

Proposition 65 Compliance 101

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Proposition 65 Clearinghouse
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Proposition 65 Overview

- Over 900 listed chemicals, any number of which are difficult to eliminate entirely from materials frequently used in consumer products
- List consists of substances determined by State to cause cancer or reproductive toxicity
- Listing mechanism
- Agency: Office of Environmental Health Hazard Assessment (OEHHA)





Proposition 65 Overview (cont'd)

- If exposure is below Safe Harbor Level warning NOT required
 - Safe Harbor Levels not available for all listed chemicals
- Environmental, occupational and consumer product exposures
 - Applies to ALL goods sold in California
- Not pre-empted by other regulations such as CPSIA, FHSA or FIFRA





Proposition 65 Facts and Trends

- Expanded from 30 to now more than 900 listed chemicals

- Trends

- > 760 settlements
- ~ 45 plaintiff groups + Attorney General
- 30 M settlements
- 21M attorney fees and costs

- Recent targets

- Food products
- Pesticides
- Plastics
- eCommerce issues

60 DAY NOTICE OF VIOLATION

SENT IN COMPLIANCE WITH CALIFORNIA HEALTH & SAFETY CODE §25249.7(d)

DATE: May 26, 2017

To: President or CEO – R.C. Bigelow, Inc.
President or CEO – Bigelow Tea
President or CEO – Amazon.com, Inc.
California Attorney General's Office;
District Attorney's Office for 58 counties;
City Attorney's for San Francisco, San Diego, San Jose, and Los Angeles.

From: Mr. Floyd Sherrod

- I. My name is Floyd Sherrod. I am a citizen of the State of California acting in the interest of the general public. I seek to promote awareness of exposures to toxic chemicals in products sold in California and, if possible, to improve human health by reducing hazardous substances contained in such items. This Notice is provided to the parties listed above pursuant to California Health & Safety Code §25249.6 et seq. ("Proposition 65"). The violations covered by this Notice consist of the product exposures, routes of exposures, and types of harm potentially resulting from exposure to the toxic chemical ("listed chemical") identified below as follows:

Product Exposure: See Section VII, Exhibit A
Listed Chemical: Lead
Routes of Exposure: Ingestion
Types of Harm: Birth Defects and Other Reproductive Harm

II. NATURE OF ALLEGED VIOLATION (PRODUCT EXPOSURE)

The specific type of product that is causing consumer exposures in violation of Proposition 65, and that is covered by this Notice, is listed under "Product Category/Type" in Exhibit A in Section VII below. All products within the type covered by this Notice shall be referred to hereinafter as the "products."

The sale of these products in the state of California dating at least as far back as March 20, 2017 are subject to this notice. As a result, exposures to the listed chemical from the use of the products have been occurring without clear and reasonable warnings as required by Proposition 65. Without proper warnings regarding the toxic effects of





Proposition 65—Unique Issues

- May be enforced by the public—there is a “bounty hunter” clause
- The burden of proof is on the defendant
- It has broad application
- Its more than Safety Data Sheet statements; it has other warning implications
- It forces you to take initiative





Option 1: Proposition 65 Compliance Strategies

- **Demonstrate chemical is below Safe Harbor Level – however...**
 - Requires that you know what's in your products
 - Requires conducting technical assessment of your products
 - Chemical testing with supplier understood criteria
 - Documentation program
 - Internal checks/auditing – off the shelf testing
 - You may still be served with a 60-day notice but you will be prepared
 - Often technical exposure assessments are used in settlement negotiations
 - Regardless of the potential for Prop 65 litigation, some just want to know the answer and have the documentation.



Option 2: Proposition 65 Compliance Strategies

- **WARN** – however....
 - Not reasonable or needed in some situations
 - Branding issues/competitor products
 - Some retailers do not want Proposition 65 labeled products
 - Over- warning issue
 - Unlikely to be served with a 60-day notice but ...
 - Requires a well managed labeling program meeting 2018 warning requirements
 - Be ready for retail and customers inquires/questions, public interest groups,





Option 3: Proposition 65 Compliance Strategies

- **Seek Safe Use Determination (SUD) from OEHHA – however...**
 - Product Specific
 - Process may be lengthy
 - SUD may not be issued
 - Can not be sought if in current litigation
 - To date relatively few but more recent activity
- **More information provided at conference session**





What is a Safe Harbor Level ?

- It is **NOT** a easily understood value
 - It is not a concentration of a chemical (NOT ppm, mg/kg or %)
 - It is not the same level as other U.S. or other International product requirements
- A level of **EXPOSURE** to a listed chemical that does not require a warning (micrograms/day $\mu\text{g}/\text{day}$)
 - NSRL (No Significant risk Level): Carcinogens
 - MADL (Maximum Allowable Dose Level): Reproductive/Developmental
- **OEHHA developed SHL for ~ 300 chemicals**
 - Some are pathway, gender, age specific (i.e., BPA 3 $\mu\text{g}/\text{day}$ dermal)



But aren't there also existing composition limits?

Many settlement reformulation limits have established de facto composition limits for ease of implementation

- Only for a FEW chemicals and they are product specific
- Laboratory testing cannot tell you if you are below a SHL – only if you are below a content concentration
- Be careful - comparison to settlement values may not be appropriate for your product

Lead

- SHL = 0.5 $\mu\text{g}/\text{day}$
- Settlements values
 - surface coatings (90 parts per million)
 - Lead- substrates (100-300 parts per million)

Phthalates

- SHL = range from 8 to 2200 $\mu\text{g}/\text{day}$
- Default settlement value
 - 1,000 parts per million (0.1%)



How can I evaluate if I have a chemical above Safe Harbor Level?

- Get as much information from supplier as you can on materials and chemical composition
- Prioritize high-risk chemicals and products
- Understand exposure potential
- Conduct targeting sampling of product
 - Is it there?
 - Does its presence create an exposure risk?
 - How much is dislodged, emitted?
 - Average user





Is exposure-based testing useful?

- YES, in certain instances.
- Requires evaluation of how your product is used, handled
 - Does NOT need to be complicated and costly
 - Has been used by plaintiffs as well as defendants
- OEHHA has granted Safe Use Determinations for products based on exposure testing for several products
- Laboratories usually do not conduct this type of testing
- Requires toxicologist or exposure assessor to conduct and evaluate the data





August 2018 Warning Requirements

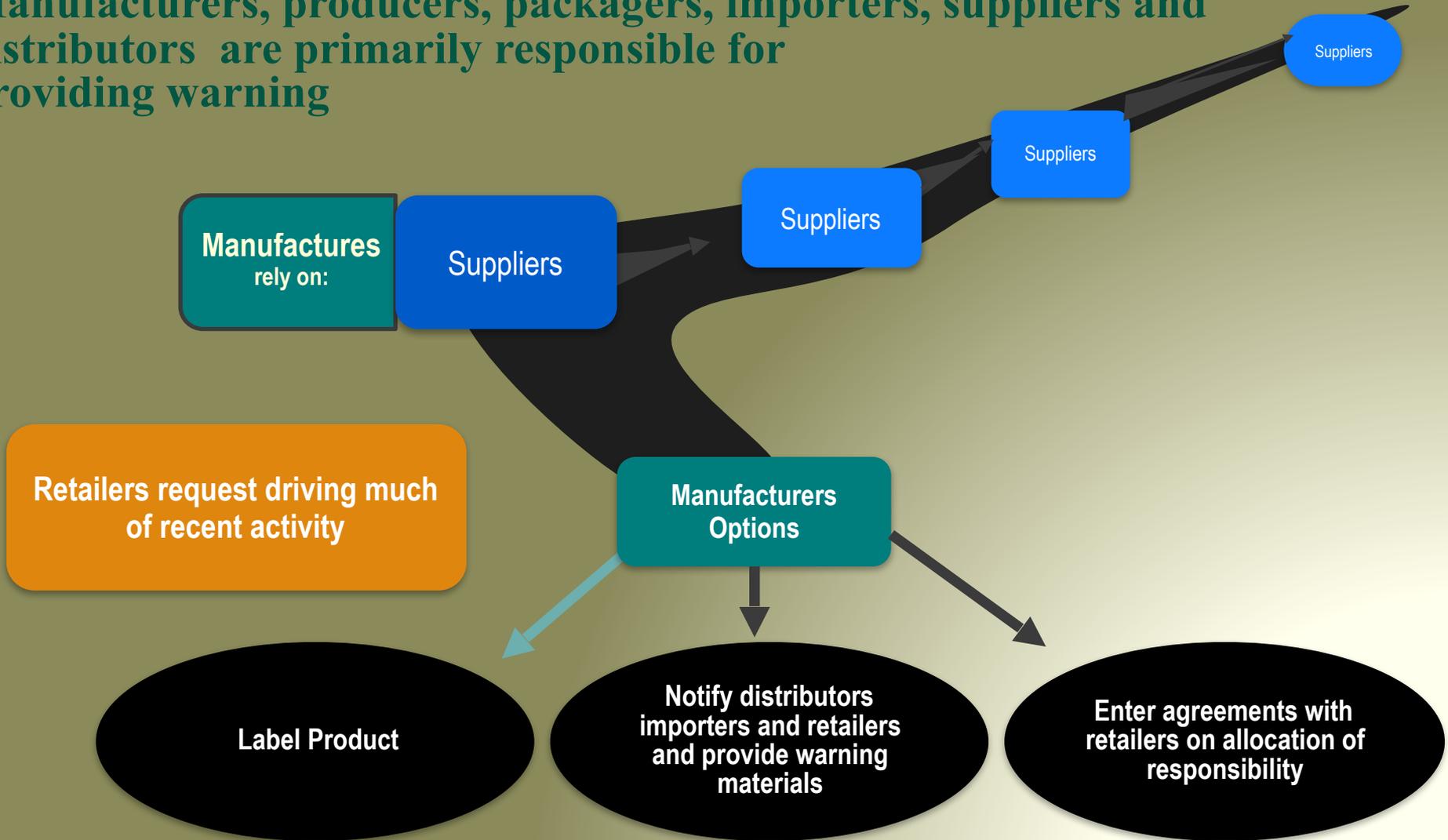


Important

- ***“The new regulations do not determine when a warning is required, they provide guidance for businesses when they have decided to provide a warning for a given exposure to a listed chemical”***
- **Guidance is in terms of warning content, method of transmission and clarification of responsibilities**



Manufacturers, producers, packagers, importers, suppliers and distributors are primarily responsible for providing warning





New Warning Requirements

- Applies to products manufactured *after* August 30, 2018
- Existing court-approved settlements/judgments are grandfathered in. Covers company and specific product
- OEHHA's safe harbor warnings deemed "clear and reasonable"



Standard Warning Cancer and Reproductive Harm

- **At least one chemical for each toxicological endpoint**
 - Include a chemical known to be a carcinogen
 - Include a chemical known to be a reproductive toxin
 - Include a chemical known to be both carcinogen and reproductive toxin
- **Refer to website**



WARNING: This product can expose you to chemicals including lead and DEHP, which 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.



Short Form Warning Cancer and Reproductive Harm

- **Only need toxicological endpoint**
- **Refer to website**



WARNING: Cancer and Reproductive Harm - w.P65Warnings.ca.gov.



Item	Requirement
<p>Yellow Warning symbol</p>	<p>Must be printed in yellow if yellow used elsewhere, otherwise black and white.</p> <div data-bbox="1644 472 1779 601" style="text-align: right;"> </div>
<p>Other Languages</p>	<p>If product instructions / warnings in language other than English, Prop 65 warning must be in those languages.</p>
<p>Size</p>	<p>At least 6 pt. type, or at least as large as other consumer warnings on label.</p>



Methods of Transmission

■ In-Store Warnings

- Label: Standard or short form
- Point of Display or shelf: Standard warning

■ Catalogue

- Must **be clearly associated** with the product being purchased

■ Internet

- **“WARNING”** on product display page
- *Prior* to completing internet purchase
- If label used for the warning, can provide a hyperlink to the warning or a photo of the warning

■



Industry Specific Warnings and methods of transmission

- Restaurants
- Dental Care
- Parking facilities
- Amusement parks
- Petroleum operations
- Designated Smoking Areas
- Service station and repair
- Cannabis Industry



Restaurant Industry Example

““Certain foods and beverages sold or served here can expose you to chemicals including acrylamide in many fried or baked foods, and mercury in fish, which 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/restaurant



Environmental Exposure

Content

- WARNING
- New Symbol
- Language



“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 [X and X], from [source]. For more information go to [www.P65Warnings .ca.gov](http://www.P65Warnings.ca.gov).”



Occupational Exposure

- A warning to an exposed employee meets the requirements if it fully complies with all warning information, training, and labeling requirements of the federal hazard Communication standard, or for pesticides, the Pesticides and Worker Safety requirements
- Additional Safe Harbor warning may be provided





What Should You Do?

■ Identify your at-risk products

- Understand if Prop 65 chemicals are present, if they are easily identified
- Evaluate potential exposure risk from use of your product. Is there a relevant exposure pathway? Presence \neq exposure!
- Consider other settlements on similar products

■ Consider business implications and legal risks

- Consult with legal counsel
- Indemnifications

■ Identify compliance strategy for different products

- Document not present (reformulate)
- Document product is below Safe Harbor Level
- Seek Safe Use Determination from OEHHA
- Label



Thank you

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