

PROPOSITION 65 COMPLIANCE 101

Proposition 65 Clearinghouse Conference
San Francisco CA
September 21, 2020

PROPOSITION 65 COMPLIANCE 101

SESSION GOAL

- **Provide an overview of the:**
 - **Nuts and bolts of compliance**
 - **Key technical and policy issues**
 - **Resources available to support compliance**

PROPOSITION 65 COMPLIANCE 101

INSTRUCTORS

- Carol Monahan Cummings – Chief Counsel, Office of Environmental Health Hazard Assessment (OEHHA), Sacramento CA
- Renee Kalmes – Principal, Exponent Oakland CA
- Matt Nevins – Research Manager, Center for Environmental Health (CEH), Oakland CA



PROPOSITION 65 COMPLIANCE 101

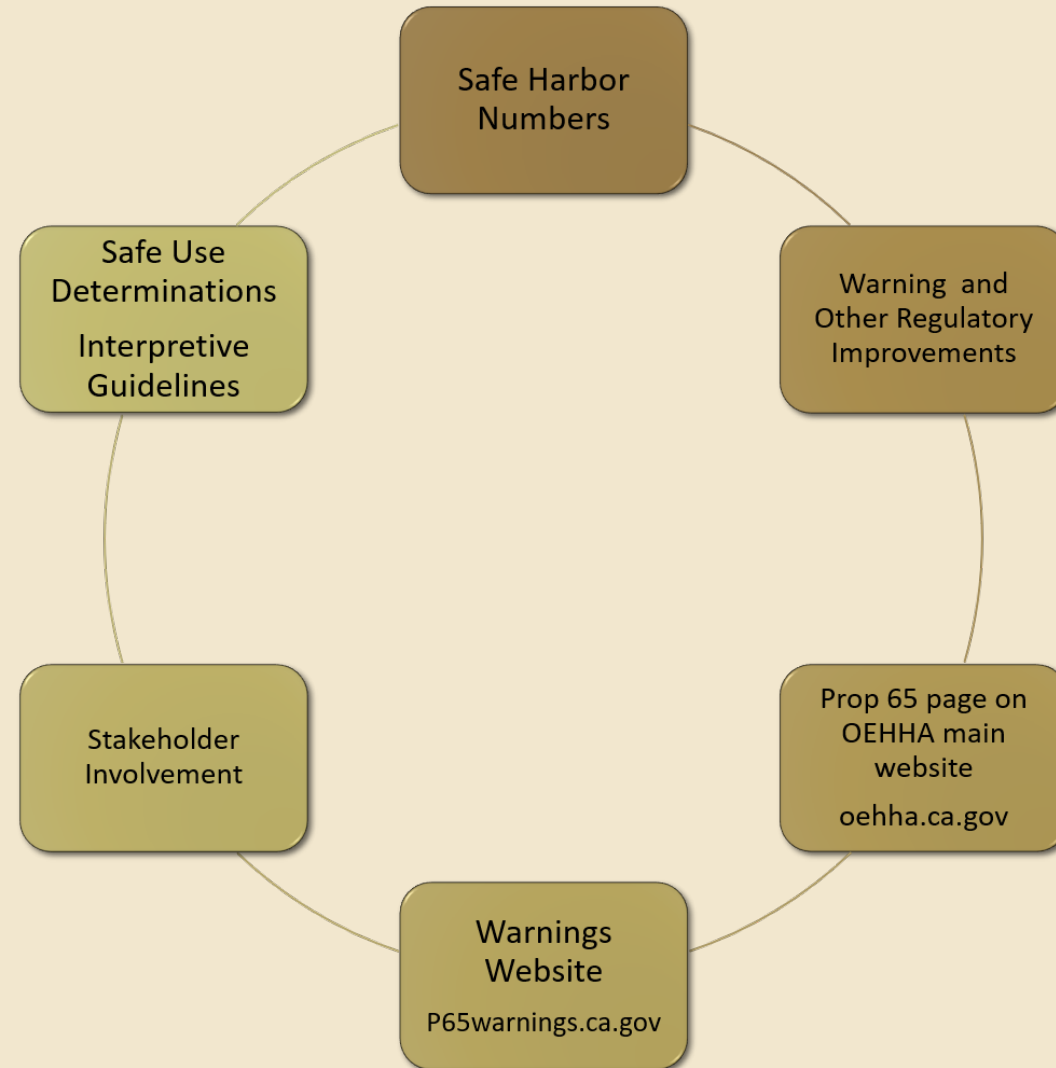
OUTLINE

- I. Introduction**
- II. Prop 65 Overview and Resources**
- III. Prop 65 Assessment**
 - A. List of chemicals**
 - B. Safe Harbor Levels**
 - C. Exposure Assessment**
- IV. Risk Management**
 - A. Warnings**
 - B. Discharge Prohibition**
 - C. Court Decisions and Consent Judgments**
 - D. Product Reformulation**
 - E. Safe Use Determinations**
- V. CEH Case Studies**

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 PROPOSITION 65 OVERVIEW

- **Voter approved initiative passed in November 1986**
- **Requires State to develop list of carcinogens and reproductive toxicants – listing mechanisms**
- **Warning requirement**
- **Discharge prohibitions**
- **OEHHA is Lead Agency – adopts (no enforcement authority)**
- **Enforced by State Attorney General, local prosecutors and private individuals acting in the public interest**
- **Burden shift**
- **Penalties**

RESOURCES



KEY RESOURCES FOR PROP 65 COMPLIANCE

- **OEHHA Webpage**
- **Safe Use Determinations (SUDs)**
- **Interpretive Guidelines**
- **Court Decisions**
- **Consent Judgements**

USEFUL LINKS FOR PROPOSITION 65 COMPLIANCE SUPPORT

- <https://oehha.ca.gov/proposition-65/about-proposition-65>
- <https://oehha.ca.gov/proposition-65/law/proposition-65-law-and-regulations>
- <https://www.p65warnings.ca.gov/>
- <https://www.p65warnings.ca.gov/fact-sheets>

USEFUL LINKS FOR PROPOSITION 65 COMPLIANCE SUPPORT

- “Safer Air, Safer Water, Safer Products”
 - Success stories from 30 years of Proposition 65 – report authored by CEH.
 - <https://www.ceh.org/wp-content/uploads/P65-Successes-2015.pdf>
- Center for Environmental Health v. Lulu NYC, LLC
 - pages 4-5: injunctive relief & lead limits in fashion accessories.
 - <https://www.oag.ca.gov/system/files/prop65/judgments/2009-00410J1053.pdf>
- Center for Environmental Health v. Lamb Weston Holdings, Inc.
 - Pages 3-4: injunctive relief & acrylamide reformulation levels.
 - <https://oag.ca.gov/system/files/prop65/judgments/2016-01412J3851.pdf>
- Center for Environmental Health v. Trend Textile, Inc.
 - Page 3: injunctive relief & cadmium reformulation levels.
 - <https://oag.ca.gov/system/files/prop65/judgments/2018-00731J4146.pdf>

HAZARD IDENTIFICATION UNDER PROP 65

- **Types of chemicals listed:**
 - Carcinogens
 - Reproductive Toxins (developmental, male reproductive, female reproductive)
- **The Prop 65 List:**
 - <https://oehha.ca.gov/media/downloads/proposition-65//p65list091319.pdf>

PROP 65 LIST

STATE OF CALIFORNIA
ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY
September 13, 2019

The Safe Drinking Water and Toxic Enforcement Act of 1986 requires that the Governor revise and republish at least once per year the list of chemicals known to the State to cause cancer or reproductive toxicity. The identification number indicated in the following list is the Chemical Abstracts Service (CAS) Registry Number. No CAS number is given when several substances are presented as a single listing. The date refers to the initial appearance of the chemical on the list. For easy reference, chemicals which are shown underlined are newly added. Chemicals or endpoints shown in ~~strikeout~~ were placed on the Proposition 65 list on the date noted, and have subsequently been removed.

<u>Chemical</u>	<u>Type of Toxicity</u>	<u>CAS No.</u>	<u>Date Listed</u>
A-alpha-C (2-Amino-9H-pyrido [2,3-b]indole)	Cancer	26148-68-5	January 1, 1990
Abiraterone acetate	developmental, female, male	154229-18-2	April 8, 2016
Acetaldehyde	cancer	75-07-0	April 1, 1988
Acetamide	cancer	60-35-5	January 1, 1990
Acetazolamide	developmental	59-66-5	August 20, 1999
Acetochlor	cancer	34256-82-1	January 1, 1989
Acetohydroxamic acid	developmental	546-88-3	April 1, 1990
2-Acetylaminofluorene	cancer	53-96-3	July 1, 1987
Acifluorfen sodium	cancer	62476-59-9	January 1, 1990
Acrylamide	cancer	79-06-1	January 1, 1990
Acrylamide	developmental, male	79-06-1	February 25, 2011
Acrylonitrile	cancer	107-13-1	July 1, 1987
Actinomycin D	cancer	50-76-0	October 1, 1989
Actinomycin D	developmental	50-76-0	October 1, 1992
AF-2;[2-(2-furyl)-3-(5-nitro-2-furyl)] acrylamide	cancer	3688-53-7	July 1, 1987
Aflatoxins	cancer	---	January 1, 1988

- **There are over 900 chemicals on the Prop 65 list.**



THE PROP 65 LIST

How do chemicals get listed under Prop 65?

- 1. Labor Code (LC)**
- 2. State's Qualified Experts (SQE)**
- 3. Authoritative Bodies (AB)**
- 4. Formally Required to be Labeled (FR)**

WARNING EXEMPTIONS LEVELS UNDER PROP 65

- **Warning Exemption Levels**
 - No Significant Risk Level (NSRL) – one in a hundred thousand lifetime incremental cancer risk
 - MADL – 1/1000 of the No Effect Level for reproductive/developmental effects
- **Where to find MADLs and NSRLs**
 - Values are described as micrograms per day (ug/day)
 - <https://oehha.ca.gov/media/downloads/proposition-65//safeharborlist032519.pdf>
- **Safe Harbor Levels**
 - Intended to provide “safe harbor” for businesses
 - Do not preclude use of alternative levels that can be demonstrated by their users as being scientifically valid.

DOSE RESPONSE ASSESSMENT UNDER PROP 65

- **What to do if no published NSRL or MADL?**
 - Still responsible for evaluating need to warn
 - Warn?
 - Develop warning exemption level for chemical/product and conduct exposure assessment



THE PROPOSITION 65 ASSESSMENT PROCESS:

- Is chemical present ?
- Does exposure require a warning?
 - Mere presence of a chemical does not indicate need for warning
 - Safe Harbor Levels
 - Conduct Exposure Assessment and compare to Safe Harbor Levels
- Consider one chemical at a time under Prop 65
 - Cumulative risk not addressed

EXPOSURE ASSESSMENT: AVERAGE EXPOSURE LEVEL

- **Proposition 65 based the average level of exposure**
 - Differs from other regulatory programs
 - Some default exposure assumptions provided in regulations
 - What is “average”
 - Naturally occurring chemicals in food exempt
 - Plus “lowest level currently feasible”

EXPOSURE ASSESSMENT: EXPOSURE AVERAGING TIME

- **Depends of health effect and mechanism of action:**
 - **Carcinogens: compare NSRL to Lifetime Average Daily Dose (LADD) (i.e., over 70 years)**
 - **Reproductive toxicants:**
 - **“The reasonably anticipated rate of exposure shall be based on the pattern and duration of exposure that is relevant to the reproductive effect which provided the basis for the determination that a chemical is known to the State to cause reproductive toxicity.**

EXPOSURE ASSESSMENT: TYPES

- **Types**
 - environmental
 - occupational
 - consumer products *****
 - food products ***
- **Assess the “reasonably anticipated rate of exposure”**

EXPOSURE ASSESSMENT: SAMPLING

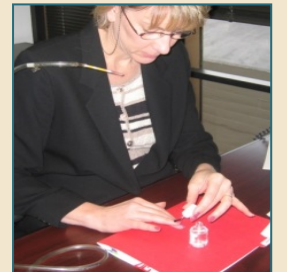
- **Do you need to sample?**
 - **OEHHA's regulations do not require a business to perform any testing**
 - **But... you need to know what is in your products**
 - **Supplier information and testing**
 - **Your own testing *****
 - **Other relevant information**
 - **Specifications – Restricted Substance Lists**
 - **Raw material controls**
 - **Test Certificates**

EXPOSURE ASSESSMENT: INTERPRETATION OF SAMPLE DATA

- **“Content” values (mg/kg or ppm) \neq safe harbor levels
“exposure” (ug/day)**
- **For some high risk chemicals (i.e., phthalates and lead) concepts have become combined and Proposition 65 settlements are often expressed in content for ease of implementation**
- **Lowest settlements values often used as “default” Prop 65 “compliance” levels although not scientifically correct and not always applicable to your product**

EXPOSURE TESTING: CONTENT VERSUS EXPOSURE

- **Typical Product Compliance sampling**
 - “Content” or “concentration” (ppm or mg/kg)
- **Exposure based sampling and risk assessment**
 - Provides more refined data to address what is released or dislodged during product use ($\mu\text{g}/\text{day}$)
 - Usually fairly simple but depends on product
 - Addresses exposures such as:
 - Oral: are chemicals released from product when mouthed?
 - Inhalation: are chemicals emitted from product (e.g., adhesives, plastics)
 - Dermal: Are chemicals dislodged from product onto skin when handled (e.g., tools, office supplies)
 - Incidental hand-to-mouth: Are chemicals ingested after touching product



EXPOSURE ASSESSMENT: GUIDANCE

- Prop 65 regulations have limited guidance on assumptions to be used to calculate exposure
 - Exposure Frequency
 - Exposure Duration
 - Behaviors (hand to mouth)
 - Averaging time
- EPA Exposure Assessment Guidance
- OEHHA proposed clarifications



RISK MANAGEMENT

- Warnings

- Detailed regulations available - Article 6 Clear and Reasonable Warnings – August 2018
- Over-warning



- Consent Judgments, Mediated Settlements, and Court Decisions

- e.g., Concentration agreements in consent judgments

- Product Reformulation

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

SAFE USE DETERMINATION (SUD)

- Process to seek a determination by OEHHA if a specific and product use is below the Safe Harbor Level
- The request matter can not be subject of a notice of violation or legal action
- Requires scope request and product and exposure data information
 - Chamber studies of air emissions, product and/or hand wipe data, leaching in artificial sweat
- Recent SUDs include styrene, BPA, silica, DiNP
- Regulations Title 27, Cal. Code of Regs., section 25204
- Safe Use Determination SUD Process Guidance
- <https://oehha.ca.gov/proposition-65/proposition-65-safe-use-determinationsud-process>

OUR SHARED GOAL: PUBLIC HEALTH

- What is the health-protective way to comply with Prop 65?
- Remove toxic chemicals from the products that Californians buy and use every day.



HAZARDOUS LEAD REMOVED FROM TOYS

- Lead-contaminated toys made headlines in 2007.
- Prop 65 litigation followed by a bipartisan federal law successfully ended this hazard.



LEAD REMOVED FROM FASHION ACCESSORIES



- Lead pigments were commonly used in the early 2000s.
- The fashion industry worked with CEH to set strict lead limits, as part of Prop 65 litigation.

ELIMINATION OF CHLORINATED TRIS FROM BABY PRODUCTS

- Tris did not provide fire safety benefits.
- Following Prop 65 litigation and a change in state regulations, manufacturers eliminated use of this chemical and other flame retardants.





REDUCTION OF ACRYLAMIDE IN SNACK FOODS

- Often found in products marketed as healthier snacks.
- Following Prop 65 litigation, companies changed production practices to successfully reduce acrylamide contamination.



CADMIUM REMOVED FROM JEWELRY SOLD AT ROSS

- Cadmium was found (in levels over 90%) in metallic jewelry attached to women's dresses sold at Ross: Dress for Less
- Following Prop 65 enforcement litigation, Ross' suppliers agreed to reformulate jewelry to $< 0.01\%$ Cd.





PRODUCT REFORMULATION

- The public health approach to complying with Proposition 65 has effectively reduced Californians' exposure to toxic chemicals.

QUESTIONS?