

CALIFORNIA ADOPTS CHANGES TO PROPOSITION 65 WARNING LABELS

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James N. Law is an attorney in Reinhart's Litigation Practice, and is a core part of a team of highly effective attorneys. James has experience with a variety of civil litigation matters including patent and IP litigation, product liability claims, civil rights litigation and commercial litigation. James also assists clients with regulatory issues involving product labeling, warranties and California Proposition 65. James also practices in the area of antitrust and trade regulation, including defending clients against claims of group boycott and other conspiracies in restraint of trade.

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Proposition 65

- California Safe Drinking Water and Toxic Enforcement Act of 1986
 - Directly approved by voters in a ballot initiative
 - A warning regime
 - Key goal: Inform consumers of risks of cancer and reproductive harm due to exposures to specific chemicals

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Proposition 65 (cont.)

- "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"
 - "Intentionally" not defined
 - "Knowingly" refers to knowledge of fact of exposure

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Why Proposition 65 Matters to Out-of-State Manufacturers & Distributors

- Over 16,000 Proposition 65 lawsuits filed since enactment
 - 2015: 583 Proposition 65 claims filed
 - Total settlements: < \$26 million
 - Civil penalties: \$5,108,341
 - Attorneys' fees: \$17,862,441 (68% of total)
- Defendants at a significant disadvantage in defending against Proposition 65 claims—burden of proving compliance is often on defendant
- Average settlement cost is \$100,000

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Penalties

- Civil penalties up to \$2,500 per day for each violation
 - Factors considered:
 - The nature and extent of the violation
 - The number of, and severity of, the violations
 - The economic effect of the penalty on the violator
 - Whether the violator took good faith measures to comply with this chapter at the time these measures were taken
 - The willfulness of the violator's misconduct
 - The deterrent effect that the imposition of the penalty would have on both the violator and the regulated community as a whole
 - Any other factor that justice may require
- Injunctive relief
- Attorneys' fees and costs

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Defendant's Burden of Proof

- Warning was reasonable (if not based on safe harbor warning)
- Exposure below safe harbor level
- Defenses
 - Naturally occurring elements
 - Cooking exemption
 - Statute of limitations
 - Federal preemption
 - 12-month grace period for newly listed chemicals

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Which Chemicals Require Warnings?

- Over 900 listed chemicals
 - <http://oehha.ca.gov/proposition-65/proposition-65-list>
- List updated annually
 - State qualified experts: scientists and health professionals
- 12-month grace period for newly listed chemicals
- Some chemicals may be delisted as risk of cancer or reproductive harm is revised

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Safe Harbor Levels

- Cancer: No significant risk level (NSRL)
- Reproductive harm: Maximum allowable dose level (MADL)
- Based on levels of exposure, not concentration

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Safe Harbor Levels (cont.)

- OEHHA established 300 safe harbor levels
 - [http://oehha.ca.gov/media/downloads/pr-
opposition-
65/report/p65safeharborlevels.pdf](http://oehha.ca.gov/media/downloads/pr-opposition-65/report/p65safeharborlevels.pdf)
 - No safe harbor level?
 - Must include warning unless it can be proven exposure level will not pose significant risk of causing cancer or reproductive harm

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Safe Harbor Levels (cont.)

- Example safe harbor levels: Lead
 - NSRL: 15 µg/day (oral)
 - MADL: 0.5 µg/day (oral)
 - 1 µg = one thousandth of a milligram (1×10^{-3})
 - µg = microgram
 - » Measurement of mass

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Safe Harbor Levels (cont.)

- Prior settlements provide a rich resource for reformulation standards for safe harbor levels
 - All Proposition 65 settlements are public
 - Available through the California Attorney General Office website
 - <https://oag.ca.gov/prop65>

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Proposition 65 Warnings

- Warnings must be "clear and reasonable"
- Use safe harbor warning—considered clear and reasonable by law

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Updated Regulations

- OEHHA published draft of proposed regulatory changes to warning requirements in March 2014
 - Effective on August 30, 2018
 - Option to comply with new regulations prior to effective date
 - Pre-amendment warnings for products manufactured prior to August 2018 will be considered clear and reasonable

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Current Safe Harbor Warnings

- Cancer
 - WARNING: This product contains a chemical known to the State of California to cause cancer
- Reproductive toxicity
 - WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm

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Current Safe Harbor Warnings (cont.)

- Cancer and reproductive toxicity
 - **WARNING:** This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm


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How Will Warning Labels Look?

- New regulations change look and language of Proposition 65 warnings generally


BEFORE	AFTER
WARNING: This product contains chemicals known to the state of California to cause cancer and birth defects or other reproductive harm.	 WARNING: 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 .

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What Is Required in Your Warning Labels?

- Product warning labeling standards
 - Standards for text size (no smaller than 6 pt)
 - Requires name of chemical to be included in warning, unless warning appears on product label
 - Label must include following symbol: 

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On-Product Warnings

- Different warning standard for on-product labels
- Sample product warning labels
 -  **WARNING:** Cancer—
www.P65Warnings.ca.gov
 -  **WARNING:** Reproductive Harm—
www.P65Warnings.ca.gov
 -  **WARNING:** Cancer and Reproductive Harm—
www.P65Warnings.ca.gov

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Internet & Catalog Sales

- Internet and catalog retails are more clearly regulated under revised regulations
 - Internet purchases: warnings must appear on product display page with a clearly marked hyperlink using the word "WARNING"
 - Warning must be provided to purchaser prior to sale
 - Catalogs: warnings must be clearly associated with product being purchased

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Product—Specific Warnings


- Food and dietary supplements
- Alcoholic beverages
- Prescription drugs and medical products
- Dental care products
- Diesel engines
- Raw wood products
- Furniture
- Vehicles and recreational vehicles
- Petroleum products

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Food Product Warnings

- Food products warning changes
 - Standards for text size (no smaller than 6 pt)
 - On-product warning label must be set off from other surrounding information in an enclosed box
 - Warning must include name of chemical(s)
 - Label must include following symbol: 
 - Internet purchases: warnings must appear on product display page
 - Catalogs: warnings must be clearly associated with product being purchased

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Food Product Warnings (cont.)

- Sample food product warning label
(including dietary supplements)



WARNING: Consuming this product can expose you to chemicals such as [name of chemicals] which is known to the State of California to cause cancer [or birth defects or other reproductive harm]. For more information, go to www.P65Warnings.ca.gov/food.

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Proposition 65 Warnings

- Who must provide the warning?
 - Primary burden of providing warnings is on product manufacturers, producers, packagers, importers, suppliers or distributors
 - Retailers can assume responsibility in limited circumstances

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Allocation of Responsibility

- Retailers may enter into agreement with their manufacturers and distributors that specifically allocates legal responsibility for providing warnings

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Sell Through

- Can update warnings prior to effective date of new regulations
- Warnings used pursuant to a court-approved settlement do not need to be changed for those products covered by the settlement agreement
- Products manufactured prior to effective date using pre-amendment warnings will still be compliant
 - Should keep records of manufacturing dates of products containing older warnings

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Questions?



Thank You!

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