

Proposition 65: Compliance 101

Proposition 65 Clearinghouse Conference
August 31, 2026

Presenters

- Sophie Castillo, partner, Keller and Heckman LLP
- Corey Friedman – Senior Counsel, OEHHA
- Emily Goswami, Principal Scientist, Roux Associates
- Meredyth Merrow – Attorney, Lexington Law Group LLP



Office of Environmental Health Hazard Assessment

Proposition 65

- Determines what chemicals are Proposition 65-listed carcinogens and reproductive toxicants.
- Issues Proposition 65 regulations and provides assistance to the public and businesses.

Other work

- Proposition 65 is one of many OEHHA programs. OEHHA is the state's lead agency for assessment of health risks from environmental contaminants.

Proposition 65



Approved in 1986 by California voters by a 63-37 margin.

A reaction to 1980s perceptions that government was not doing enough to regulate toxic chemicals.

No person in the course of doing business shall knowingly discharge or release a chemical known to the state to cause cancer or reproductive toxicity into water or onto or into land where such chemical passes or probably will pass into any source of drinking water.....

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...



What Does “expose” Mean?

“Expose” means to cause to ingest, inhale, contact via body surfaces or otherwise come into contact with a listed chemical. An individual may come into contact with a listed chemical through water, air, food, consumer products and any other environmental exposure as well as occupational exposures.

Title 27, Article 6, Sec. 25102(i)



Clear and Reasonable Warnings

- For consumer products - manufacturer, producer, packager, importer, supplier, or distributor of a product, and retail seller.
- OEHHA's regulatory warnings are presumptively clear and reasonable.
- "Safe harbor." Can use other warnings that are clear and reasonable.
- Consumer Product Warnings – Tit. 27 § 25601 -25603

 **WARNING:** Can expose you to formaldehyde,
a carcinogen and toluene, a reproductive toxicant.
See www.P65Warnings.ca.gov



When is a warning not needed?

Exemptions

Safe Use
Determinations
(SUD)

Safe Harbor Levels

- No Significant Risk Level (NSRL)
- Maximum Allowable Dose Level (MADL)

Review guidance
from OEHHA



When a Warning is Needed – Methods of Warning

- Sign, shelf tag, shelf sign at each point of display of the product
- On the Label
- Online
- Catalog
- Electronic device that automatically provides warning prior to or during purchase
- As per the specific regulation



Content of Safe Harbor Warnings

- Full-length warning
- Short-form warning
- Tailored warnings

 **WARNING:** This product can expose you to chemicals including formaldehyde, which is known to the State of California to cause cancer, and toluene, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

 **WARNING:** Cancer -- www.P65Warnings.ca.gov.

* Not for use
after Jan. 1, 2028

 **WARNING:** Can expose you to formaldehyde, a carcinogen. See www.P65Warnings.ca.gov.

 **CA WARNING:** Cancer risk from exposure to formaldehyde. See www.P65Warnings.ca.gov.



OEHHA updates

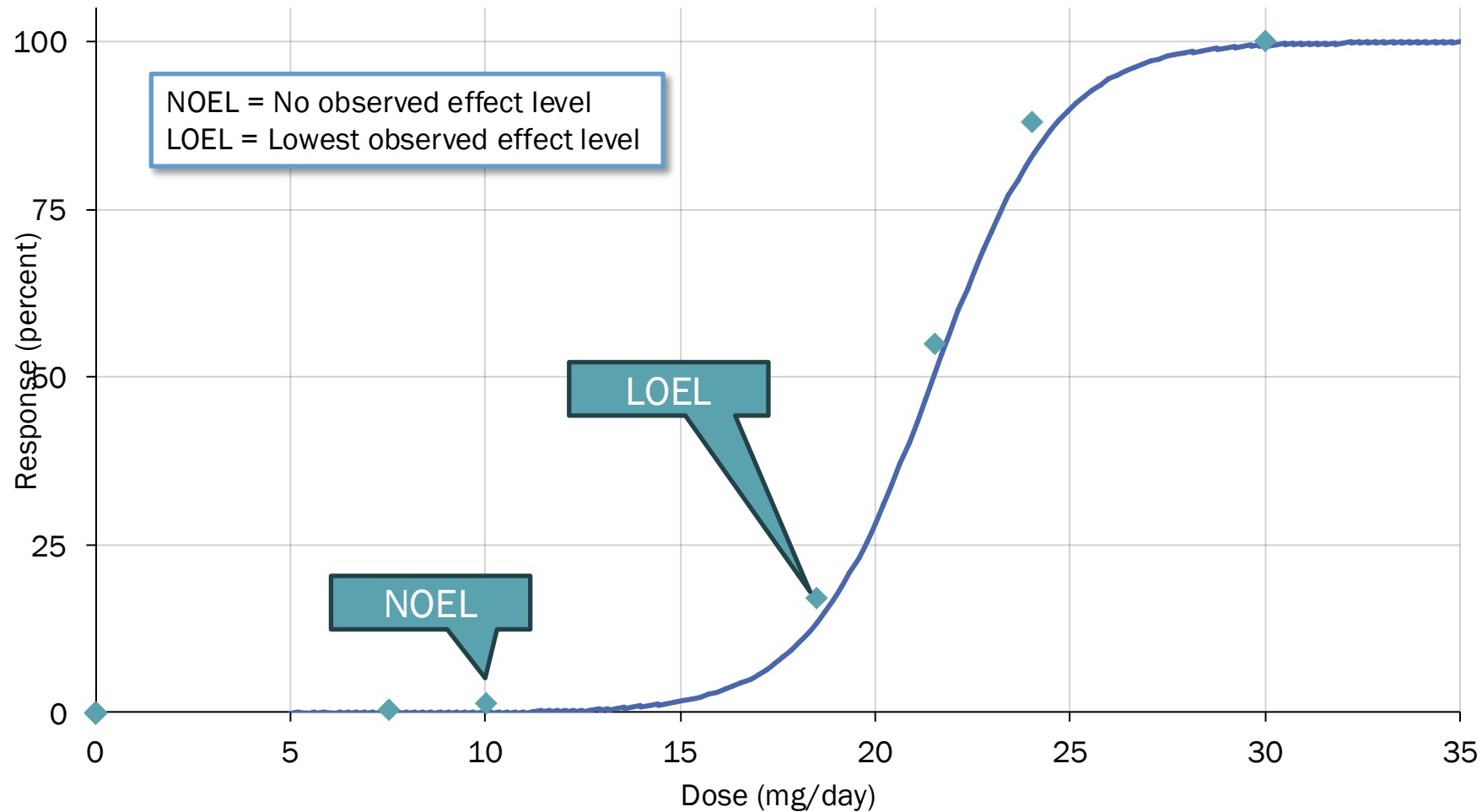
- NSRLs for 1-BP and DEA
- OEHHA held an informal public meeting about an “omnibus” package of multiple regulatory amendments.

Safe Harbor Levels

- Maximum Allowable Dose Level (MADL) for chemicals that can cause reproductive or developmental toxicity
- No Significant Risk Level (NSRL) for carcinogens
- Units of EXPOSURE in micrograms/day ($\mu\text{g}/\text{day}$)
- It is NOT a concentration or content level of a chemical (% , ppm, mg/kg, etc.)
- Some are pathway-specific (oral/inhalation)
- Only 1/3rd of listed chemicals have an SHL (346/1015)

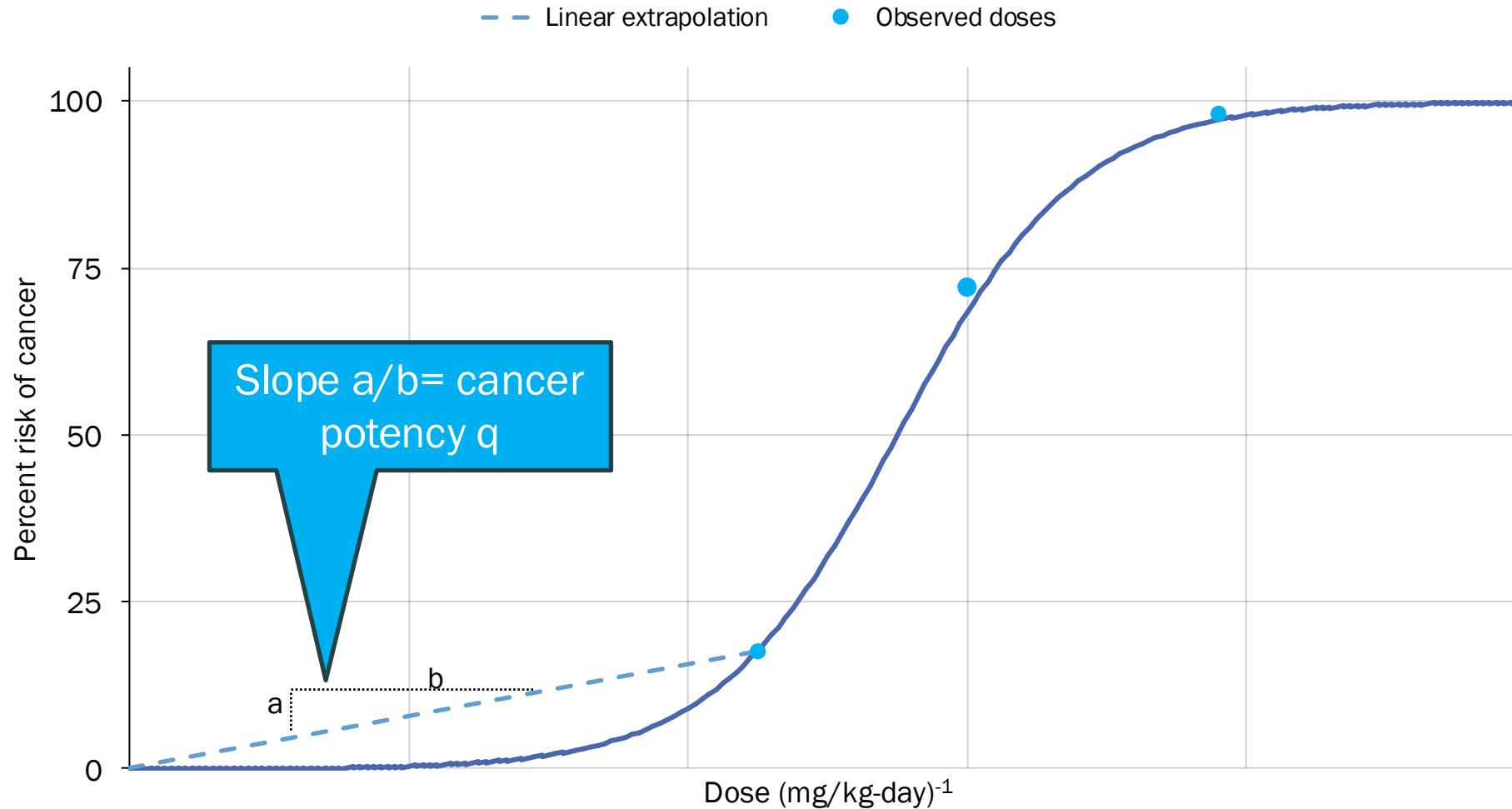


Developmental/Reproductive Toxicants: MADL Development



$$MADL = \frac{NOEL}{1000}$$

Carcinogens: NSRL Development

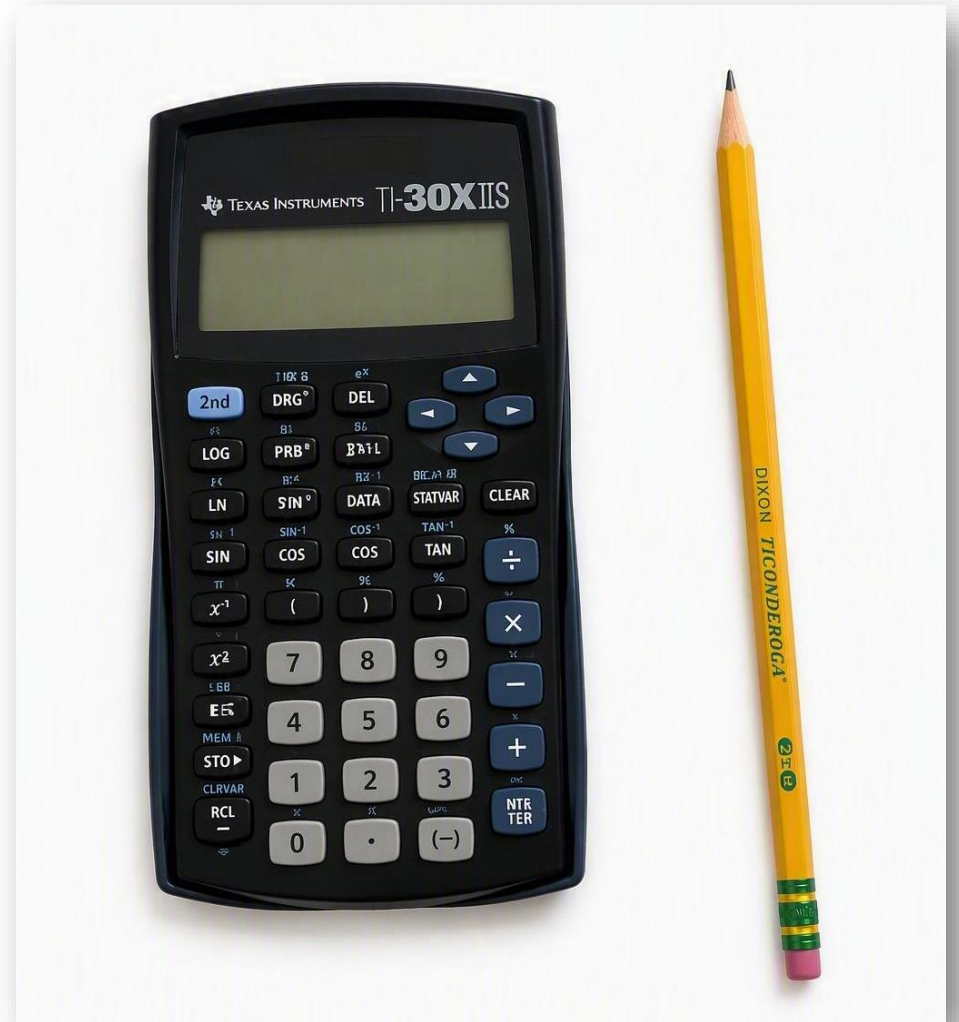


$$NSRL = \frac{10^{-5} \times 70 \text{ kg}}{q}$$

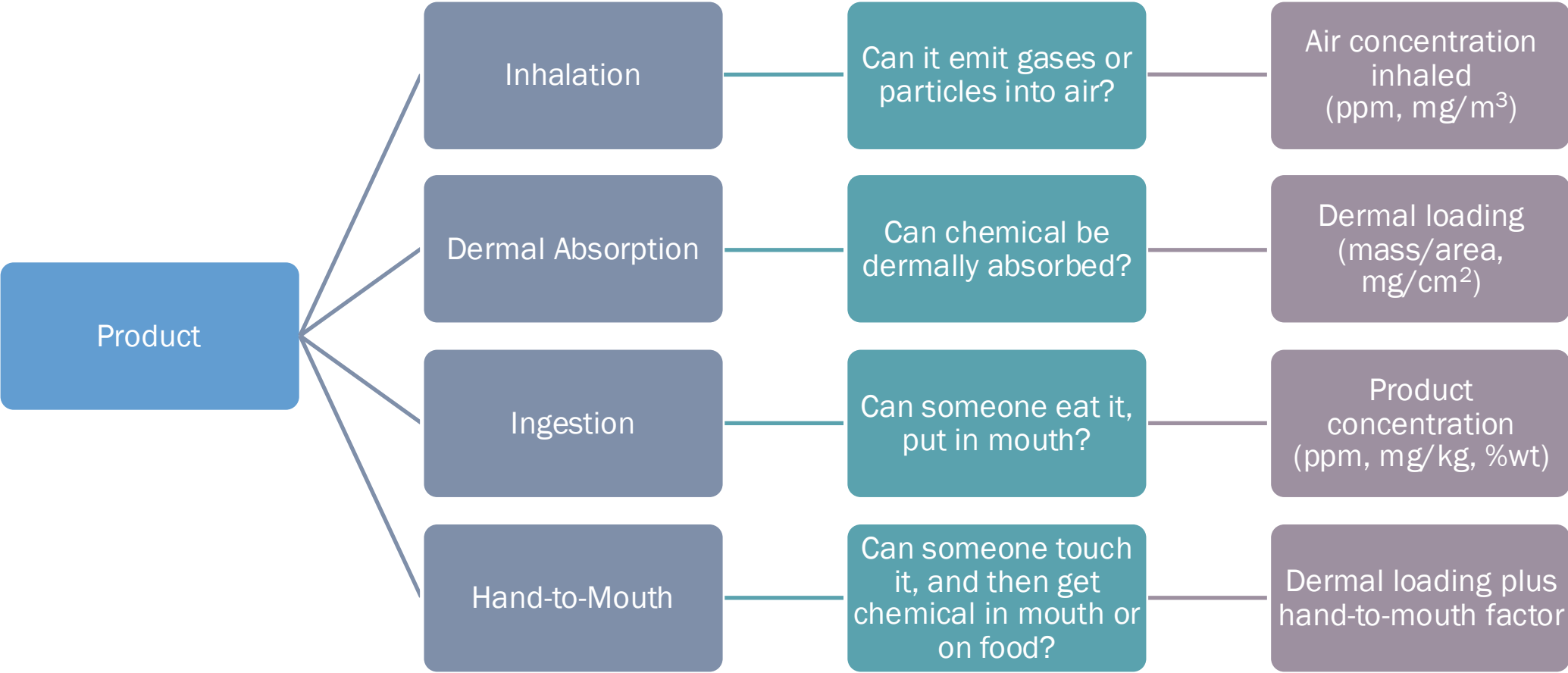
The daily intake causing no more than one excess cancer case in 100,000 people

What if there is no SHL?

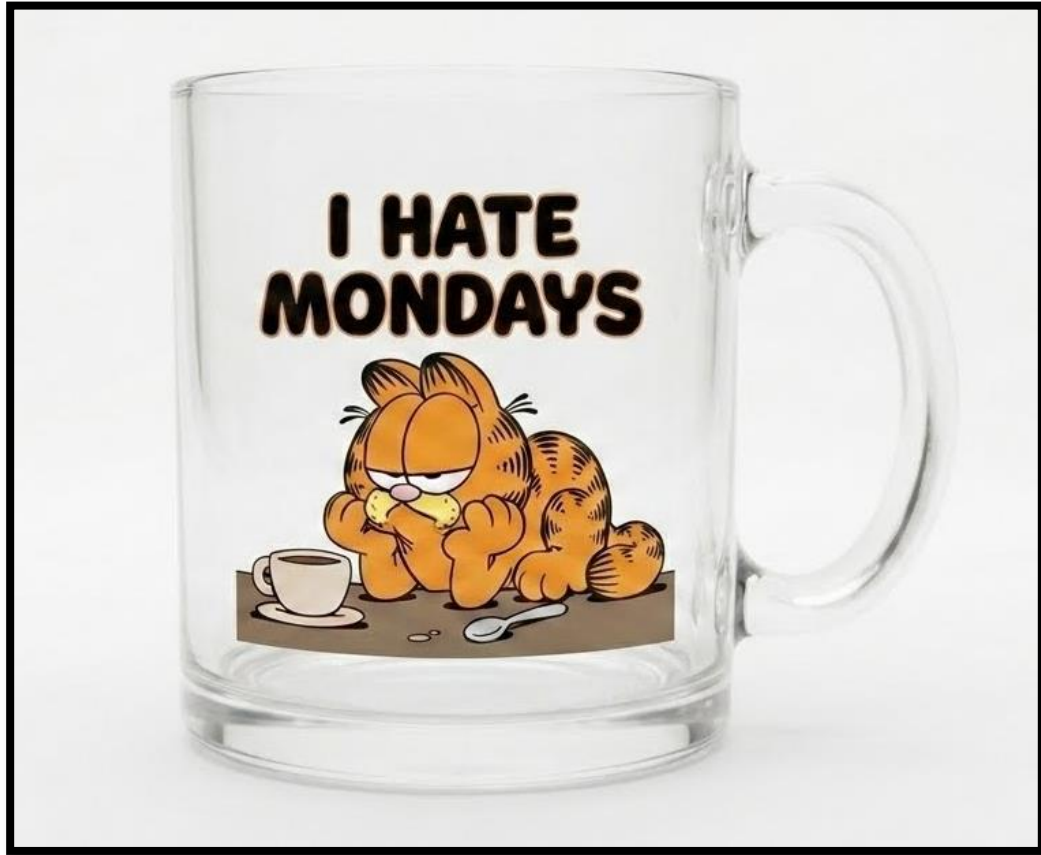
- Develop a SHL
 - For NSRL – need cancer potency factor
 - For MADL – need NOEL
 - Toxicity values: Use agency recommended values OR analyze the published literature
 - If OEHHA develops a lower SHL later on, you may need to re-evaluate



Exposure Pathways and Measurements



Case Study: Coffee Mug w/Lead Paint*



**Not an actual product on the market*

Can it emit gases or particles into the air?



Can chemical be dermally absorbed?



Can someone eat it or put it in their mouth?



Can someone touch it, and then get chemical in mouth or on food?



Case Study: Testing



- Estimate the “Reasonably anticipated rate of exposure”
- Test product for lead content
 - Usually not a measure of exposure, but can be useful if levels are very low
- Conduct wipe sampling and submit to accredited lab for lead analysis
 - Use a standard method (e.g., NIOSH 9100)
 - Determine how much lead may be dislodged and into mouth, if any
- Conduct simulation of use
 - Wipe fingertips to see how much lead can get onto fingertips and subsequently into mouth
 - Use blanks
- If using existing testing data, understand methods, sample handling, preparation

Case Study: Analysis

- Determine other exposure parameters
 - Exposure frequency for consumers: events per day
 - Contact surface area
 - Hand-to-mouth transfer efficiency
- Ideally use published data, especially for food products
- Can use professional judgment
- Estimate “average rate of intake or exposure for average users of the consumer product”
- Calculate Average Daily Dose (ADD):

$$ADD = \text{Exposure Rate} \left(\frac{\mu g}{\text{event}} \right) \times \text{Event Frequency} \left(\frac{\text{events}}{\text{day}} \right)$$

- Compare value to published MADL for: 0.5 µg/day for lead
- NSRL also exists (15 µg/day) for lead. For carcinogens, use *Lifetime* Average Daily Dose

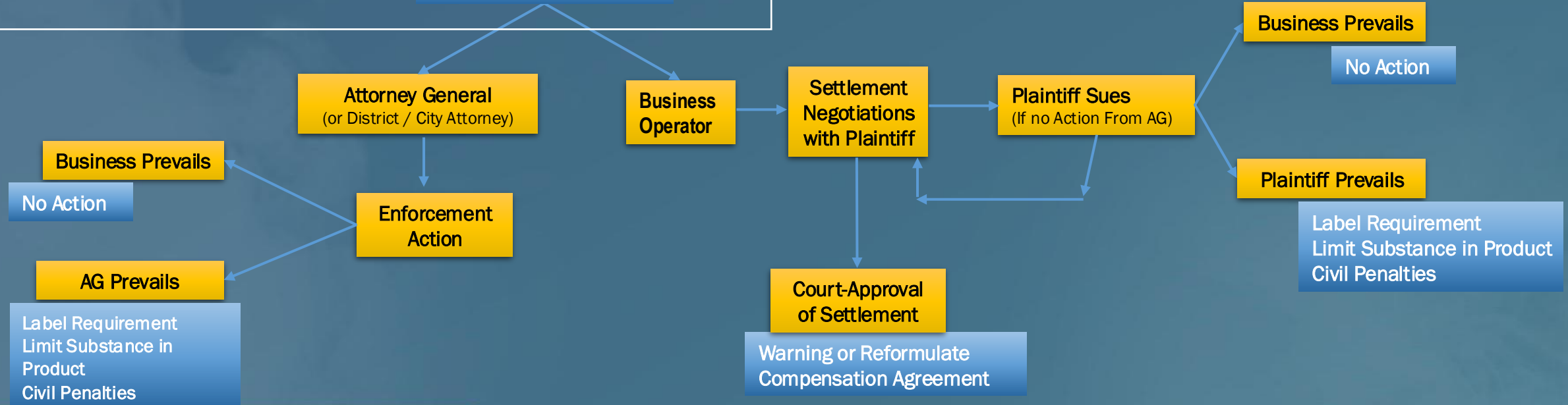
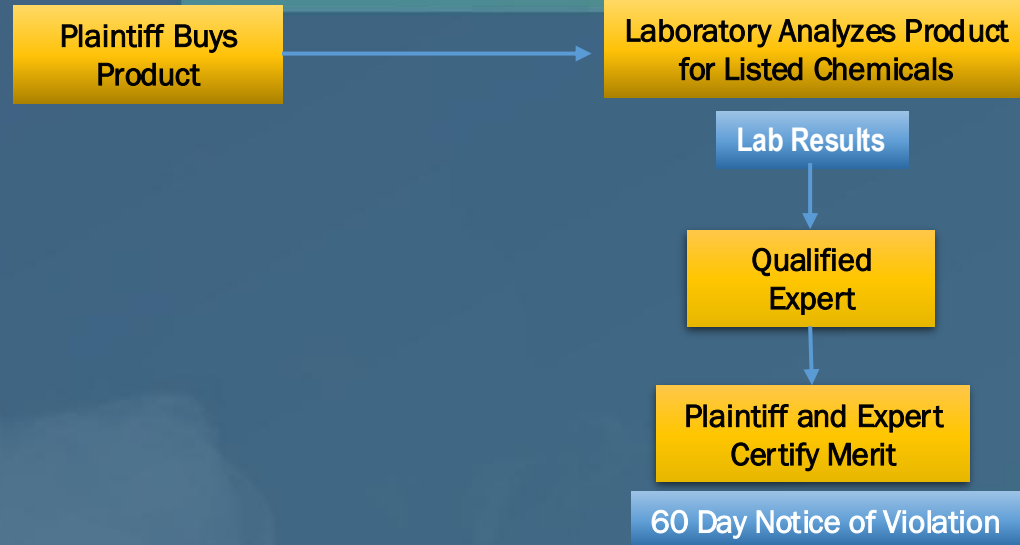
Enforcement of Proposition 65

- **Public Enforcers**
 - Attorney General
 - District Attorneys
 - City Attorneys for cities with a population > 750,000
- **Private Enforcers**
 - “Any person in the public interest”

The Enforcement Action Process



The Enforcement Action Process



Prerequisites to Private Enforcement

- 60-Day Notice of Violation
- Certificate of Merit
- No public prosecutor has commenced and is diligently prosecuting an action against the violation
- 60 days has elapsed since service of Notice

Requirements for 60 Day Notices

- Basic Contents of a 60-Day Notice of Violation
 - Description of violation
 - Warning Notices must include route of exposure to listed chemical
 - OEHHA Proposition 65 Summary must be included!
- Additional specific requirements for Notices vary by type
 - Discharge Notice
 - Consumer Product Exposure Notice
 - Occupational Exposure Notice
 - Environmental Exposure Notice

60-Day Notices – What's Not Required?

- UPC, SKU model or design number or stock number or other more specific identification of products.
- Specific retail outlet, time or date where product was purchased
- Level of exposure to listed chemical
- Evidence to prove violation
- Legal description of location of violation

60 Day Notices – Checklist of Requirements

- Contents of a 60-Day Notice of Violation
 - Description of violation
 - Noticing entity information
 - Violator identity
 - Time period during which violation occurred
 - Listed chemical(s) at issue
 - Warning Notices must include route of exposure to listed chemical
 - Ingestion
 - Inhalation
 - Dermal
 - OEHHA Proposition 65 Summary must be included
 - Additional specific requirements for Notices vary by type
- Discharge Notice
 - General identification of discharge or release
 - Identification of source of drinking water where discharge took place
- Consumer Product Exposure Notice
 - Name of specific type of consumer product
 - Description must be specific enough to allow recipients to distinguish those products or services from others sold or offered by the alleged violator for which no violation is alleged
- Occupational Exposure Notice
 - Geographic location where exposures occurred, or
 - Description of occupation or type of task performed by those exposed
- Environmental Exposure Notice
 - Identity, location and source of exposure

Certificate of Merit Requirement

- What is a Certificate of Merit?
 - Requirement added to statute in 2003
 - Certificate is form set forth in statute and regulations and must be signed by counsel for noticing party
 - Certifier must state that he or she has
 - “consulted with one or more persons with relevant and appropriate experience or expertise who has reviewed facts, studies, or other data regarding the exposure to the listed chemical that is the subject of the action, and that, based on that information, the person executing the certificate believes there is a **reasonable and meritorious case for the private action.**”
 - Certificate of Merit is not required for discharge notices.

How to Support Your Certificate of Merit

- Confidential factual support for certificate of merit is served on the Attorney General
 - Must include identity of persons with relevant and appropriate experience that were consulted;
 - Facts, studies or other data regarding exposure to listed chemical that is subject of Notice;
 - Support that there is merit to each element of claim where Plaintiff has the burden of proof.
- Confidential support is not discoverable

Alternative to Warning: Reformulation

- Businesses can comply with Proposition 65 in two ways:
 - (1) Clear and reasonable warnings
 - (2) Reformulating the products so that no warning is required.
- The health-protective way to comply with Proposition 65 is to remove toxic chemicals from the products that Californians buy and use every day.
 - Reformulation can occur via “quiet compliance” without the threat of litigation or through Proposition 65 enforcement settlements.

Other ways to reduce warnings



Ask OEHHA to consider developing safe harbor levels that would be helpful to your business.



Carefully consider asking OEHHA to develop Interpretive Guidelines or Safe Use Determinations.

Tips for Complying with Proposition 65

- Know your suppliers and control your supply chain
- Keep up to date on the science that is coming out surrounding the products you sell
- Test your products
- Maintain a restricted substances list and send specifications to your suppliers for Proposition 65 chemicals commonly found in those products
- Check past settlements to see what standards have been set for Proposition 65 chemicals in products you sell

July 2026: Summary of Notices of Violation for Food, Beverages, and Drugs

PRODUCT EXAMPLES	NUMBER OF NOTICES	CHEMICALS
Dietary supplements	108	Cadmiunum and Lead and lead compounds
Fruits and vegetables	74	Cadmiunum and Lead and lead compounds
Prepared food and snacks	72	Cadmium and cadmium compounds and Lead and lead compounds
Dried Fruit and Snacks	42	Aflatoxins and Ochratoxin A
Seafood	30	Cadmium and cadmium compounds and Lead and lead compounds
Noodles, Pasta, Rice, and Grains	26	Cadmium and Lead and lead compounds
Spices, Sauces, and Tea	26	Cadmium and Lead and lead compounds
Alcoholic beverages	14	Ethyl alcohol in alcoholic beverages
Vitamin A	6	Retinol
Vegan Lifestyle Mix	1	Lead and lead compounds and Perfluorooctanoic Acid (PFOA)
Turkish figs, corn meal, and corn tortillas	5	Fumonisin B1
THC products	5	delta-9-tetrahydrocannabinol

Total NOV's for Food, Beverages, and Drugs: 409

July 2026: Summary of Notices of Violation for Consumer Products

PRODUCT EXAMPLES	NUMBER OF NOTICES	CHEMICALS
Glass, Ceramics, and Brass Items	144	Lead and lead compounds
Bags and Vinyl Items	32	Di(2-ethylhexyl)phthalate (DEHP), Diisononyl phthalate (DINP), and Di-n-butyl phthalate (DBP)
Household Items and Clothing	14	Perfluorooctanoic Acid (PFOA)
Leather goods	13	Chromium (hexavalent compounds)
Cosmetics and Personal Care Products	5	Diethanolamine and Coconut oil diethanolamine condensate (cocamide diethanolamine)
Unleaded gasoline (wholly vaporized)	3	Unleaded gasoline
Receipts	1	Bisphenol S (BPS)

Total NOV for Consumer Products: 212

Useful Resources

- Main OEHHA website, Prop 65 specific page
 - <https://oehha.ca.gov/proposition-65>
- Prop 65 Warnings website
 - www.P65warnings.ca.gov/
- The Prop 65 List
 - <https://oehha.ca.gov/proposition-65/proposition-65-list/>
- Laws and Regulations
 - <https://oehha.ca.gov/proposition-65/law/proposition-65-law-and-regulations>
- Fact Sheets home page
 - <https://www.p65warnings.ca.gov/fact-sheets>



Useful Resources

- Prop 65 Business compliance assistance webpage
 - <https://www.p65warnings.ca.gov/businesses>
- Where to find MADLs and NSRLs
 - <https://oehha.ca.gov/proposition-65/general-info/current-proposition-65-no-significant-risk-levels-nsrls-maximum>
- California Attorney General – Prop 65 Enforcement Reporting
 - <https://oag.ca.gov/prop65>

