# Proposition 65: New Regulations for "Clear and Reasonable" Warnings

Presented by:
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For the
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### **Presenter**



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**Dentons US LLP: 2015 - Present** 

McKenna Long & Aldridge LLP: 1983 - 2015

### **Proposition 65 Warning Requirement**

• § 25249.6: Required Warning Before Exposure To Chemicals Known to Cause Cancer Or Reproductive Toxicity. No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.

#### **Overview**

- Title 27, California Code of Regulations, Article 6
- First Significant Amendments to Warning Regulations
- Extensive Rulemaking
  - Pre-Rulemaking "Workshop" in 2014
  - Notice of Proposed Rulemaking and Initial Statement of Reasons November 2015
  - Voluminous Public Comments
  - Final Statement of Reasons September 2, 2016
  - Available at: http://oehha.ca.gov/proposition-65/crnr/notice-adoption-article-6-clear-and-reasonable-warnings

### **Overview**

#### • Other OEHHA Resources at OEHHA Website:

- Regulatory Text (Strikethrough)
- Regulatory Text (Clear)
- Side-by-Side Comparison of Old and New Regulatory Provisions

### • Scope:

• Summary of public comments and responses is 273 pages long

#### • Important Dates:

- Adopted August 30, 2016
- Effective August 20, 2018

### **Color-coded Key to New Warning Regulations**

- Challenge: comprehensive changes to warning regulations create an entirely new warning scheme; package is large, complicated and tedious
- Solution: amended regulations color-coded in red, green, blue and purple.
  - Colors correspond as follows:
    - Red identifies the portions that pertain to warnings for "Consumer Product Exposures."
    - Green identifies the portions that pertain to warnings for "Occupational Exposures."
    - Blue identifies the portions that pertain to warnings for "Environmental Exposures."
    - **Purple** identifies the portions that have eye-popping importance.

### § 25600 General

- (b) This article will become effective two years after the date of adoption. A person may provide a warning that complies with this article prior to its two-year effective date; such warning will be deemed to be clear and reasonable. A warning for a consumer product manufactured prior to the effective date of this article is deemed to be clear and reasonable if it complies with the September 2008 revision of this article.
- (e) A person that is a party to a <u>court-ordered settlement or final judgment</u> establishing a warning method or content for a consumer product or environmental warning is deemed to be providing a "clear and reasonable" warning for that exposure for purposes of this article, if the warning fully complies with the order or judgment.
- (f) Nothing in this subarticle shall be construed to preclude a person from providing a warning using content or methods other than those specified in this article that nevertheless complies with Section 25249.6 of the Act.

### § 25600.1 Definitions

- (d) "Consumer product" means any article, or component part thereof, including food, that is produced, distributed or sold for the personal use, consumption or enjoyment of a consumer.
- (e) "Consumer product exposure" means an exposure that results from a person's acquisition purchase, storage, consumption or any reasonably foreseeable use of a consumer product, including consumption of a food.
- (f) "Environmental exposure" means an exposure that occurs 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, through inhalation, ingestion, or skin or other contact with the body. All exposures that are not consumer product exposures or occupational exposures are environmental exposures.

### § 25600.1 Definitions

- (k) "Occupational exposure" means an exposure to any employee at his or her place of employment.
- (l) "Retail seller" means a person or business that sells or otherwise provides consumer products, including foods, directly to purchasers and consumers by any means, including via the internet. For purposes of this article, a retail seller includes those functions of a business involved in the sale of consumer products, including foods, directly to purchasers and consumers, even if the business or facility is primarily devoted to non-retail activities.

# § 25600.2 Responsibility to Provide Consumer Product Exposure Warnings

- (a) Section 25249.11 of the Act requires the lead agency to minimize the burden on retail sellers of consumer products when it adopts regulations concerning clear and reasonable warnings except where the retail seller itself is responsible for introducing a listed chemical into the product.
- (b) The manufacturer, producer, packager, importer, supplier, or distributor of a product may comply with this section article either by affixing a <u>label</u> to the product bearing a warning that satisfies Section 25249.6 of the Act, <u>or by providing a written notice</u> directly to the authorized agent for a retail seller who is subject to Section 25249.6 of the Act, which:

# § 25600.2 Responsibility to Provide Consumer Product Exposure Warnings

- (e) <u>The retail seller is responsible</u> for providing the warning required by Section 25249.6 of the Act for a consumer product exposure <u>only when</u> one or more of the following circumstances exist:
  - (1) The retail seller is selling the product under a <u>brand or trademark that is owned or licensed by the retail seller</u> or an affiliated entity;
  - (2) The retail seller has knowingly and intentionally <u>introduced a listed chemical</u> into the product, or knowingly caused a listed chemical to be created in the product;
  - (3) The retail seller has <u>covered</u>, <u>obscured or altered a warning label</u> that has been affixed to the product pursuant to subsection (b);
  - (4) The retail seller has <u>received warning information and materials</u> (or an offer to provide warning materials) for the exposure pursuant to subsections (b) and (c) and the retail seller has sold the product without conspicuously posting or displaying those warning materials; or
  - (5) The retail seller has <u>actual knowledge of the potential consumer product exposure</u> requiring the warning, and there is no manufacturer, producer, packager, importer, supplier, or distributor of the product who:

WARNING: This product contains a chemical known to the State to cause cancer, birth defects or other reproductive harm.

(Consumer Product Warning)

WARNING: This area contains a chemical known to the State to cause cancer, birth defects or other reproductive harm.

(Environmental Warning)

WARNING: This area contains a chemical known to the State to cause cancer, birth defects or other reproductive harm.

(Occupational Warning)

# THESE WARNINGS WERE "CLEAR" FOR OVER TWENTY-FIVE YEARS

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

WARNING: This product contains a chemical known to the State to cause cancer, birth defects or other reproductive harm.

WARNING: This area contains a chemical known to the State to cause cancer, birth defects or other reproductive harm.

WARNING: This area contains a chemical known to the State to cause cancer, birth defects or reproductive harm.

### **BUT NOT ANY MORE!!!**

New regulations, when they take effect, will require this symbol:



And consumer product exposures will require a statement with some combination of these elements:

**WARNING:** This product can expose you to chemicals such as [name of one or more chemical], which is [are] known to the State of California to cause cancer [birth defects or other reproductive harm] [and birth defects or other reproductive harm]. For more information go to www.P65Warnings.ca.gov.

New regulations, when they take effect, will require this symbol:



And environmental exposures will require a statement with some combination of these elements:

**WARNING:** Entering this area can expose you to chemicals known to the State of California to cause cancer [birth defects or other reproductive harm] [and birth defects or other reproductive harm], including [name of one or more chemicals], from [name one or more sources of exposure]. For more information go to www.P65Warnings.ca.gov.

New regulations, when they take effect, will require this symbol:



And occupational exposures will require a statement with some combination of these elements:

**WARNING:** This product can expose you to chemicals such as [name of one or more chemical], which is [are] known to the State of California to cause cancer [birth defects or other reproductive harm] [and birth defects or other reproductive harm]. For more information go to www.P65Warnings.ca.gov.

**WARNING:** Entering this area can expose you to chemicals known to the State of California to cause cancer [birth defects or other reproductive harm] [and birth defects or other reproductive harm], including [name of one or more chemicals], from [name one or more sources of exposure]. For more information go to www.P65Warnings.ca.gov.

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

(a) A warning is "clear and reasonable" within the meaning of Section 25249.6 of the Act if the warning complies with all applicable requirements of this article.

#### From Subarticle 1, § 25600 General:

(f) Nothing in this subarticle shall be construed to preclude a person from providing a warning using content or methods other than those specified in this article that nevertheless complies with Section 25249.6 of the Act.

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

(b) Except as provided in Section 25603(c), a warning meets the requirements of this article if the name of one or more of the listed chemicals for which the warning is being provided person has determined a warning is required is included in the text of the warning, to the extent that an exposure to that chemical or chemicals is at a level that requires a warning. Where a warning is being provided for more than one endpoint (cancer and reproductive toxicity) the warning must include the name of one or more chemicals for each endpoint, unless the named chemical is listed as known to cause both cancer and reproductive toxicity and has been so identified in the warning.

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

- (d) Consumer product exposure warnings must be prominently displayed on a label, labeling, or sign, and must be displayed with such conspicuousness as compared with other words, statements, designs or devices on the <u>label</u>, <u>labeling</u>, <u>or sign</u>, as to render the warning likely to be read and understood by an ordinary individual under customary conditions of purchase or use.
- (e) Environmental exposure warnings must be provided in <u>a conspicuous manner</u> <u>and</u> under such conditions as to make the warning likely to be seen, read, and understood by an ordinary individual <u>in the course of normal daily activity</u>.

# § 25602 Consumer Product Exposure Warnings – Methods of Transmission

- (a) Unless otherwise specified in Section 25607, a warning meets the requirements of this article if it complies with the content requirements in Section 25603 and is provided using one or more of the following methods:
- (1) A **product-specific warning** provided on a posted sign, shelf tag, or on a shelf sign, for the consumer product at each point of display of the product.
- (2) A **product-specific warning provided** via any electronic device or process that automatically provides the warning to the purchaser prior to or during the purchase of the consumer product, without requiring the purchaser to seek out the warning.
- (3) A **label** that complies with the content requirements in Section 25603(a).
- (4) An **on-product warning** that complies with the content requirements in Section 25603(b). The entire warning must be in a type size no smaller than the largest type size used for other consumer information on the product. In no case shall the warning appear in a type size smaller than 6-point type.

# § 25602 Consumer Product Exposure Warnings – Methods of Transmission

- (b) For Internet purchases, a warning that complies with the content requirements of Section 25603(a) must be provided by including either the warning on the product display page, or a clearly marked hyperlink using the word "WARNING" on the product display page, or by otherwise prominently displaying the warning to the purchaser prior to completing the purchase. 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. For purposes of this subarticle, a warning is not prominently displayed if the purchaser must search for it in the general content of the website.
- (c) For catalog purchases, the warning must be provided in the catalog in a manner that clearly associates it with the item being purchased. 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.
- (d) If any label, labeling or sign that provides consumer information about a product is provided in a **language** other than English, then a warning must also be provided in that language in addition to English.

### § 25603 Consumer Product Exposure Warnings – Content

- (a) Unless otherwise specified in Section 25607 et seq., a warning meets the requirements of this article if it is provided using one or more of the methods required in Section 25602 and includes all the following elements:
- (1) **A symbol** consisting of a black exclamation point in a yellow equilateral triangle with a bold black outline. Where the sign, label or labeling for the product is not printed using the color yellow, the symbol may be printed in black and white. The symbol shall be placed to the left of the text of the warning, in a size no smaller than the height of the word "WARNING".

### § 25603 Consumer Product Exposure Warnings – Content

- (2) **The word "WARNING**" in all capital letters and bold print, and:
- (A) For exposures to listed carcinogens, the words, "This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov."
- (B) For exposures to listed reproductive toxicants, the words, "This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov."
- (C) For exposures to both listed carcinogens and reproductive toxicants, the words, "This product can expose you to chemicals including [name of one or more chemicals] which is [are] known to the State of California to cause cancer, and [name of one or more chemicals] which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov."
- (D) For exposures to a chemical that is listed as both a carcinogen and a reproductive toxicant, the words, "This product can expose you to chemicals such as [name of one or more chemical], which is [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."

### § 25603 Consumer Product Exposure Warnings – Content

- (b) An on-product warning label may be provided using all the following elements:
  - (1) The symbol required in subsection (a)(1).
  - (2) The word "WARNING" in all capital letters, in bold print.
- (A) For consumer products that cause exposure to a listed carcinogen, the words, "Cancer www.P65Warnings.ca.gov/product."
- (B) For consumer products that cause exposures to a listed reproductive toxicant, the words, "Reproductive Harm www.P65Warnings.ca.gov/product."
- (C) For consumer products that cause exposures to both a listed carcinogen and a reproductive toxicant, the words, "Cancer and Reproductive Harm www.P65Warnings.ca.gov."
- (c) A person providing an on-product warning label pursuant to subsection (b) is not required to include within the text of the warning the name or names of a listed chemical.

### **Environmental Exposures**

### From § 25600.1 Definitions

(f) "Environmental exposure" means an exposure that occurs 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, through inhalation, ingestion, or skin or other contact with the body. All exposures that are not consumer product exposures or occupational exposures are environmental exposures.

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

- (a) A warning is "clear and reasonable" within the meaning of Section 25249.6 of the Act if the warning complies with all applicable requirements of this article.
- (b) Except as provided in Section 25603(c), a warning meets the requirements of this article if the name of one or more of the listed chemicals for which the warning is being provided person has determined a warning is required is included in the text of the warning, to the extent that an exposure to that chemical or chemicals is at a level that requires a warning. Where a warning is being provided for more than one endpoint (cancer and reproductive toxicity) the warning must include the name of one or more chemicals for each endpoint, unless the named chemical is listed as known to cause both cancer and reproductive toxicity and has been so identified in the warning.

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

(e) Environmental exposure warnings must be provided in a conspicuous manner and under such conditions as to make the warning likely to be seen, read, and understood by an ordinary individual in the course of normal daily activity.

# § 25604 Environmental Exposure Warnings – Methods of Transmission

(a) Unless otherwise specified in Section 25607, a warning for an environmental exposure meets the requirements of this article if it complies with the content requirements in Section 25605 and is provided using one or more of the following methods:

# § 25604 Environmental Exposure Warnings – Methods of Transmission

- (1) For indoor environments or outdoor spaces with clearly identified entrances, **a warning sign** posted at all public entrances to the affected area in no smaller than 72-point type. The warning must:
- (A) Clearly identify one or more sources of exposure.
- (B) Be provided in a conspicuous manner and under such conditions as to make it likely to be seen, read, and understood by an ordinary individual in the course of normal daily activity.
- (C) Be provided in English and in any other language used on other signage in the affected area.
- (2) A warning provided in a notice mailed, sent electronically, or otherwise delivered to each occupant in the affected area. The notice must:
- (A) Clearly identify the source of the exposure.
- (B) Include a map that clearly identifies the affected area.
- (C) Be provided at least every three months.
- (D) Be provided in English and in any other language ordinarily used by the business person to communicate with the public.

## § 25604 Environmental Exposure Warnings ---Methods of Transmission

- (3) A warning published in the main or local news section of a newspaper with the largest circulation in the area for which the warning is given, at least once every three months. The warning must:
  - (A) Clearly identify the source of the exposure.
  - (B) Be at least a quarter-page in size in the print version.
  - (C) Include a map that clearly identifies the affected area.
  - (D) Also be published in the electronic version of the publication, if any.
- (E) If a newspaper published in a language other than English is circulated in the affected area, the warning must be published in that newspaper and in that language, in addition to being published in English in at least one Englishlanguage newspaper that circulates in that area.

### § 25605 Environmental Exposure Warnings – Content

- (a) Unless otherwise specified in Section 25607, a warning meets the requirements of this article if it is provided using one or more of the methods required in Section 25604 and includes all the following elements:
  - (1) The **symbol** required in Section 25603(a)(1).
  - (2) The word "WARNING" in all capital letters and bold print.
- (3) For exposures to listed carcinogens, the words, "Entering this area can expose you to chemicals known to the State of California to cause cancer, including [name of one or more chemicals], from [name one or more sources of exposure. For more information go to www.P65Warnings.ca.gov."
  - (A) For exposures to a single carcinogen, the words, "Entering this area can expose you to chemicals known to the State of California to cause cancer, including [name of one or more chemicals], from [name one or more sources of exposure. For more information go to <a href="www.P65Warnings.ca.gov">www.P65Warnings.ca.gov</a>."

### § 25605 Environmental Exposure Warnings – Content

- (4) For exposures to listed reproductive toxicants, the words, "Entering this area can expose you to chemicals known to the State of California to cause birth defects or other reproductive harm, including [name of one or more chemicals], from [name one or more sources of exposure]. For more information go to www.P65Warnings.ca.gov."
  - (A) For exposures to a single reproductive toxicant, the words, "Entering this area can expose you to a chemicals known to the State of California to cause birth defects or other reproductive harm, including [name of chemicals], from [name one or more sources of exposure]. For more information go to <a href="www.P65Warnings.ca.gov">www.P65Warnings.ca.gov</a>."
- (5) For exposures to both listed carcinogens and reproductive toxicants, the words, "Entering this area can expose you to chemicals known to the State of California to cause cancer and birth defects or other reproductive harm, including [name of one or more chemicals], from [name one or more sources of exposure]. For more information go to www.P65Warnings.ca.gov."
- (6) For exposures to a single chemical that is listed as both a carcinogen and a reproductive toxicant, the words, "Entering this area can expose you to [name of chemical] from [name one or more sources of exposure]. [Name of chemical] is 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."

## § 25606 Occupational Exposure Warnings

### From § 25600.1 Definitions

(k) "Occupational exposure" means an exposure to any employee at his or her place of employment.

## § 25606 Occupational Exposure Warnings

- (a) A warning to an exposed employee about a listed chemical which meets the requirements of this article if it fully complies with all warning information, training and labeling requirements of the federal Hazard Communication Standard (29 Code of Federal Regulations, section 1910.1200), the California Hazard Communication Standard (Title 8, California Code of Regulations section 5194), or, for pesticides, the Pesticides and Worker Safety requirements (Title 3, California Code of Regulations section 6700 et seq.) meets the requirements of this article.
- (b) For occupational exposures to chemicals not covered by subsection (a), warning may be provided consistent with sections 25601, 25602, 25603, 25604, 25605 and 25607, et seq. of this article.

# § 25607 Specific Product, Chemical and Area Exposure Warnings

- Food
- Alcoholic Beverage
- Food and Non-Alcoholic Beverage
- Prescription Drug and Emergency Medical or Dental Care
- Raw Wood Product.
- Furniture Product
- Diesel Engine

- Vehicle
- Recreational Vessel
- Enclosed Parking Facility
- Amusement Park
- Petroleum Products
- Service Station and Vehicle Repair Facilities
- Designated Smoking Area

# **Questions?**



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