



**CONVENTION &
PLASTICS SHOWCASE**

**OCTOBER 1-4, 2018
WASHINGTON, D.C., USA**



**WARNING: California's Proposition 65 Is Hazardous
to Your Business**

Carol Brophy, Esq.
Steptoe & Johnson, LLP

AGENDA

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- **Introduction – How California Is Using Prop 65 to Regulate the World**
- **Brief Overview of Proposition 65**
- **Stated Reasons for Changing the Warning Requirements**
- **The New Warning Regulations**
- **Addressing Practical Realities of Compliance**
- **Compliance Best Practices**
- **Q & A**

- **Proposition 65:**
 - Establishes a List of Chemicals Known to the State of California to cause:
 - Cancer
 - Reproductive Toxicity
 - Prohibits discharges into a source of drinking water;
 - Requires warnings, which can be avoided based on testing and exposure assessments
 - Private enforcement with burden of proof shift to defendants
 - Private enforcers sue “in the public interest” no injury required
 - Private enforcers get 25% of any civil penalty assessed
 - Private enforcers get “reasonable attorneys fees and costs” from defendants

*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.*

HSC § 25249.6

- **Provide Useful Information to Consumer**
 - Requires that at least one chemical be identified in the warning
 - Identify the State's Prop 65 website where additional information can be obtained
 -  Signal symbol to insure the warning is easily seen and not buried
- **Prevent “Prophylactic Warning” - Overwarning**
- **Push the Warning Requirement UP the Supply Chain to Manufacturers and Importers**
- **Eliminates CA Retailer Responsibility in Some Circumstances**

- **Comprehensive change :**
 - Requires at least one chemical to be named.
 - Requires yellow warning symbol 
 - Requires OEHHA website: www.P65Warnings.ca.gov
 - Short warning for small labels – more alarmist – but no chemical identification
 - Internet warnings mandated
- **In effect now – products manufactured after Aug 30, 2018**
 - New warnings on product manufactured on or after. **Inventory grandfathered**
 - Old warnings can be used on products in inventory

- **Consumer Products**



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 birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

- **Food Warnings** – In lieu of yellow triangle may set apart and put in a black box



WARNING: Consuming 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/food

- **Consumer Product Warning Short Form** – only used on package. Signs and internet, catalogue – long form only.

 **WARNING:** Cancer and Reproductive Harm - www.P65Warnings.ca.gov.

- **Must be given to any purchaser who wants products shipped to California**
- **Internet Warnings Must be given before check out –**
 - On the Product Display Page –
 - At the least the word “Warning” must appear on the display page, but the word “Warning” may serve as a link to the full text on another web page.
 - On the check out page, if the warning is clearly associated with the product requiring the warning
- **Catalog Warnings Must Be Associated with the Product**
 - On the display page
 - By telephone or internet order

OVERVIEW OF PROP 65 COMPLIANCE REQUIREMENTS

- **Requirements and Responsibilities Depend Upon Where You “Fit” into the Supply Chain.**
- **DIRECT – Responsibility Imposed by the Statute, and Enforced by Lawsuits:**
 - Retailer, Manufacturer, Importer, Distributer, Licensor (brand name)
- **INDIRECT - Responsible by Indemnity Agreements and Contract:**
 - Foreign manufacturers, distributors and importers ; companies with fewer than 10 employees; Licensees
 - Ingredient/Component Suppliers

OVERVIEW OF PROP 65 COMPLIANCE REQUIREMENTS

- **DIRECT Responsibility – Consumer Product/Service :**
- **Manufacturer, Importer, Distributor, Licensor (brand name)**
- **Retailer** - depends on circumstances (Steptoe Retailer Webinar)
 - **Responsible** to provide warnings if one of 5 circumstances exist:
 1. Retailer owns the brand (house brands/private label)
 2. Retailer knowingly introduced the chemical
 3. Retailer defaced the warning
 4. Retailer was notified by manufacturer and failed to post warning materials provided
 5. Retailer has actual knowledge of the exposure and
 - The manufacturer has fewer than 10 employees or
 - The manufacturer does not have an agent for service or place of business in CA
 - **Not Responsible**: Sell third party products and do not have actual knowledge.

OVERVIEW OF PROP 65 COMPLIANCE REQUIREMENTS

- **INDIRECT - Responsible by Indemnity:**
 - Foreign manufacturers, distributors and importers ; companies with fewer than 10 employees; Licensees
 - **Ingredient/Component Suppliers**
 - Its complicated – but Best Practice: Use SDS to provide information
 - Consider offering “cleaner” product alternatives
- **INDIRECT – Industrial Use Only Products– Companies Outside of California**
 - OSHA preempts state laws unless approved by Fed OSHA.
 - As a condition of approving CA HazCom Plan, California cannot enforce Prop 65 against out of state manufacturers of industrial use products . (62 FR 31159, 6/6/97)
 - CAUTION: If the product is sold to consumers, warnings are required

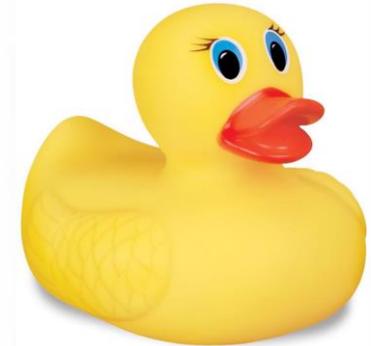
- **California Retailers are requiring vendors and suppliers to accept liability for Proposition 65 compliance.**
 - Vendor Indemnity
 - Some retailers refuse to accept products with warnings, and require reformulation and testing as proof.
- **Distributors and Importers Should Require Upstream Compliance by Manufacturers**
 - Increased demands for reformulation, testing and certifications
- **Manufacturers**
 - Compliance Audit: evaluate component/ingredient sources, set specifications, regulatory options.
- **Ingredient/Component Suppliers:** Compliance Audit: evaluate reformulation options, set specifications, regulatory options.

- **OCCUPATIONAL/INDUSTRIAL USE WARNINGS**
- **DIRECT– OPERATIONS IN CALIFORNIA:**
 - OCCUPATIONAL EXPOSURE – Exposure to *an employee*
 - Workplace Prop 65 – given via California OSHA Hazard Communication Standard
 - Include: Labels, SDSs, Training, Signs in the workplace.
 - Industrial Use Only Products –If you make them/ship them from CA the labeling and SDS Governed by CAL OSHA (8 CCR § 338)
- **For companies located outside of CA** – Occupational Use only Chemical labeling and warnings are controlled by the state/jurisdiction in which the chemicals are placed in commerce. (See Indirect Responsibility)

- **ENVIRONMENTAL EXPOSURES**
- **DIRECT Responsibility – OPERATIONS IN CALIFORNIA:**
 - Any exposure that is not a consumer product exposure or an occupational exposure is an environmental exposure.
 - Warnings given by:
 - Mailed notices
 - Signs posted in the area
 - Printed in the newspaper.
 - Example: Fixed facility in CA, and Mobile Operations

- **Have a Proposition 65 Compliance Program**
 - **Have a Written Procedure**
 - Designate a **responsible individual** – or a team
 - **Include all relevant functions** - e.g. purchasing, manufacturing, QA/QC, operations, regulatory
 - **Integrate Prop 65 compliance** into the way you currently do business
 - **Do a Proposition 65 audit**
 - **Know what products contain listed chemicals**
 - Which are found in your ingredients?
 - Which are formed during manufacture/processing?
 - Which may be found in packaging?
 - **Determine whether you can reformulate or otherwise avoid warning** – Exposure Assessment/Regulatory Options
 - **Provide warnings if necessary**
 - **Have a plan for working with others in the stream of commerce**

- **Step 1: Is there a Proposition 65 chemical present in the product?**
 - Exterior Components targeted by plaintiffs (examples)
 - Brass
 - PVC (soft plastic)
 - Polycarbonate Plastic
 - Other
 - Food, Dietary Supplements, Cosmetic:
 - Safety Data Sheet
 - Analytical Data
 - Other



- **Step 2: Who is exposed & how?**

- **Receptors**

- Consumers
- Workers
- DIY
- Others

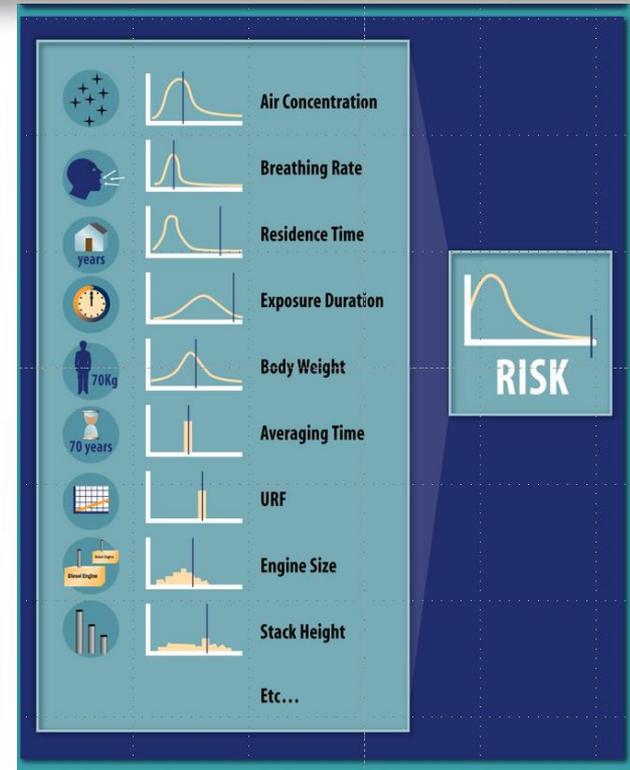


- **Route of Exposure**

- Dermal
- Ingestion
- Inhalation



- **Step 3: Does exposure pose a “significant risk”?**
 - **Is there a “Safe Harbor” level?**
 - 300 numerical levels established (inhalation, ingestion and dermal)
 - Identify cancer potency factor or no observed effect level
 - If no Safe Harbor – Develop One
 - **Data needs**
 - Obtain in literature
 - Develop it
 - Time & costs
 - **Determining Exposure**
 - Safe Use Determinations
 - Interpretive Guidelines
 - Other sources - case law/ consent judgments
 - **Compare Exposure to “Safe Harbor” level**



PUTTING IT ALL TOGETHER

Proposition 65 compliance works best when it is integrated into your company business operations. This means it takes a team. And each business will have unique needs and questions.

- Purchasing/Contracting:
 - Distribution/Contracting;
 - Research and Development : (reformulation and new product development)
 - QA/QC (assist with testing and monitoring)
 - Regulatory – (monitor new developments and relevant case law)
 - Legal/Risk Management
-
- Consider retaining experienced legal/technical team to help implement



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**Carol René Brophy
Steptoe & Johnson LLP
415.365.6724
cbrophy@steptoe.com**