

INTRODUCTION

This is a pre-regulatory proposal published for stakeholder discussion and public comment. It may change significantly prior to any formal regulatory proceeding. Proposed amendments are shown in underline/strikeout format, as they would appear within the existing regulation. Changes can be found in pages 2-3 (definitions) and pages 8-13 (substantive).

These draft amendments would be added to the existing “safe harbor” warning regulations found in Title 27, Cal. Code of Regulations, section 25601 so that any manufacturer/retailer that chooses to participate in the warning program may do so. These are voluntary actions and all food manufacturers or retailers are still free to provide a warning via any other “safe harbor” method or any other method that provides a clear and reasonable warning.

OEHHA intends for these draft amendments to generate more and better information for the public and provide additional safe harbor warning content and methods for manufacturers and retailers of foods sold at the retail level. The draft amendments create a food warning program that allows manufacturers to comply with the Proposition 65 warning requirement by communicating the necessary product-specific warning information to participating retailers through a central web-based system. The draft amendments provide retailers with a source for obtaining product-specific warning content and a “menu” of warning methods from which they can choose one or more methods for communicating the warning message that best suits their business need. In addition to the warning materials that would be provided in the retail stores, the public would also have access to the web-based database, which would contain product-specific warning information that is easily searched by product name, manufacturer, retailer, or chemical name.

Note: These draft amendments are intended to comply with *Ingredient Communication Council v. Lungren et al.* where the court determined that in order to comply with the Proposition 65 warning requirement, a consumer must not have to seek out a warning message: “An invitation to inquire about possible warnings on products is not equivalent to providing the consumer a warning about a specific product.”¹

¹ *ICC v. Lungren et al.* (1992) 2 Cal. App. 4th, 1480 at 1494

California Environmental Protection Agency
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
Possible Amendments to
TITLE 27, CALIFORNIA CODE OF REGULATIONS
ARTICLE 6. Clear and Reasonable Warnings

§ 25601 Clear and Reasonable Warnings

Whenever a clear and reasonable warning is required under Section 25249.6 of the Act, the method employed to transmit the warning must be reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure. The message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm. Nothing in this section shall be construed to preclude a person from providing warnings other than those specified in this article that satisfy the requirements of this article, or to require that warnings be provided separately to each exposed individual.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code

§ 25602 Definitions

(a) "Affected area" means the area in which an exposure to a chemical known to the state to cause cancer or reproductive toxicity is at a level that requires a warning.

(b) "Consumer products exposure" is an exposure that results from a person's acquisition, purchase, storage, consumption, or other reasonably foreseeable use of a consumer good, or any exposure that results from receiving a consumer service.

(c) "Environmental exposure" is an exposure that may foreseeably occur as the result of contact with an environmental medium, including, but not limited to, ambient air, indoor air, drinking water, standing water, running water, soil, vegetation, or manmade or natural substances, either through inhalation, ingestion, skin contact, or otherwise. Environmental exposures include all exposures that are not consumer products exposures, or occupational exposures.

(d) "Food provider" means a manufacturer, producer, processor or distributor of a food, other than a restaurant or other facility as defined in Health and Safety Code section 113789(a).

(e) "Food retailer" means a person or business that sells food directly to consumers in a retail setting, not including a restaurant or other facility as defined in Health and Safety Code Section 113789(a).

(f) "General information sign," means a sign that is posted in one or more locations within a retail food store that is likely to be seen by customers prior to purchase of a food. Locations may include, but are not limited to, the point of sale, checkout counter, floor display or at store entrances, as long as such locations ensure that the sign is likely to be seen by customers prior to purchase of a food. The content of the General Information Sign is established by the lead agency pursuant to subsection 25603.4(c)(1) and is available for download from the Retail Food Warning Program Website.

(gd) "Label" means a display of written, printed or graphic matter upon a product or its immediate container.

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

(if) "Occupational exposure" means an exposure to any employee in his or her employer's workplace.

(j) "Retail Food Warning Program" means the food warning program established in subsection 25603.4.

(kg) "Sign" means a presentation of written, printed, or graphic matter.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Section 25249.6, Health and Safety Code

§ 25603 Consumer Products Warnings

(a) Warnings for consumer products exposures that include the methods of transmission and the warning messages as specified by this section shall be deemed to be clear and reasonable.

(b) To the extent practicable, warning materials such as signs, notices, menu stickers, or labels shall be provided by the manufacturer, producer, or packager of the consumer product, rather than by the retail seller.

(c) A person in the course of doing business, who manufactures, produces, assembles, processes, handles, distributes, stores, sells, or otherwise transfers a consumer product which he or she knows to contain a chemical known to the state to cause cancer or reproductive toxicity in an amount that requires a warning shall provide a warning to any person to whom the product is sold or transferred unless the product is packaged or labeled with a clear and reasonable warning.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code

§ 25603.1 Consumer Products Exposure Warnings – Method of Transmission

The warning may be provided by using one or more of the following methods singly or in combination:

(a) A warning that appears on a product's label or other labeling.

(b) Identification of the product at the retail outlet in a manner which provides a warning. Identification may be through shelf labeling, signs, menus, or a combination thereof.

(c) The warnings provided pursuant to subparagraphs (a) and (b) shall be prominently placed upon a product's label or other labeling or displayed at the retail outlet with such conspicuousness, as compared with other words, statements, designs, or devices in the label, labeling or display as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase or use.

(d) A system of signs, public advertising identifying the system and toll-free information services, or any other system that provides clear and reasonable warnings.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code

§ 25603.2 Consumer Products Exposure Warnings – Content

(a) The warning message must include the following language:

1. For consumer products that contain a chemical known to the state to cause cancer:

"WARNING: This product contains a chemical known to the State of California to cause cancer."

2. For consumer products that contain a chemical known to the state to cause reproductive toxicity:

"WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code

§ 25603.3 Warnings for Specific Consumer Products Exposure

(a) For food, other than alcoholic beverages, sold, served, or otherwise provided in food facilities, as defined in Health and Safety Code Section 27521(a), which is intended for immediate consumption:

"WARNING: Chemicals known to the State of California to cause cancer, or birth defects or other reproductive harm may be present in foods or beverages sold or served here."

(b) For fresh fruits, nuts, and vegetables:

"WARNING: This product may contain a chemical known to the State of California to cause cancer, or birth defects or other reproductive harm."

(c) For prescription drugs, the labeling approved or otherwise provided under federal law and the prescriber's accepted practice of obtaining a patient's informed consent shall be deemed to be a clear and reasonable warning.

(d) For exposures resulting from emergency or urgent medical or dental care as defined in Section 25102(g), the accepted practice of obtaining the patient's informed consent shall be deemed to be a clear and reasonable warning when any of the following circumstances exists:

1. the patient is unconscious; or
2. the procedure must be undertaken because the licensed medical personnel, licensed dental personnel, or certified emergency medical personnel responsible for administering the care, as these terms are defined in Sections 25102(q), 25102(d), and 25102(b), respectively, reasonably believes that the procedure should be undertaken immediately; and therefore, there is insufficient time to fully inform the patient; or
3. the procedure must be performed on a person legally incapable of giving consent, and the licensed medical personnel, licensed dental personnel, or certified emergency medical personnel responsible for administering the care reasonably believes the procedure should be undertaken immediately; and therefore, there is insufficient time to obtain the informed consent of a person authorized to give such consent for the patient.

(e) Alcoholic Beverages. For alcoholic beverages, including, without limitation, beer, malt beverages, wine and distilled spirits:

1. The warning message must include the following language:

"WARNING: Drinking Distilled Spirits, Beer, Coolers, Wine and Other Alcoholic Beverages May Increase Cancer Risk, and, During Pregnancy, Can Cause Birth Defects."

2. Beverages primarily intended for consumption off the premises where sold or distributed:

(A) at least one notice or sign, no smaller than 10 inches wide by 10 inches high, and bearing the warning message set forth in subparagraph (e)(1) of this subsection; or

(B) at least one horizontal strip marker no smaller than 10 1/2 inches wide by 1 1/4 inches high, and bearing the warning message set forth in paragraph (e)(1) of this subsection; or

(C) a notice no smaller than 5 inches by 5 inches, and bearing the warning message set forth in subparagraph (e)(1) of this subsection.

(D) If signs 10 inches high by 10 inches wide are used, the word "warning" shall be centered three-quarters of an inch from the top of the sign in ITC Garamond bold condensed type face all in one-inch capital letters. Three-sixteenths of an inch from the base of the word "warning" shall be a line extending from left to right across the width of the sign one-sixteenth of an inch in thickness. Centered one-half inch below the line shall be the body of the warning message in 36/50 ITC Garamond bold condensed type face with the initial letter of each word, other than the conjunctive "and," capitalized. For the body of the warning message, left and right margins of at least one-half of an inch, and a bottom margin of at least one-half inch shall be observed. Larger signs shall bear substantially the same proportions of type size and spacing to sign dimension as the sign 10 inches high by 10 inches wide.

(E) If the 10 1/2 inch by 1 1/4 inch horizontal strip markers are used, the word "WARNING," punctuated by a colon, shall be justified left and located three-sixteenths of an inch from the top of the strip notice in ITC Garamond bold condensed type face all in capital letters measuring eleven sixteenths of an inch in height. Three thirty-seconds of an inch from the base of the word "WARNING" shall be a line extending from left to right across the width of the word "WARNING" and the punctuating colon one thirty-second of an inch in thickness. Located one-fourth of an inch from the top and one-fourth of an inch from the bottom of the strip notice, and to the immediate right of the word "WARNING," shall be the body of the warning message in 12/16 point ITC Garamond bold condensed type face with the initial letter of each word, other than the conjunctive "and," capitalized. The word "WARNING" shall be one-half inch from the left edge of the strip notice and the requisite warning message shall extend to within one-half inch from the right edge.

(F) If the 5 inch by 5 inch signs are used, they shall bear substantially the same proportions of type size and spacing to sign dimension as the sign 10 inches high by 10 inches wide, with both the word "WARNING" and the warning text set in white on a contrasting red background.

(G) Such sign or notice shall be placed in the retail establishment so as to assure that it is readable and likely to be read either at each retail point of sale or each point of display. Such sign or notice shall be placed either at all retail points of sale or all points of display, but need not be placed at both. If 10 inch by 10 inch signs or notices are placed at the point of display, each shall be placed no more than ten feet from any alcoholic beverage container and in a manner associating the sign or notice with the display. If horizontal strip notices are used, they shall be placed at ten-foot intervals horizontally along the display. If a 5 inch by 5 inch sign is used, it shall be conspicuously placed at each retail point of sale (e.g., check-out counter, cash register, cash box) so that it is likely to be read and understood during the sales transaction.

(H) All measurements specified or referred to in paragraphs (D), (E) and (F), above, are not required to be precisely accurate.

3. For beverages provided for consumption on the premises at tables served by food or beverage persons, or sold or distributed through over the counter service;

(A) a notice or sign displayed at each of the tables where alcoholic beverages are served or may be consumed at least 5 inches high by 5 inches wide bearing substantially the same type face and substantially the same proportion of type size and spacing to sign dimension as described in paragraph (e)2. (F); or

(B) the warning message set forth in subparagraph (e)(1) of this subsection, placed upon a menu or list in association with the alcoholic beverages listed thereon and served at such premises, or if alcoholic beverages are not listed thereon, on any menu or list provided to patrons in association with the listing of food or beverage offerings, in type size and design, such that the text is conspicuous and likely to be read prior to consumption of alcoholic beverages or,

(C) at least one 10 inch by 10 inch sign, meeting the specifications set forth in subparagraph (e)2. (D) of this subsection, placed so that it is readable and likely to be read by patrons as they enter each public entrance to the establishment. If the establishment does not have clearly defined physical boundaries delineating those areas where, by permit or license, alcoholic beverages are served, the 10 inch by 10 inch sign shall be posted so that it is readable and likely to be read by patrons as they enter the area or areas where, by permit or license, alcoholic beverages are served; and

(D) If sold or distributed through over-the-counter service, at least one sign, meeting the specifications set forth in paragraph (e)2. (D) of this subsection, placed in the retail establishment so that the warning message is, prior to the consumption of alcoholic beverages, readable and likely to be read from all counter locations available to the public. Therefore, a retail establishment providing a warning pursuant to the preceding sentence, also would be required to provide a warning in accordance with either paragraph 3. (A), 3.(B) or 3.(C) of this subsection.

4. For premises which are specially licensed to sell and serve alcoholic beverages both on and off the licensed premises (e.g., in facilities that offer both "tasting" and retail sales), the off-sale portion of the premises shall comply with the provisions of subparagraph (e)2, above, and the portion of the premises where alcoholic beverages are served shall comply with the provisions of subparagraph (e)3, above.

5. For alcoholic beverages sold or distributed to consumers through the mail or package delivery services, warnings may be provided by incorporating or placing the warning message set forth in subparagraph (e)(1) on or in the shipping container or delivery package in such a manner so that the warning message is likely to be read by the recipient prior to consumption of the alcoholic beverage(s).

6. All signs or notices referred to in subparagraphs (e)2., (e)3. and (e)4., above, shall be displayed so that they are clearly visible under all lighting conditions normally encountered during business hours.

7. For alcoholic beverages, the placement and maintenance of the warning shall be the responsibility of the manufacturer or its distributor at no cost to the retailer, and any consequences for failure to do the same shall rest solely with the manufacturer or its distributor, provided that the retailer does not remove, deface, or obscure the requisite signs or notices, or obstruct, interfere with, or otherwise frustrate the manufacturer's reasonable efforts to post, maintain, or periodically replace said materials.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code

§ 25603.4 Warning Program for Foods Sold at Retail Establishments

- (a) This section establishes a voluntary food warning program that persons subject to the Act may choose in lieu of existing methods authorized under Section 25603.3, for providing warnings for exposures to listed chemicals in foods, except fresh fish² sold at the retail level. This food warning program may be used by food providers and food retailers and others in the chain of distribution to easily provide and access information concerning the content of warnings that are required for exposures to listed chemicals that occur through foods. This section also establishes certain methods of providing warnings for exposures to listed chemicals in food that are deemed "clear and reasonable" for purposes of the Act.

² OEHHA may adopt specific warning content and methods for fresh fish at a future time.

(b)

Food Provider:

1. A Food Provider shall be deemed to have satisfied its warning obligations under Health and Safety Code section 25249.6, as to foods, except fresh fish, that require a warning under the Act and are sold by Food Retailers that participate in the Retail Food Warning Program, if such Food Provider completes ALL of the following steps prior to the alleged exposure.
 - i. Register to participate in the Retail Food Warning Program on the Website established by the lead agency, AND
 - ii. Provide all the information requested on the website, including, but not limited to; the name and address of the food provider; name, brand, Uniform Product Code (UPC) and other identifying code or similar information for all of its foods that require a warning under the Act; the names and Chemical Abstracts Service(CAS) numbers, if available, for each listed chemical in the food; AND
 - iii. Update its information on the website at least annually; AND
 - iv. Update its information within 30 days of becoming aware that any of its foods requires a warning under the Act, that it had not previously identified on the Website, AND
 - v. Upload to the Retail Food Warning Program website proposed product-specific warning message content for each of its foods that require a warning under the Act.
 1. All food warnings must prominently and clearly state that the food contains a listed chemical and must provide a clear and reasonable warning consistent with the provisions of this Article.
 2. Food warning content may include explanatory information provided by the U.S. Food and Drug Administration or any other appropriate state or federal regulatory agency, or any other information approved by the lead agency.
 3. The lead agency reserves the right to disapprove any food-specific warning other than as set forth in section 25603.2, by providing written notice to the person submitting the proposed warning message explaining the reasons for the disapproval.
 4. Receipt of such a disapproval notice may not be used as evidence of non-compliance with this section where the person receiving such notice modifies the warning message to correct the insufficiencies identified in the notice and resubmits the modified warning to the lead agency within thirty (30) days, AND
 - vi. Certify that it has notified, in writing, each food retailer , distributor or other person to which it directly sells a food subject to the warning requirements of the Act, that:
 1. a warning is required for the food, AND

2. it has provided that person with the warning message for the food and the Retail Food Warning Program website address, AND
- vii. Timely pay any fees established by the lead agency to participate in the Retail Food Warning Program.

(c) **Food Retailers:**

1. A Food Retailer shall be deemed to have satisfied its warning obligations under Health and Safety Code section 25249.6 for all foods, except fresh fish, sold by the Food Retailer if such Food Retailer completes ALL the following steps:
 - i. Register to participate in the Retail Food Warning Program on the website established by the lead agency, AND
 - ii. Check the Program website at least once every three months following the effective date of this section to determine if there are any foods sold by the Food Retailer that require a warning, or any new food-specific warnings that have become available; AND
 - iii. Update its in-store information within 30 days after determining that new warnings are required, AND
 - iv. Conspicuously post a General Information Sign, as defined, in one or more locations within the retail establishment where it is reasonably expected to be seen by consumers prior to purchase of any food product requiring a warning.
 1. The General Information Sign must be no smaller than 8 1/2 inch by 11 inch and printed in no smaller than 28 point type.
 2. The content of the General Information Sign must be obtained from the Retail Food Warning Program website, and must be consistent with the method of warning chosen by the Food Retailer in subsection 25603.4 (c)(1)(v).
 3. The Food Retailer must post any new or revised General Information Sign within 30 days after it becomes available on the Retail Food Warning Program website, AND
 - v. Provide to its customers all product-specific warning messages available for download from the Retail Food Warning Program Website, that apply to foods sold by the Food Retailer, using one or more of the following approved methods.
 1. A product-specific warning provided with or on the cash register receipt.
 - a. The entire warning message must be in a legible print font no smaller than 12 point type.

- b. Each food subject to the warning requirement must be separately identified on the face of the cash register receipt.
 - c. The printed warning message must contain the Retail Food Warning Program Website address and either the warning language established in Section 25603.2, OR, product-specific warning language available on the Retail Food Warning Program Website.
- 2. A product-specific warning provided on or with the shelf price tag for the product at the point of display of the product.
 - a. The entire warning message must be in a print font no smaller than 12 point type.
 - b. The printed warning message must contain the Retail Food Warning Program Website address and either the warning language established in Section 25603.2, OR, product-specific warning language available on the Retail Food Warning Program Website.
- 3. A product-specific warning in a brochure offered to each customer at the checkout counter prior to purchase of the product.
 - a. The brochure must contain the brand name or other similar identifying information for each product sold by the Food Retailer that requires a warning under the Act and full product-specific warnings for each named product.
 - b. Where a Food Provider includes an on-product Proposition 65 identifier on a food, that identifier may be used in conjunction with this method of transmitting the warning message to assist consumers in identifying foods requiring a warning. All on-product Proposition 65 identifiers must be approved in advance by the lead agency.
 - c. The content and format of the brochure must be approved in advance by the lead agency.

4. A product-specific warning provided via any electronic device or process that automatically provides the warning to the customer while the customer is in the store, without requiring the consumer to seek out the warning.
 - a. Where a Food Provider includes an on-product Proposition 65 identifier on a food, that identifier may be used in conjunction with this method of transmitting the warning message to assist consumers in identifying foods requiring a warning. All on-product Proposition 65 identifiers must be approved in advance by the lead agency.
 - b. Electronic device warning methods must be approved in advance by the lead agency.
5. Product-specific warning content or methods required by a court order or settlement for that product.
6. A product-specific warning provided via any other method approved in advance by the lead agency, AND
 - vi. Timely pay any participation fees established by the lead agency.
2. Nothing in this section releases a food retailer from its duty to provide a warning for an exposure to a listed chemical where the food retailer has received actual, written notice from a food provider that a warning is required for a food that it sells and thereafter fails to provide a clear and reasonable warning.

(d)

Lead Agency Responsibilities:

1. Develop and maintain a website capable of containing the Retail Food Warning Program information described in this section and make all such information available at no cost to the general public.
2. Approve, approve with conditions requiring specific modifications, or reject requests for lead agency approval described in this section.
 - i. All requests submitted to the lead agency under this section shall be made in writing.
 - ii. For any response other than unconditional approval, the Lead Agency shall provide the requester with an explanation, and allow the requester 30 days to modify and resubmit the request or to seek reconsideration of the response.
 - iii. Requests for approval and lead agency responses, other than unconditional approval under this section, and all communications

related to such requests, shall remain confidential unless confidentiality is waived by the requesting party and shall be inadmissible in any enforcement action arising from an assertion that warnings provided pursuant to this section are not clear and reasonable under Section 25249.6 of the Act.

- iv. The lead agency must respond to all requests for approval under this section within 90 days of receipt, which may be extended for good cause, with written notice to the requester.
3. Develop appropriate content, format and placement guidance for General Information Signs.
4. Establish fees to defray costs for all lead agency functions described in this section.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code