

PROPOSITION 65 COMPLIANCE 101

Proposition 65 Clearinghouse Conference
San Francisco CA
September 23, 2019

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

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PROPOSITION 65 COMPLIANCE 101

OUTLINE

- I. Introduction**
- II. Prop 65 Overview and Resources**
- III. Risk Assessment Under Prop 65**
 - A. Hazard Identification**
 - B. Dose-Response Assessment**
 - C. Exposure Assessment**
 - D. Risk Characterization**
- IV. Risk Management**
 - A. Warning**
 - B. Discharge Prohibition**
 - C. Court Decisions and Consent Judgments**
 - D. Product Reformulation**

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

- **Voter approved initiative, November 1986**
- **Requires State to develop list of carcinogens and reproductive toxicants – listing mechanisms**
- **Warning requirement**
- **Discharge prohibitions**
- **OEHHA is Lead Agency – adopts regulations (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**

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

PROP 65 LIST

- **There are over 900 chemicals on the Prop 65 list.**
- **Each of these chemicals causes cancer and/or reproductive harm.**

DOSE RESPONSE ASSESSMENT UNDER PROP 65

- **Warning Exemption Levels**
 - No Significant Risk Levels – one in a hundred thousand lifetime incremental cancer risk
 - MADL – 1/1000 of the No Effect Level for reproductive/developmental effects
- **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

**Office of Environmental Health Hazard Assessment
Proposition 65 No Significant Risk Levels (NSRLs) for Carcinogens and
Maximum Allowable Dose Levels (MADLs) for Chemicals Causing Reproductive Toxicity**

Below is a list of NSRLs and MADLs that provide "safe harbor" for businesses subject to the requirements of Proposition 65. These NSRLs and MADLs are established in regulation in Title 27, Cal. Code of Regulations, Sections 25705, 25709 and 25805. These safe harbor levels do not preclude the use of alternative levels that can be demonstrated by their users as being scientifically valid. A hyperlink is provided for those NSRLs or MADLs for which the documentation of their derivation is electronically available.

Chemical	NSRL (µg/day) ^a	MADL (µg/day) ^a
A-alpha-C (2-Amino-9H-pyrido[2,3-b]indole)	2	
Acetaldehyde	90 (inhalation)	
Acetamide	10	
2-Acetylaminofluorene	0.2	
Acrylamide	0.2	
Acrylonitrile	0.7	140
Actinomycin D	0.00008	
AF-2;[2-(2-furyl)-3-(5-nitro-2-furyl)]acrylamide	3	
Aldrin	0.04	
2-Aminoanthraquinone	20	
o-Aminoazotoluene	0.2	
4-Aminobiphenyl (4-aminodiphenyl)	0.03	
3-Amino-9-ethylcarbazole hydrochloride	9	
1-Amino-2-methylantraquinone	5	
2-Amino-5-(5-nitro-2-furyl)-1,3,4-thiadiazole	0.04	
Amitrole	0.7	
Aniline	100	
o-Anisidine	5	
o-Anisidine hydrochloride	7	
Aramite	20	

DOSE RESPONSE ASSESSMENT UNDER PROP 65 (CONTINUED)

- **What to do if no published NSRL or MADL?**
 - Still responsible for warning
 - Warn?
 - Develop warning level for chemical/product?

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)**
 - **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. (For example, an exposure of short duration is appropriate for a teratogenic chemical whereas a chronic or protracted exposure is appropriate for one that retards fetal growth.)”

RISK CHARACTERIZATION

- **Consider one chemical at a time under Prop 65**
 - Cumulative risk not addressed
- **Is estimated exposure below warning exemption level?**
 - Presence of a warning does not necessarily mean warning is above warning exemption level?

RISK MANAGEMENT

- **Warnings**
 - Detailed regulations available
 - Over-warning
- **Discharge Prohibition**
- **Consent Judgments, Mediated Settlements, and Court Decisions**
 - e.g., Concentration agreements in consent judgments
- **Product Reformulation**

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.

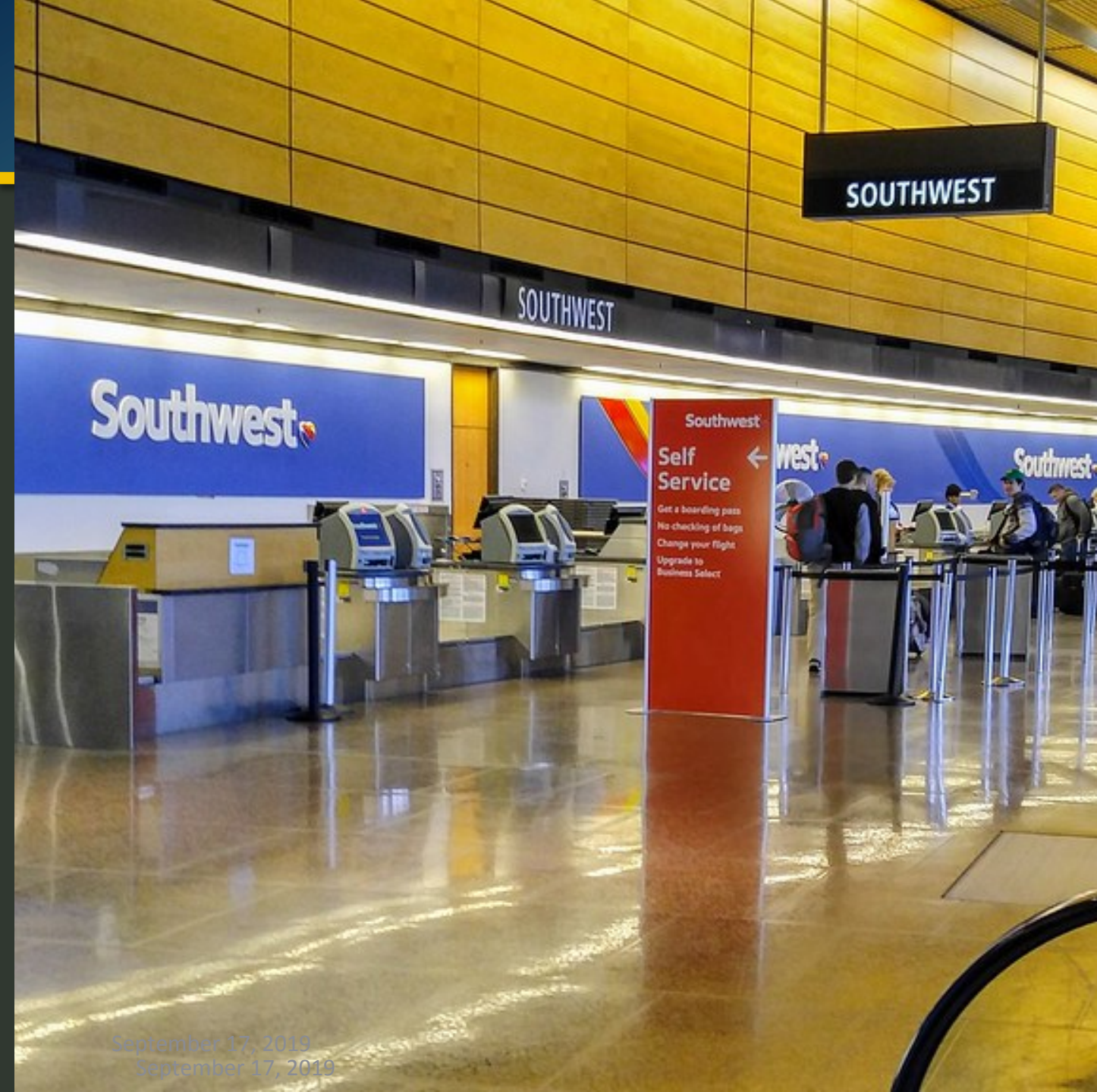
ELIMINATION OF CHLORINATED TRIS FROM BABY PRODUCTS

- 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.

BISPHENOL A (BPA) NO LONGER USED IN BOARDING PASSES



- BPA was commonly used in thermal paper, e.g. boarding passes and receipts.
- Following Prop 65 enforcement litigation, Southwest Airlines switched to BPA-free paper and electronic boarding passes.

A close-up photograph of a young boy with short, dark hair, wearing an orange and black striped shirt. He is peeking over a field of tall, green grass, with only his eyes, nose, and mouth visible above the blades. The background is a soft-focus green field.

PRODUCT REFORMULATION

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

QUESTIONS?

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>
- <https://oehha.ca.gov/media/downloads/proposition-65//p65list091319.pdf>
- <https://oehha.ca.gov/media/downloads/proposition-65//safeharborlist032519.pdf>

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>