Safe Harbor Levels and Exposure Assessments: Best Practices in Assessing Proposition 65 Compliance

Moderator:

Judith Praitis
Partner
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Panelists:

Renee Kalmes
Principal Scientist
Exponent

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Gradient

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OEHHA

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Agenda

- We will discuss "best practices" from the **compliance**, not the litigation, perspective
- We will generally avoid active litigation (*e.g.*, DEA/BPS) but focus on high-enforcement risk areas
- Our expert panelists will assess "best compliance practices" in four categories:
  - **Foods**
  - **Phthalates**
  - **Lead in Consumer Products** (non-food products)
  - **Per- and Polyfluoroalkyl Substances (PFAS)**

Agenda

- For each category, the panelists will cover their views and experiences, and options to address (at least) two core questions:

- "**To Test or Not to Test**" *and*

- Exposure Assessments —
    - "**To Do or Not to Do**"
    - How to do an Exposure Assessment and avoid doing too little or too much

Agenda

- We will try to offer practical observations
- Explain why “cookie cutter” approaches over time could backfire and yield unreliable or inaccurate assessments
- We will consider what sort of documentation to generate; how to select labs; what to do when no NSRL/MADL exists; and how to assess which back up resources are more credible than others

OEHHA Input

- We will hear from the California Office of Environmental Health Hazard Assessment (OEHHA) on the discussion throughout the panel presentations.

OEHHA Input Includes:

- When is it best to contact OEHHA with technical inquiries?

- Does OEHHA have suggestions on how best to use the guidance documents it has issued to conduct exposure assessments or for other purposes of Proposition 65 compliance? Are there time limits on the guidance (even if not formally withdrawn)?

- OEHHA commentary on Safe Use Determinations: when are they useful? Are SUDs better than negotiated or litigated outcomes?

Now, Let’s Turn to the Experts

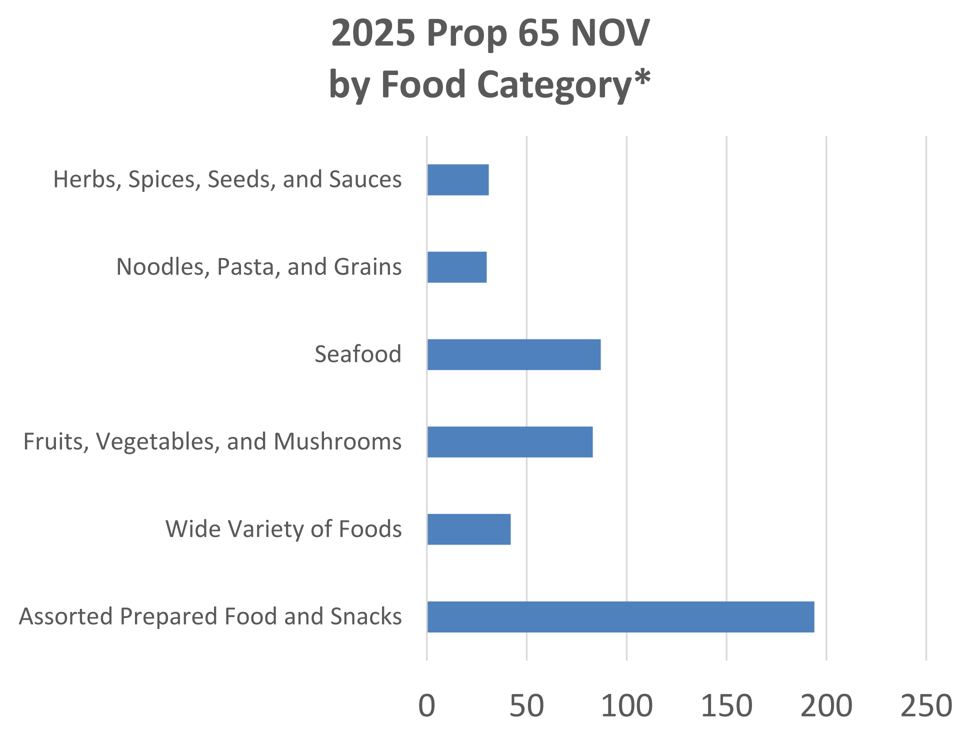
Foods

Steven Boomhower, Gradient

Meg Whittaker, ToxServices

Mouth-Watering Facts About Food and Prop 65

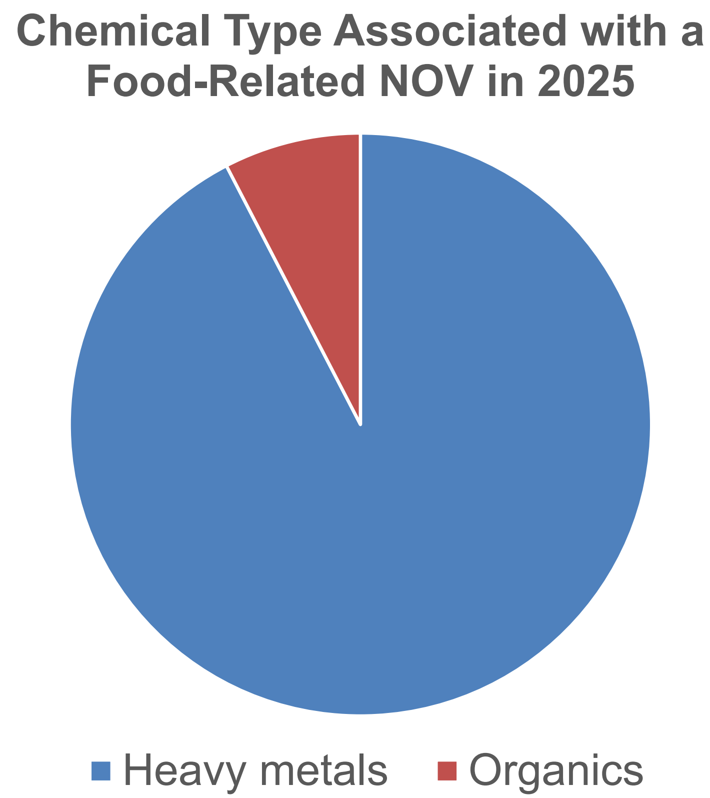
- Food products often receive Notice of Violations (NOVs)
- 20% of the 2,144 NOVs filed in 2025 (up to June 30, 2025) are associated with some type of food
- Most common food category receiving NOVs are prepared foods and snack foods



*Using Keller & Heckman's *Pulse* Newsletter Product Categories

Mouth-Watering Facts About Food and Prop 65

- **Which Prop 65 chemicals in food often receive NOVs?**
  - Heavy metals dominate (primarily lead and cadmium and related compounds but also mercury)
  - Organics trail behind (*e.g.*, BPAs, PFAS, pulegone, nitrous oxide)
- **In 2025, heavy metals accounted for >90% of the food-related NOVs**
- **Likely reasons heavy metals dominate food NOVs:**
  - Inexpensive to purchase food items for testing
  - Inexpensive to test for metals (~$100-$200/test)
  - Background levels of heavy metals are ubiquitous in food ingredients, such as grains and root vegetables
  - Safe Harbor Limits are relatively low for metals (particularly for lead, which has a MADL of 0.5 µg/day and NSRL of 15 µg/day)
  - (https://oehha.ca.gov/proposition-65/chemicals/lead)



Prop 65 Compliance and Food Products

What Is the Food Product?

Consumption Frequency

Food Product Sourcing

Level of Safe Harbor Limit

Testing

Analytical Testing

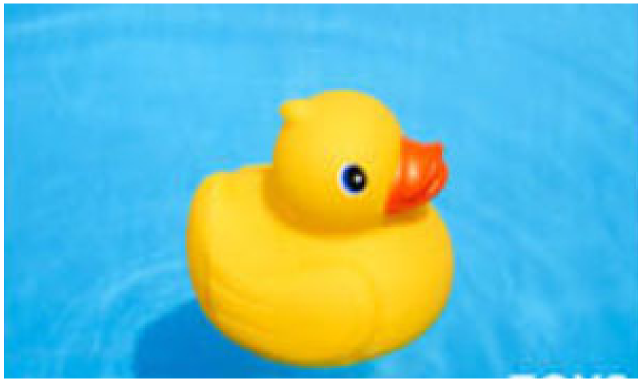
Number of Samples

Exposure Assessment

Level of Detail Needed

Developing Safe Harbor Level

Phthalates



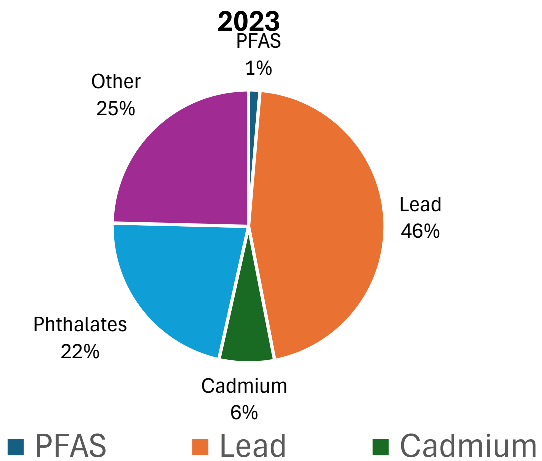
Renee Kalmes, Exponent

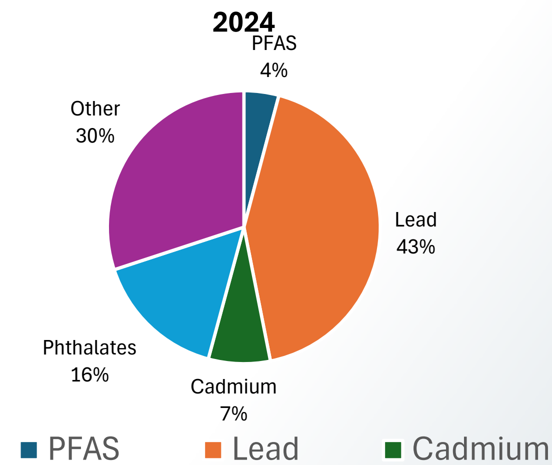
"Plus ça change, plus c'est la même chose,"

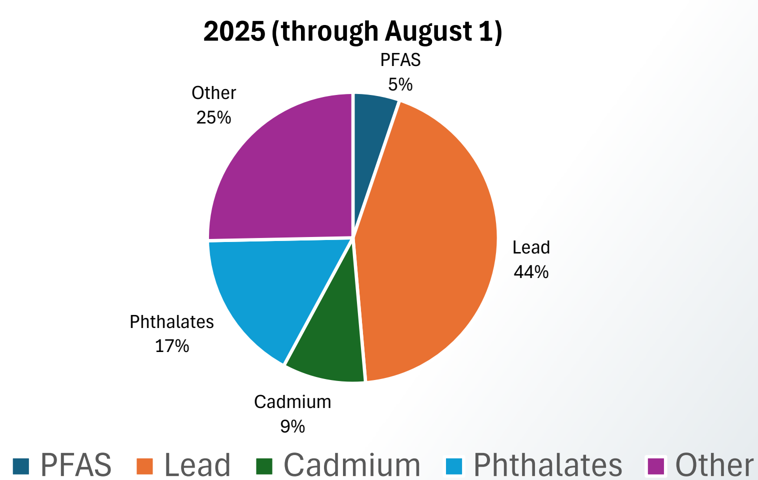
– coined by Jean-Baptiste Alphonse Karr in 1849

"The more things change the more they stay the same"

2025 looks to be similar!







Phthalate Compliance

Phthalate	Safe Harbor Level
DBP	8.7 µg/day (MADL)
DiNP	146 µg/day (NSRL)
DEHP	410 µg/day (MADL)*
BBP	1,200 µg/day (MADL)
DnHP	2,200 µg/day (MADL)
DIDP	2,200 µg/day (MADL)

*adult MADL- NSRL 310 ug/day

Numerous de facto phthalate settlements at 1,000 ppm (0.1%) for any phthalate

Basis – CPSIA children's products

Relevance to adult low-contact consumer products?

OEHHA has issued SUDs 9-25% DiNP

- product specific/use condition

Exposure pathways of interest

- Dermal Contact
- Incidental hand to mouth

Testing of products is common

Is Having 0.1% De Facto Settlement Level Helpful for Compliance?

Perhaps! If testing shows below 0.1% (1,000 ppm)

If >0.1%

Exposure based sampling/tools examples

Product wipe sampling*

Skin loading

Modeling

Best Practices: Evaluate Exposure

- What becomes dislodged and available NOT merely the content in the plastic
- Reasonable product use and interaction
- Use of exposure-based sampling/ tools

* Beware of limitations

Lead in Consumer Products (Non-foods)

Meg Whittaker, ToxServices

Lead Overview

- "*Heavy metal is immortal, but we're not*" – Rob Halford of Judas Priest

- Lead is metal, so it won't volatilize or disappear from your product, so don't ignore it!

- Multiple forms of lead are listed on Proposition 65:
  - Elemental lead
  - Lead compounds (Lead acetate, Lead phosphate, Lead subacetate)

- Consumer products with lead often dominate Prop 65 Notice of Violations
  - Cookware, Glassware, Candle holders
  - Tools, Household items, Decorative items, Fishing sinkers

Best Practices – Assessing Lead in Consumer Products

- **To Test or Not to Test**
  - **Option 1:** For many consumer product types, a Prop 65 warning won't put off consumers (depending on product type), so a warning label may be a good choice
  - **Option 2:** Use of test data and exposure assessment to demonstrate safe harbor may be necessary
    - If you've received a notice of violation
    - Consider using other side's test report that quantifies lead in product before sending your product out for testing (avoids disagreement over test methods)

- **Exposure Assessment Best Practices**
  - Use peer-reviewed sources that pertain to exposure scenarios for specific product type and lifetime
  - Use of OEHHA defaults leaves less to argue about (e.g., SA of fingertips/hands, transfer efficiency of chemical from object to food to mouth, 3% dermal lead absorption)
  - For lead, both dermal and indirect oral exposure (hand to mouth <u>and</u> hand to food to mouth) must be estimated

Total Exposure to Lead in Consumer Product

Chemical (CAS No.)	Dermal Exposure (µg/day)	Total IOE (µg/day)	Total Exposure (µg/day)
Lead (7439-92-1) and Lead compounds	5.66E-04	2.67E-02	2.73E-02

Safe Harbor Determination for Lead in Consumer Product

Chemical (CAS No.)	Total Exposure (µg/day)	Proposition 65 Safe Harbor Level (µg/day)	Safe Harbor Demonstrated ?
Lead (7439-92-1) and Lead compounds	2.73E-02	0.5	Yes

PFAS

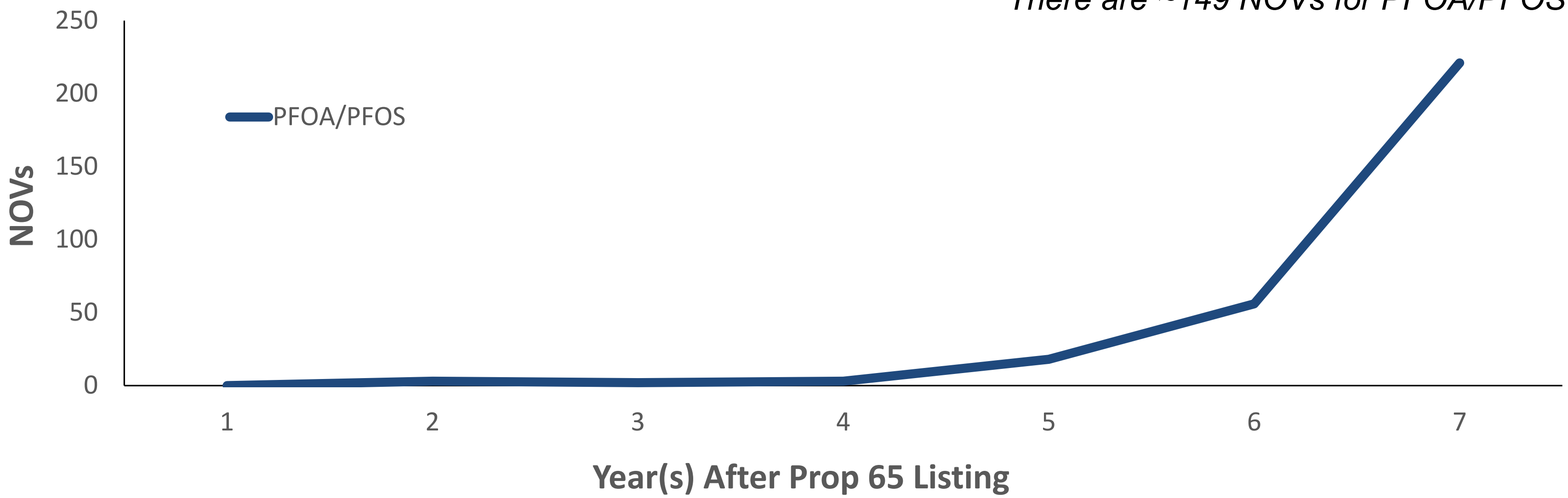
Steven Boomhower, Gradient

Renee Kalmes, Exponent

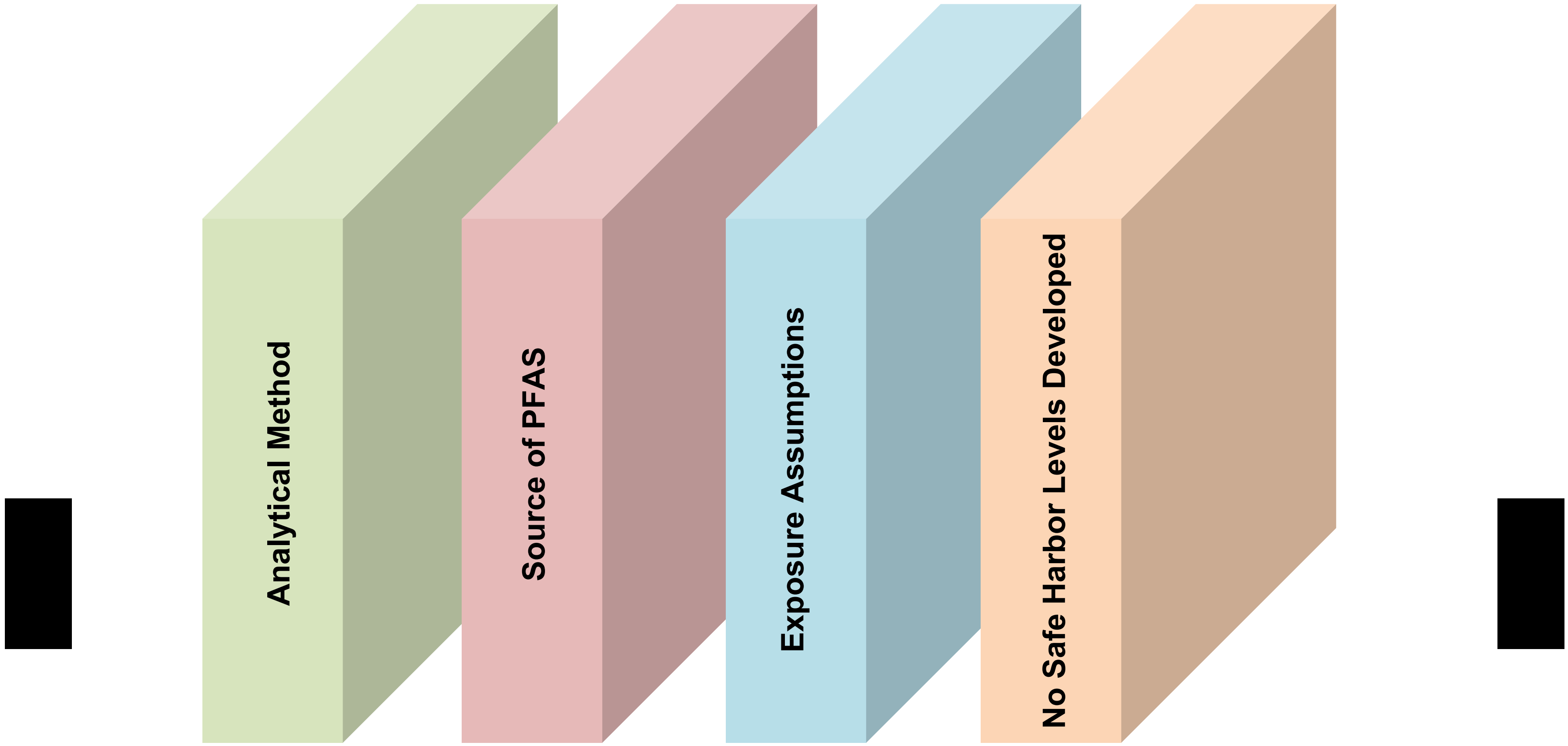
NOVs Related to PFAS in Consumer Products

- PFAS on Prop 65 list
  - PFOA/PFOS – cancer and reproductive toxicity
  - PFNA – reproductive toxicity
- NOVs for PFOA/PFOS are growing each year

**There are ~149 NOVs for PFOA/PFOS in 2025 so far*



Best Practices on PFOA, PFOS, PFNA (for Now)



Thanks!

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