






**UNDERSTANDING CALIFORNIA  
PROPOSITION 65:**

*Issues for Out-of-State Manufacturers and Distributors*

COMPLIMENTARY WEBINAR | June 2, 2016

**Reinhart**  
Attorneys at Law



**UNDERSTANDING  
CALIFORNIA PROPOSITION 65:  
Issues for Out-of-State  
Manufacturers and Distributors**

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## Presenter



**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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## Agenda

- 11:45 a.m. CDT Attendees Sign On
- 12:00 p.m. CDT Presentation
- 12:55 p.m. CDT Questions and Answers

### **Asking Questions**

Throughout the webinar, type your questions using the "QUESTIONS" section in the webinar panel. We will answer as many questions as possible during our Q & A session at the end of the webinar.

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### **Asking Questions**

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### **Information**

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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: informing 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

- Citizen suits: Cottage Industry for environmental advocates and plaintiffs' firms
  - As You Sow: <http://www.asyousow.org/>
    - \$501,500 in settlements in 2015
- Defendants at a significant disadvantage in defending against Proposition 65 claims
- Average settlement cost \$100,000

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## Why Proposition 65 Matters to Out-of-State Manufacturers & Distributors (cont.)

- 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)

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## What 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/position-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

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

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## Proposition 65 Warnings

- Warnings must be "clear and reasonable"
- Use safe harbor warning—considered clear and reasonable by law
- Method of transmission
  - Product labeling
  - Posted notices
  - Warning must be made available prior to exposure

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## Proposition 65 Warnings

- Who must provide the warning?
  - Any person who manufactures, produces, assembles, processes, handles, distributes, stores, sells or otherwise transfers a consumer product containing a listed chemical must provide a warning
  - To the extent practicable, obligation is on the manufacturer to provide warning
    - Obligation on retailer if responsible for introducing chemical

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## 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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## 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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## 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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## Enforcement Structure

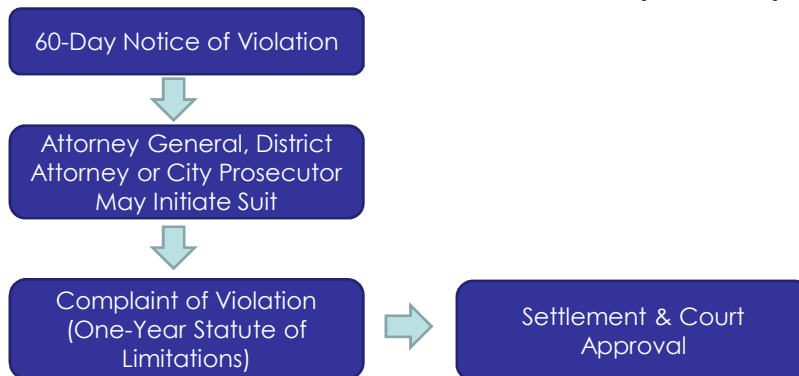
- Who can file a complaint?
  - Attorney General, district attorneys or, in some cases, a city prosecutor
  - Citizens in the public interest
    - Entitled to receive reasonable attorneys' fees and costs
    - 75% of civil penalties must be allocated to the Safe Drinking Water and Toxic Enforcement Fund
    - 25% to plaintiff

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## Enforcement Structure (cont.)



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## 60-Day Notice

- Plaintiff cannot file complaint until expiration of 60-day notice and no public prosecutor initiates a suit
- Notice must include:
  - Party's name
  - Defendant's name
  - Listed chemical identified
  - Route and type of exposure
  - Identification of product
  - Certificate of merit sent to the Attorney General
- Notices are public

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## Plaintiff's Burden of Proof

- Product contained a listed chemical
- Product did not contain a warning
- Plaintiff does not bear burden of proof regarding safe harbor levels or that chemical did not pose a risk of cancer or reproductive harm

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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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## Settlements vs. Litigation

- Who has the leverage?
  - Plaintiff—low burden
    - Only need to have reasonable basis that warning required
  - Defendant's burden to establish safe harbor level or that warning was not required
    - Litigation cost vs. settlement

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## Prior Settlements Available?

- All settlements approved by courts are public
  - <https://oag.ca.gov/prop65>
- Important resource to discover
  - Average settlement range
  - Methods of testing
  - Reformulation methodology (safe harbors)
  - Warning provisions

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## Response to 60-Day Notice

- Halt sales of identified products in California
  - Reduce potential damages
  - Provide time for investigation into alleged violations
- Common goal: obtain settlement without high costs

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## Response to 60-Day Notice (cont.)

- Key settlement terms
  - Warning—language and methods of transmission
  - Reformulation of products
    - Below safe harbor
    - Removal of chemical
    - Monitoring

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## Prevention/Compliance Best Practices

- Product testing/tracking listed chemicals
  - Can you use safe harbor warning for products containing a listed chemical?
- Indemnification/certification
- No contractual indemnity/warranties for Proposition 65?
  - Equitable indemnification under Restatement (Second) Torts § 886B(2)

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## Insurance

- Wells Fargo—Insurance for six listed chemicals for plasticizers:
  - DEHP, DBP, BBP, DIDP, DnHP, DINP
- Policies covering false advertising/failure to warn claims
- Commercial general liability policies:
  - Must closely scrutinize policy language
    - See, e.g., *Ulta Salon, Cosmetics & Fragrance, Inc. v. Travelers Prop. Cas. Co. of Am.*, 197 Cal. App. 4<sup>th</sup> 424 (2011)

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## Proposed Regulations


- OEHHA published draft of proposed regulatory changes to warning requirements in March 2014
  - Still in public comment phase of regulatory amendment process
  - Update may occur as early as end of 2016 or early 2017

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## Proposed Regulations (cont.)


- Product warning changes
  - Standards for text size (no smaller than 6pt)
  - Requires name of chemical to be included in warning, unless warning appears on product label
  - 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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## Proposed Regulations (cont.)

- Food products warning changes
  - Standards for text size (no smaller than 6pt)
  - 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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## Proposed Regulations (cont.)

- Sample product warning labels
  - ⚠ **WARNING:** Cancer—  
[www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)
  - ⚠ **WARNING:** Reproductive Harm—  
[www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)
  - ⚠ **WARNING:** Cancer and Reproductive Harm—[www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

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## Proposed Regulations (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](http://www.P65Warnings.ca.gov/food).

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**Questions?**

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**Thank You!**