	
Short-form warning on 3" x 1.75" Product Surface Area	

## Summary

Proposition 65<sup>1</sup> requires businesses to provide a clear and reasonable warning before they knowingly and intentionally cause an exposure to a chemical listed as known to the state to cause cancer or reproductive toxicity. 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

to those concerns, OEHHA included the option to provide a "short-form" warning on a product label. An example of a short-form warning is the following:

**WARNING:** Cancer and Reproductive Harm - <u>www.P65Warnings.ca.gov</u>.

Implementation of the warning regulations has revealed the need for express limits on the use of the short-form warning for consumer products. The regulation did not limit application of the short-form warning to a maximum label surface area. While OEHHA intended for this warning option to only be used for small products or containers with insufficient space for the longer warning, businesses have used the short form warning on a wide range of consumer products that have more than enough label space for the longer warning. Just as concerning, the short-form warning is also being placed on some products even when the

<sup>&</sup>lt;sup>1</sup> Health and Safety Code Section 25249.5 et seq., The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as "Proposition 65". Hereafter referred to as "Proposition 65" or "the Act".

business has no knowledge of an exposure to a listed chemical requiring a Proposition 65 warning.

This rulemaking would amend the safe harbor warning regulations to improve the short-form warnings by communicating additional information about chemical exposures to consumers including the chemical name, so the consumer can obtain more specific information about it on the OEHHA website. The rulemaking would expressly modify the existing short-form warning provisions as follows:

- Only allow use of the short-form warning on products with 5 square inches or less of label space.
- Eliminate use of short-form warnings for internet and catalog warnings.
- Clarify how short-form warnings can be used for food products.
- Require that the name of at least one chemical be included in the short-form warning.

For businesses that choose to use the modified short-form warning, the proposed regulation provides a one-year phase-in period for existing products to allow a smooth transition to the modified warning. Further, the proposed regulation provides an unlimited sell-through period for products that had compliant warnings when they were manufactured, thus allowing businesses to avoid recalling items in the stream of commerce to apply the modified short-form warning.

An example of the proposed short-form warning is the following:

**WARNING:** Cancer Risk From Formaldehyde and Reproductive Risk From Toluene Exposure - www.P65Warnings.ca.gov.

Without these changes, use of the short-form warning will continue to be inconsistent with the intent of the Act and OEHHA's intent in adopting the 2016 regulations — that warnings communicate meaningful information about chemical exposures to consumers, and that short-form warnings be used only on labels for small products that cannot accommodate the full-length warning content described in Section  $25603(a)^2$ .

# Background/Problem to be Addressed by the Proposed Rulemaking

OEHHA seeks to address in this regulatory proposal the following primary concerns with the current uses of the short-form warnings: 1) Businesses are not required to identify a chemical or chemicals in the short-form warning, which significantly limits the usefulness of the warnings to consumers, 2) Businesses

<sup>&</sup>lt;sup>2</sup> Article 6 Clear and Reasonable Warnings, Initial Statement of Reasons (2015), p.31.

use the short-form warning for products that can easily accommodate a longer warning, and 3) Businesses use the short-form warning prophylactically when no warning is required.

OEHHA explained its intent regarding use of short-form warnings in the Initial Statement of Reasons (ISOR)<sup>3</sup> and Final Statement of Reasons (FSOR)<sup>4</sup> for the 2016 rulemaking:

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 onproduct 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.<sup>5</sup> (emphasis added)

After OEHHA adopted the Article 6 regulations in August 2016, OEHHA discovered that many businesses were using the short-form warning for all kinds of consumer products, regardless of product size. OEHHA also did not anticipate the widespread use of short-form warnings for food products but received numerous inquiries from businesses seeking clarification as to how and whether the short-form warning could be used as a safe harbor warning for food products. Further, OEHHA determined that many businesses are using the short-form warning because it protects them from potential litigation without requiring them to name a specific chemical exposure. As a result, these businesses likely have provided warnings for exposures that do not or cannot occur from use of their products.

OEHHA frequently receives inquiries from the public regarding exposures from a

<sup>&</sup>lt;sup>3</sup> Article 6 Clear and Reasonable Warnings Regulations, Initial Statement of Reasons (2015), available at

https://oehha.ca.gov/media/downloads/crnr/112715warningreg20isor.pdf (last accessed May 15, 2020).

<sup>&</sup>lt;sup>4</sup> Article 6 Clear and Reasonable Warnings Regulations, Final Statement of Reasons (2016), available at <u>https://oehha.ca.gov/media/downloads/crnr/art6fsor090116.pdf</u> (last accessed May 15, 2020).

<sup>&</sup>lt;sup>5</sup> Article 6 Initial Statement of Reasons (2015), *supra* note 3.

wide range of consumer products labeled with a short-form warning. An informal tally of public inquiries to OEHHA related to Proposition 65 warnings during December 2019 through December 2020, nearly 70% of consumer inquiries requested more information about a specific product, and at least 18% of consumer inquiries included a request for information regarding a short-form consumer product exposure warning. These consumers wanted to know the name of the chemical to which they might be exposed.

As an example, during the current COVID-19 emergency, OEHHA has received multiple inquiries from members of the public concerning short-form warnings provided on HEPA vacuum filters because consumers were using the filters in home-made face masks. Consumers wanted information regarding the chemical(s) for which the businesses were providing a warning, so that they could make an informed decision whether to use the product.

Further, while a short-form warning may be appropriate for a small item such as specialty adhesives in very small tubes or similar products where label space is very limited, short-form warnings have been provided on a wide range of consumer products which do not have such constraints. For example, many manufacturers are providing short-form warnings on large appliances such as refrigerators, ranges, washers, and dryers; as well as on miscellaneous consumer products such as backpack leaf blowers, guitars, nursery plant containers, luggage, and vacuum cleaners.<sup>6,7</sup> There is no reason to use short-form warnings for such products. There is ample space on the packages of these products for businesses to provide warnings that name a chemical or chemicals so consumers know they can be exposed to those chemicals through use of the product.

To address these types of issues and obtain information for the public regarding consumer exposures to listed chemicals, OEHHA sent 17 letters during 2019-2020 to businesses providing short-form warnings requesting chemical exposure information for the Proposition 65 Warnings Website (http://www.p65/warnings.ca.gov) as allowed by Section 25205 of the regulations. OEHHA received limited chemical exposure information from some businesses; other companies failed to respond to OEHHA's request for information. Most did not identify an exposure that likely needed a warning.

For example, a manufacturer of appliances displaying short-form warnings

<sup>&</sup>lt;sup>6</sup> See Appendix A for examples of actual short-form warnings in use on consumer products.

<sup>&</sup>lt;sup>7</sup> In one instance, a hunting, shooting, and fishing retailer posted short-form warnings for cancer and reproductive toxicity at the front entrance of one of their retail locations. Such a warning clearly does not comply with the safe harbor requirements of Article 6.

stated,

"...due to the complexity of the appliances we manufacture, many of the components are located within interior parts of our appliances, and thus, the average consumer may not ever be exposed to the listed chemicals. Despite this, [manufacturer] chooses to include the Proposition 65 warning out of an abundance of caution."

A guitar manufacturer replied,

"...two chemicals were listed as ingredients in paint ... that is applied on to some guitars ... that under normal use conditions ... [manufacturer] does not anticipate that its guitars would expose a customer to these chemicals, but that the warnings were provided out of an abundance of caution."

Some consumers have informed OEHHA of instances where a business representative told them that they are required to provide a Proposition 65 warning for all products sold in California but when asked would not provide the name of the listed chemical that the warning was provided for, because the business is not required to do so, because such information is "confidential", or the specific chemical name is unknown. These practices are contrary to the statutory requirement to give clear and reasonable warnings for *exposures* to *listed chemicals*, and OEHHA's stated intention in the 2016 rulemaking to provide more meaningful and informative warnings for consumer product exposures.

The current short-form warning facilitates such "over-warning" by providing businesses with safe harbor protection from enforcement actions without requiring the business to provide sufficient information to consumers. The warning includes the address of OEHHA's Proposition 65 warnings website, but the sheer number and variety of products with short-form warnings have made it impossible for OEHHA to obtain and post information about many of these products on its website. Thus, consumers must contact the manufacturer or seller of the product to try to determine why they are being warned, and what the warning means.

After carefully assessing businesses' use of the short-form warning since the regulations were adopted in 2016,<sup>8</sup> OEHHA has determined that changes to the regulations are necessary. Without these proposed changes, use of the short-form warning will continue to result in many warnings being inconsistent with the intent of the Act, OEHHA's intent in adopting the 2016 regulations, and its stated intent for adopting the short-form warning<sup>9</sup>.

<sup>&</sup>lt;sup>8</sup> The revised Article 6 Clear and Reasonable Warnings regulations were adopted on August 30, 2016 and became operative on August 30, 2018.
<sup>9</sup> Article 6 ISOR (2015), *supra* note 3.

Based on OEHHA's experience with the current short-form warning, OEHHA has determined that, in order for a business to obtain safe harbor protection. consumer product warnings must include the name of at least one listed chemical to which the consumer may be exposed. While OEHHA still acknowledges the need for product warnings on very small packages, OEHHA does not believe the small size of a package justifies the failure to include any chemical-exposure information. Further, OEHHA anticipates that some businesses may stop the practice of over-warning as a strategy to receive safe harbor protection if they must warn customers of a specific chemical exposure that can occur through use of their product. A reduction in over-warning furthers the purposes of the Act by reducing the unnecessary proliferation of Proposition 65 warnings where a chemical exposure is unlikely to occur and ensuring that consumers are provided with truthful, accurate information about anticipated exposures to listed chemicals from consumer products where they can occur. Each of the proposed amendments to the warning regulations is discussed below.

## **Proposed Amendments**

## § 25601 Safe Harbor Clear and Reasonable Warnings – Methods and Content

## Subsection (b)

The phrase, "Except as provided in Section 25603(c)," would be deleted, along with Section 25603(c). Section 25603(c) currently provides that a short-form consumer product exposure warning does not require the name of a listed chemical. By removing Section 25603(c), the proposed amendments to Section 25603, discussed in detail below, would require a business to provide the name of one or more listed chemicals for which the warning is being given. Thus, the reference in Section 25601(b) would also be removed.

## § 25602. Consumer Product Exposure Warnings – Methods of Transmission.

### Subsection (a)

OEHHA is proposing a non-substantive amendment to subsection (a) by replacing the existing reference to Section 25607.1 with a reference to Section 25607. This change is proposed to correct a typographical error in the existing regulation.

OEHHA is additionally proposing substantive changes to subsection (a). The word "product" would be added before the word "label" in subsections (a)(3) and (a)(4), to clarify that use of this warning method is limited to the physical

parameters of a consumer product label and therefore cannot be used in other circumstances such as warnings for environmental exposures.

Amendments to Subsection (a)(4) specify the three conditions that would allow for the use of a short-form warning on a consumer product. Namely, a short-form warning may only be used if:

- (A) the total surface area of the product available for labeling is 5 square inches or less, and;
- (B) the package shape or size cannot accommodate the full-length warning content described in Section 25603(a), and
- (C) the entire warning is printed in a type size no smaller than the largest type size used for other consumer information on the product, but in no case no smaller than 6-point type.

Appendix B to this initial statement of reasons provides examples of the proposed short-form warning content in 6, 8, and 10-point type sizes on an approximately 5 square inch surface area.

In Subsection 25602(a)(4)(C), which sets forth the minimum 6-point type in a short-form warning,<sup>10</sup> the words "must be" are deleted as no longer necessary because of the proposed addition of the phrase "may only be used if" in subsection (a)(4). The words "is printed" were added for consistency with the requirement that the short-form warning be used only on product labels.

These proposed requirements would assure uniform prominence, conspicuousness, and readability of the warning on small product packages while eliminating the use of the short-form warning on labels for larger consumer products that can easily accommodate the full warning message. The amendments will ensure that a short-form warning option is still available for consumer products sold in small packages.

## Subsections (b) and (c)

Because there are generally fewer space limitations on a webpage or in a catalog, use of a short-form warning is not appropriate in those contexts. The amendments would delete the provisions stating, "If a warning is provided using the short-form warning label..., the warning provided on the website may use the same content" and "If a short-form warning is being provided on the label...the warning provided in the catalog may use the same content" respectively. This amendment is consistent with OEHHA's determination that the short-form warning should only be used for products with small packaging, and that there

<sup>&</sup>lt;sup>10</sup> The existing type size requirement of Section 25602, subsection (a)(4) is unchanged by this rulemaking proposal.

are no comparable space limitations on a webpage or product catalog. Because, as discussed below, the short-form warning will include specific chemicalexposure information, the additional information needed for a website or catalog warning will be minimal. In addition, these amendments will help reduce potentially unnecessary warnings for products sold online or via a catalog when the business does not know there is an exposure to a listed chemical from that consumer product. OEHHA believes these amendments will discourage unnecessary prophylactic warnings which dilute the effectiveness of warnings for actual exposures to listed chemicals.

## Subsection (e)

New subsection (e) would provide a one-year delayed operative date after the effective date of the amendments to allow businesses time to make the necessary changes to their safe harbor warnings. During this one-year phase-in period, businesses would have the option of using either the 2016 version of the short-form regulations that became operative in 2018, or the amended provisions. OEHHA is aware that modifying the short-form warning provisions may require some retooling by businesses who chose to comply with these safe harbor regulations. These effects should be short-term, however, and any related costs can be spread over the one-year phase in period.

Proposed subsection (e) also includes a "sell-through" provision to facilitate compliance with the amended regulations. During the 2016 rulemaking, some manufacturers 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 produced with compliant warnings and a long shelf-life. To alleviate similar concerns, OEHHA has included a "sell-through" provision for products manufactured before the operative date of the amendments to the short-form warning provisions.

In other words, short-form warnings on products manufactured prior to the operative date of the amendments will continue to be considered compliant if they comply with the earlier regulations. Although the proposed amendments are narrowly focused and will impact only those businesses currently providing short-form safe harbor warnings, OEHHA believes the sell-through period will help mitigate or avoid potential logistical issues and will allow manufacturers and retailers sufficient time to transition to the new content without the need to locate and re-label products already in the chain of commerce. Similar sell-through provisions would be added to the amended consumer product exposure warnings content in Section 25603 and the food exposure warnings content in Section 25607.2.

### § 25603. Consumer Product Exposure Warnings – Content.

### Subsection (a)

OEHHA is proposing a non-substantive amendment to subsection (a) by replacing the existing reference to Section 25607.1 with a reference to Section 25607. This change is proposed to correct a typographical error in the existing regulation.

## Subsection (b)

The proposed amendments would revise subsections (b)(2)(A) - (b)(2)(C) and add new subsection (b)(2)(D). The words "pursuant to Section 25602(a)(4)" are proposed for addition to subsection (b) to make clear that short-form warnings may only be used when the applicable requirements of Section 25602(a)(4) concerning the available surface area on a product label and the ability to accommodate a full-length warning, and the minimum type size requirements are met. The amended regulation would change the safe harbor short-form warning content to require that the name of one or more listed chemicals for which the warning is being provided is stated in the warning. Subsection (b)(2)(D) would be added to provide short-form warning content for an exposure to a chemical that is listed as both a carcinogen and reproductive toxicant. This is consistent with the full-length warning in Section 25603(a)(2)(D) which addresses the same scenario.

The warning content has also been modified by adding the terms "risk" and "exposure" to warn a consumer that there is a risk of cancer and/or reproductive harm from exposure to a listed chemical from a consumer product. This warning is more precise and informative than the current short-form warning that only refers to the end point, i.e., "Cancer" and/or "Reproductive Harm".

The term "risk", added with reference to the applicable endpoint(s), will help better convey the risk a consumer is facing from exposure to the listed chemical. OEHHA has previously determined that informing people regarding *exposures* to listed chemical chemicals is consistent with the right-to-know purpose of the Act. As OEHHA noted in the 2015 ISOR for Article 6:

"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."<sup>11</sup>

OEHHA has determined that the concept of exposure is an important component of the full-length Proposition 65 safe harbor warnings and should likewise be incorporated in the short-form consumer product exposure warnings. As an example, a short-form warning for a consumer product exposure to the carcinogen Diisononyl Phthalate (DINP) would read thus:

> ▲ WARNING: Cancer Risk From Diisononyl Phthalate (DINP) Exposure – www.P65Warnings.ca.gov.

The short form warning authorized in the proposed regulations thus would provide businesses with the continued option to use truncated, short-form warning content for consumer products that have little available surface space for a warning. At the same time, the inclusion of the name of at least one listed chemical (or two chemicals if the exposures are to a carcinogen and a reproductive toxicant) would further consumers' right-to-know about listed chemicals they may be exposed to from a consumer product.

The proposed modifications would also help curb the current business practice of providing unnecessary "prophylactic" warnings without knowledge of any exposure to a listed chemical from the consumer product.

## Subsections (c) and (d)

Subsection (c) would be deleted because the changes to subsections (b)(2)(A) - (b)(2)(C) and new subsection (b)(2)(D) would require the name of one or more listed chemicals in short-form consumer product exposure warnings. The elimination of subsection (c) necessitates the renumbering of current subsection (d) to (c).

New subsection (d) would be added to include the one-year delayed operative

<sup>&</sup>lt;sup>11</sup> Article 6 ISOR (2015), *supra* note 3.

date discussed above for the amendments to Section 25603 to facilitate transition to the amended safe harbor warnings. It would also provide a sell-through provision, as described above in the discussion of Section 25602. Additionally, the amended regulations would not become operative until one year after their adoption. During this one-year period, businesses will have the option of using either 2016 version of the short-form warning provisions that became operative in 2018, or the modified short-form warning. The "sell-through" provision in subsection (d) applies to products manufactured before the operative date of the amendments to this section. Under this provision, compliance with the 2016 version of the short-form warning regulation will be considered compliant with the proposed regulation if the consumer product was manufactured prior to the operative date of the proposed amended regulation.

## § 25607.2. Food Exposure Warnings – Content.

The proposed amendments would add new subsections (b)(1) - (b)(6) and (c) to the tailored warning for food exposures. When OEHHA adopted the short-form warning content for safe harbor consumer product exposure warnings in the 2016 Clear and Reasonable Warnings rulemaking, OEHHA did not anticipate businesses using short-form warnings for food products. As businesses began providing Proposition 65 warnings using the new safe harbor warning methods and content, OEHHA received numerous inquiries from businesses seeking clarification as to whether the short-form warning could be used as a safe harbor warning for food products. This proposed rulemaking would clarify that short-form warnings may be used to provide safe harbor warnings for food products, with appropriate modifications to conform to the existing full-length warning requirements for food exposure warnings (i.e., the warning symbol is not required for foods, but the warning must be enclosed in a box).

## Subsection (a)

Subsection (a) would be modified by replacing the words "is provided via" and adding the words "complies with" to emphasize that compliance with the methods in Section 25607.1 for food exposure warnings is required for safe harbor protection. Existing Section 25607.1(a) requires that the safe harbor warning for food exposures be provided using one or more of the methods required in Section 25602 for consumer product exposures, in addition to the requirements specific to food exposures described in Section 25607.1, subsections (b) and (c).

## Subsection (b)

OEHHA has determined that certain elements of the existing tailored warning for food exposure warnings should be retained in the short-form warning content. New subsections (b)(1)-(6) would provide short-form warning content that is generally consistent with the other proposed amendments to the short-form warning content for consumer product exposure warnings and would incorporate existing elements of the full-length warning content for food exposures. Thus the proposed short-form food exposure warning would be subject to the requirements in Section 25602(a)(4) regarding available surface space on a product label and the inability to accommodate a full-length warning, and the minimum type-size requirements; would omit the warning symbol and would require the warning to be enclosed in a box on food labels, consistent with the current full-length warning for food exposures.<sup>12</sup> The warning message would include the signal word "**WARNING**", the endpoint (cancer and/or reproductive toxicity), the name of one or more of the listed chemicals for which the warning is being provided, and the food exposure warnings URL: www.P65Warnings.ca.gov/food.

As an example, a short-form warning for a food product exposure to the carcinogen and reproductive toxicant benzene would read thus:

**WARNING:** Risk of Cancer and Reproductive Harm From Benzene Exposure – www.P65Warnings.ca.gov/food.

As with other safe harbor warnings, including those on consumer products other than food, where a chemical is both a carcinogen and reproductive toxicant the level of exposure may require a warning for one endpoint but not the other. In this scenario a warning should be given only for the endpoint requiring a warning. For example, for the carcinogen and reproductive toxicant acrylamide, if the exposure exceeds the No Significant Risk Level of 0.2 micrograms/day for cancer but is below the Maximum Allowable Dose Level of 140 micrograms/day for reproductive toxicity, a warning should be given only for the increased risk of cancer:

**WARNING:** Cancer Risk From Acrylamide Exposure – www.P65Warnings.ca.gov/food.

### Subsection (c)

Subsection (c) provides the same one-year delayed operative date for the amendments and sell-through provision as described in the discussion of Sections 25602 and 25603 above. The sell-through provision in subsection (c)

<sup>&</sup>lt;sup>12</sup> Section 25607.1(b).

applies to warnings on food products manufactured or produced and labeled before the operative date of the amendments to this section. As noted above, the version of the short-form warning which became operative in 2018 will be considered compliant with the proposed regulation if the food product was manufactured or produced prior to the operative date of the amended regulation.

## Necessity

The proposed regulation is necessary to stop businesses' use of the short-form warning described above on large packages, in catalogs and on-line to discourage its use to warn prophylactically. Those uses of the short-form warning are contrary to OEHHA's intention when adopting the 2016 warning regulations that businesses provide consumers with more meaningful and informative warnings, avoid over-warning, and only use the short form warning where the full-length warning will not fit on the label. The same is true for warnings provided in catalogs and on-line as there are not the same space limitations in those situations. In addition, the proposed regulation is necessary to ensure that, when appropriately used on products with small packages, the short-form warning names at least one chemical and clarifies that use of the product can cause a chemical exposure.

## Benefits of the Proposed Regulation

The health and welfare of California residents will likely benefit because the regulation will improve the quality of information provided in Proposition 65 consumer-product warnings by ensuring all safe-harbor warnings name at least one listed chemical to which the user of the product can be exposed. The regulation will also benefit Californians by discouraging and reducing unnecessary prophylactic warnings that can mislead consumers into thinking a product causes an exposure to a listed chemical when that is not the case.

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

OEHHA did not rely on any technical, theoretical, and/or empirical studies, reports, or documents as part of this rulemaking.

# Reasonable Alternatives to the Regulation and the Agency's Reasons for Rejecting Those Alternatives

OEHHA considered repealing the short-form warning provisions entirely. OEHHA decided that in certain limited circumstances, namely when product packaging size constraints cannot accommodate full-length warnings, provisions for shortened yet informative warnings are necessary. Thus, OEHHA has determined there are no reasonable alternatives to the proposed regulatory action that would carry out the purposes of the Act. The action provides clarification and specificity to the existing regulations.

## Reasonable Alternatives to the Proposed Regulatory Action that Would Lessen Any Adverse Impact on Small Business and the Agency's Reasons for Rejecting Those Alternatives

OEHHA considered the alternative of repealing the short-form provisions in their entirety but determined that the short-form warnings are necessary when the surface area of a product label is very limited and the package shape or size cannot accommodate a full-length warning, as was originally intended when OEHHA adopted the short-form warning as a safe harbor warning method for consumer product exposures. OEHHA has determined that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to the attention of OEHHA, including alternatives that would lessen any adverse impact on small business, would be as effective or less burdensome on small business. In addition, OEHHA has determined that the proposed regulatory action will not impose any mandatory requirements on small businesses. Proposition 65 expressly exempts businesses with less than 10 employees<sup>13</sup> from the requirements of the Act.

## Evidence Supporting Finding of No Significant Adverse Economic Impact on Business

The proposed regulatory action will not have a significant adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The action does not impose any new requirements upon private persons or businesses because the safe harbor regulations are non-mandatory guidance.

### Efforts to Avoid Unnecessary Duplication or Conflicts with Federal Regulations Contained in the Code of Federal Regulations Addressing the Same Issues

Proposition 65 is a California law that has no federal counterpart. OEHHA has determined that the regulatory action does not duplicate and will not conflict with federal regulations.

<sup>&</sup>lt;sup>13</sup> Health and Safety Code section 25249.11(b).

# Economic Impact Assessment Required by Gov. Code section 11346.3(b)

#### Creation or Elimination of Jobs within the State of California

The proposed regulatory action will not impact the creation or elimination of jobs within California. The proposed amendments will ensure that that the safe harbor short-form warnings are only used where, due to limited label space on a consumer product, a full-length warning will not fit. The proposed warnings will include the name of at least one listed chemical to which the person may be exposed to provide consumers with sufficient information about the exposure. The proposed action will also provide clarification and specificity regarding use of short-form warnings for exposures to listed chemicals from food.

## Creation of New Businesses or Elimination or Expansion of Existing Businesses within the State of California

The proposed regulatory action will not impact the creation of new businesses or the elimination or expansion of existing businesses within California. The proposed amendments will ensure that that the safe harbor short-form warnings are only used where, due to limited label space on a consumer product, a fulllength warning will not fit. The proposed warnings will include the name of at least one listed chemical to which the person may be exposed to provide consumers with sufficient information about the exposure. The proposed action will also provide clarification and specificity regarding the use of short-form warnings for exposures to listed chemicals from food.

# Benefits of the Proposed Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment

The proposed regulatory action will benefit the health and welfare of California residents by providing more meaningful information regarding their exposures to listed chemicals and help eliminate over-warning for non-existent exposures to listed chemicals. The action will also provide clarification and specificity regarding the use of short-form warnings for exposures to listed chemicals from food. The proposed action furthers the right-to-know purposes of the statute and therefore promotes public and worker health and safety.



## Appendix A – Examples of Actual Short-Form Warnings

**Residential Trash Bin Warning** 



**Ceramic Tower Heater – On-Product Label** 

#### Appendix A – Examples of Actual Short-Form Warnings, cont.



Electric Range – On-Product Label

Configuration and Ove	rview
ADA COMPLIANT	No
DECIBEL LEVEL DBA	39
PROP 65	CALIFORNIA RESIDENTS ONLY - WARNING: Cancer and Reproductive Harm - www.P65Warnings.ca.gov.

Dishwasher - Website Warning

Prop 65 CALIFORNIA RESIDENTS ONLY -WARNING: Cancer and Reproductive Harm www.P65Warnings.ca.gov.

#### **Top Freezer Refrigerator - Website Warning**

Appendix A – Examples of Actual Short-Form Warnings, cont.



**Refrigerator - On-Product Label** 

Prop 65 CALIFORNIA RESIDENTS ONLY – WARNING: Cancer and Reproductive Harm – www.P65Warnings.ca.gov.

#### **Clothes Dryer - Website Warning**

WARNING: Cancer and Reproductive Harm - www.p65Warnings.ca.gov.

#### Guitar, Bass and Ukulele - Website Warning



Luggage – On-Product Label

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT INITIAL STATEMENT OF REASONS TITLE 27, CALIFORNIA CODE OF REGULATIONS AMENDMENTS TO ARTICLE 6

### Appendix B - Examples of Short-form Warnings Compliant with the Proposed Amended Regulations on 5 sq. in Product Surface Area\*

\*all dimensions are approximate

Short-form warning on 5" x 1" product surface area

**WARNING:** Risk of Reproductive Harm From Toluene Exposure – www.P65Warnings.ca.gov.

Reproductive Harm risk (8 pt.)

**WARNING:** Risk of Cancer and Reproductive Harm From Benzene Exposure – www.P65Warnings.ca.gov.

Cancer and Reproductive Harm risk from same chemical (8 pt.)

**WARNING:** Risk of Cancer From Formaldehyde and Reproductive Harm From Toluene Exposure – www.P65Warnings.ca.gov.

Cancer and Reproductive Harm risk from different chemicals (8 pt.)

# Examples of Short-form Warnings Compliant with the Proposed Amended Regulations on 5 sq. in, cont.

#### Short-form warning on 3" x 1.75" Product Surface Area

**WARNING:** Cancer Risk From Formaldehyde Exposure - www.P65Warnings.ca.gov.

Cancer risk (8 pt.)

**WARNING:** Risk of Cancer and Reproductive Harm From Benzene Exposure www.P65Warnings.ca.gov.

Cancer and Reproductive Harm risk from same chemical (8 pt.)

**WARNING:** Risk of Cancer From Formaldehyde and Reproductive Harm From Toluene Exposure - www.P65Warnings.ca.gov.

Cancer and Reproductive Harm risk from different chemicals (8 pt.)

Examples of Short-form Warnings Compliant with the Proposed Amended Regulations on 5 sq. in, cont.

Short-form warning on 2.5" x 2" Product Surface Area



Reproductive Harm risk (8 pt.)

**WARNING:** Risk of Cancer and Reproductive Harm From Benzene Exposure www.P65Warnings.ca.gov.

Cancer and Reproductive Harm risk from same chemical (8 pt.)

▲ WARNING: Risk of Cancer From Formaldehyde and Reproductive Harm From Toluene Exposure - www.P65Warnings.ca.gov.

Cancer and Reproductive Harm risk from different chemicals (8 pt.)