

Proposition 65

Safe Harbor Warnings

Mario Fernandez

Office of Environmental Health Hazard
Assessment (OEHHA)

Public Hearing

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Proposition 65

“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....”

Health & Safety Code Section 25249.6

Regulatory Proposal: Background

- P65 statute does not define “clear and reasonable” for purposes of a warning.
- Current regulation was promulgated in 1988.
- Pre-regulatory workshops in July 2013 and April 2014.
- Rulemaking proposed in January 2015. Comment period on regulatory draft from January to April 2015.
- Notice of Decision Not to Proceed published November 2015, concurrent with new rulemaking proposal (restarts one-year clock).

Regulatory Proposal: Overview

- Provides more clarity regarding the responsibility to provide warnings
- Retains “safe harbor” approach for warnings to provide flexibility for businesses.
 - Includes changes to safe harbor warning methods and content
 - Commissioned UC Davis Extension Center study regarding effectiveness of existing and proposed warnings
- Added “tailored” warnings for specific kinds of exposures.
 - Examples: alcoholic beverages, dental care, furniture, diesel engines, automobiles, recreational vessels, amusement parks.

General Provisions: Manufacturer/Retail Seller Responsibilities

- Product manufacturers have primary responsibility for warning.
- Manufacturer can label product or:
 - Provide notice to distributor/importer/retail seller that a warning is required
 - Offer to provide or pay for warning signs or materials.
 - Retail sellers must confirm receipt of notice and act as “pass-through” for warning.
- Provide non-English language warnings in certain situations.

General Provisions, cont.

- Phase-in period of two years, i.e., the “effective date” of the regulation is two years following adoption.
- Warnings for consumer products that are manufactured prior to the effective date and meet the existing safe harbor will not require new warnings.
- Court-approved warnings are expressly recognized and considered “clear and reasonable.”
 - Jan 2015 proposal did not contain this provision

Safe Harbor Methods and Content: “Expose” vs. “Contain”

- Use of phrase: “This product *can expose you to....*” rather than “This product *contains....*”
 - More consistent with P65 statute, which requires warnings only for *exposures*, not the mere presence of a listed chemical.
 - More informative
 - Discourages “over-warning”

Safe Harbor Methods and Content: Chemical Name(s)

- Safe harbor requires the name of at least one chemical name in the warning.
 - Ex. Business required to provide warning for product causing exposure to chemicals A and B. The business can include the name of A or B, or *both*.
 - Jan 2015 proposal required identification of chemicals from a list of 12 chemicals
- Business has discretion to select which chemical(s) to include in warning
 - Named chemical(s) must be one(s) for which warning is being provided
- Answers question: "What am I being exposed to?"
 - Over 2/3 of people (67.1%) in warnings study found a warning with a chemical name more helpful than a generic warning with no chemical name

Safe Harbor Methods and Content: Other Changes

- Over 3/4 (75%) of the participants in the warnings effectiveness study indicated that the proposed warnings were overall more helpful than the current warnings.
- OEHHA web site URL
- Warning symbol 
 - In warnings effectiveness study, most participants understood symbol to mean “warning” and few reported being confused or scared.
- Occupational and prescription drug warning provisions substantially unchanged
- Anticipate on-going additions to “tailored” warning section

Safe Harbor Warnings: Comparison of Current and Proposed Content

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

Ex. 1 Current safe harbor warning

 **WARNING:** This product can expose you to arsenic, a chemical known to the State of California to cause cancer. For more information go to: www.P65Warnings.ca.gov/product

Ex. 2 Proposed safe harbor warning

Regulatory Proposal Timeline

- Notice of Proposed Rulemaking published in California Regulatory Notice Register on November 27, 2015
- Public hearing on January 13, 2016
- Comment period closes January 25, 2016
- Rulemaking record must be submitted by November 27, 2016

For additional information:

Mario Fernandez

Staff Counsel III, OEHHA

Phone: 916.323.2635

mario.fernandez@oehha.ca.gov