Complying with Prop65: Don't Let the Perfect Be the Enemy of The Good

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Prop65

- Options for compliance
 - Reformulate to remove Prop65 chemicals
 - Not possible for metals (or many organics)
 - Add warning to everything
 - Expensive!
 - May be particularly difficult given the new language
 - May alarm your customers (e.g., outside CA)
 - Not really compliant
 - Test everything
 - There are ~970 Prop 65 listed chemicals in total
 - Even with limited testing, could be ~\$1500/sample
 - Analyze multiple samples to understand variability
 - With 500 products = \$2M in analytical costs alone!



Case Example: Using Data to Develop Reasonable Testing Programs

All Prop65 Chemicals (970 chemicals) All products (hundreds) Chemicals likely to be in the products? (~30 chemicals, fewer products) **Priority for testing (3-4** tests, few products) **Identification of high** priority products

Data on Product Composition (e.g., BOM)

Chemical Use Databases (e.g., CPCAT)

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Prop65 60-day Notice Database

Chemicals detectable by common methods



How Many samples?

- How many samples?
 - The more samples you test, the greater your certainty; you need to find the spot where your comfort lies
 - No good guidance, your approach should be logical
 - A single sample isn't reasonable, no sense of product variability
 - 3 samples at least allows some stats
 - Resample annually or any time supply chain has a substantial change





Reasonable Cost Screening Methods

- X-ray fluorescence for metals
 - Lead, cadmium, etc.
 - Need at least a few confirmatory samples analyzed via lab
- Surface reactivity methods
 - Simple spray and color indicator method
 - Available for a small but growing number of organic chemicals
 - Not super quantitative, not great for showing your below the NSRL



What If There's No Existing Safe Harbor Value?

- Requires data review and modeling to establish a safe level
- First Stage
 - Do what OEHHA is likely to do
- Possible second stage: what are the uncertainties?
 - Are there better data sets?
 - Is a non-threshold effect is reasonable?
 - Are there relevant species differences?
 - May be useful if you ever find an exceedance
- Costs will depend on the level of data review and the documentation needed



Dose



Final Points

- Be Reasonably Proactive about Prop65
 - Avoid Prop 65 chemicals where possible (may be hard)
 - Require your supply chain to provide test data and notify you of any process changes
 - Develop a written compliance plan based on logic and knowledge of your product
- There is no foolproof compliance solution but taking some action can substantially reduce your risk



