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

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Prop65

- Prop65 contains both hazard and risk elements
  - Chemicals are placed on the Prop65 list largely due to hazard (i.e., dose doesn't matter)
  - Prop65 claims are often *de facto* hazard based ("it's there")
  - Defense against a Prop65 claim is risk-based (is the consumer/worker exposure below the allowed limit?)

Prop65

- Key Question: How much of Chemical X will the product user to be exposed to?
  - You need to simulate exposure (e.g., either by leaching or wiping for skin contact items)
  - Test the extract or wipe for the chemical of concern
  - Determine what the consumer's exposure would be (contact frequency, duration, amount of exposure)
  - Determine if the exposure amount is below the Prop 65 Safe Harbor value (assuming one exists)
  - If the exposure is less than the Safe Harbor, warnings not required
  - Total concentration data aren't useful except in certain cases

Prop65

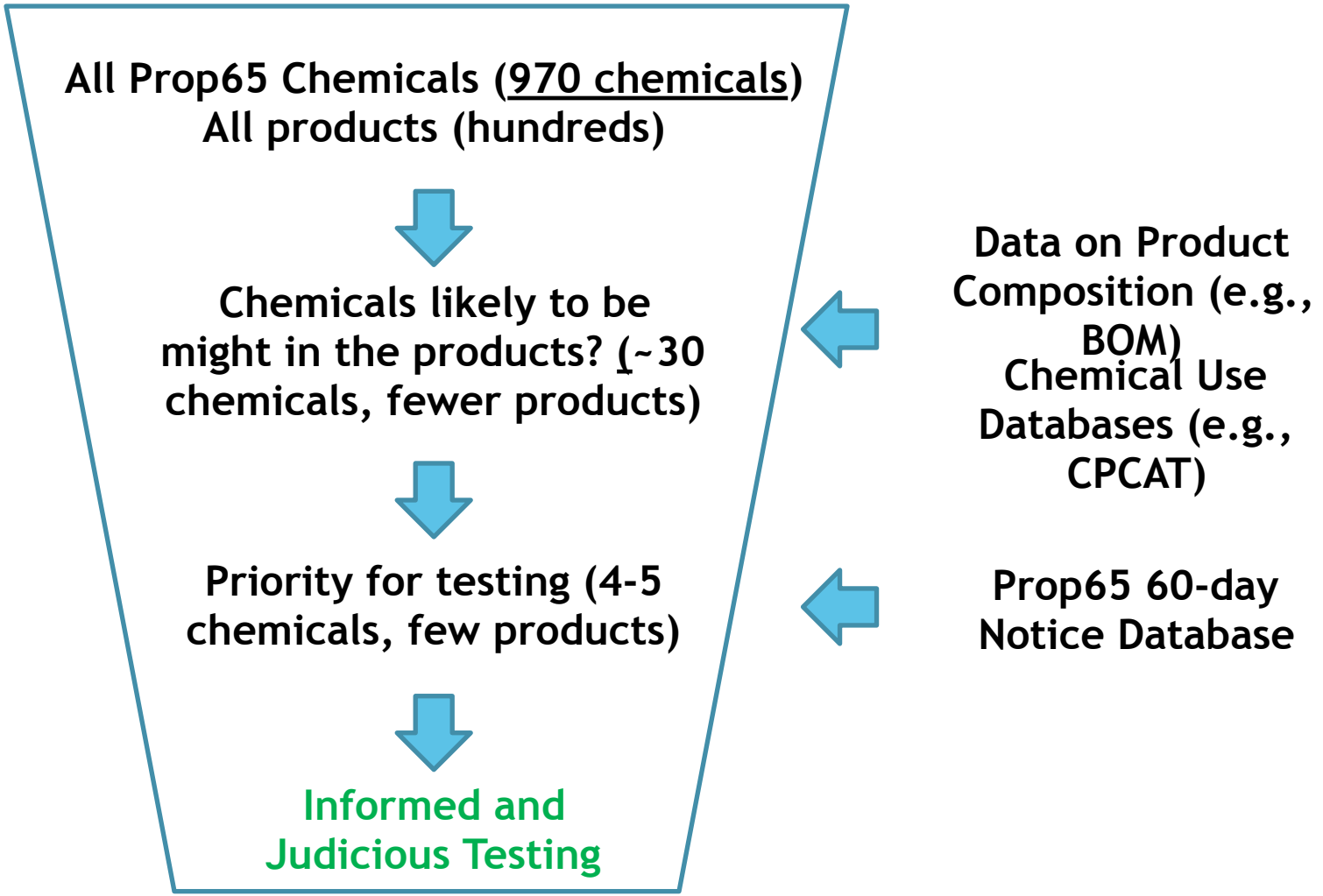
- Options for compliance
  - Remove all Prop65 chemicals from your product
    - Not possible for metals (or many organics)
  - Add warning to everything
    - Expensive!
    - May be particularly difficult given the new language
    - May alarm your customers (e.g., outside CA)
    - Not really compliant
  - Test everything
    - There are ~970 Prop 65 listed chemicals in total
    - Even [illegible]300/sample
    - Analy[illegible]l variability
    - With [illegible]osts alone!

Avoid complete sentences; if you use phrases then you dont seem like you are reading from the slide.

Prop65

- Options for compliance
  - Judicious testing
    - Use existing information to maximize knowledge of pro
    - Focus on chemicals likely to be the subject of a suit
    - Focus on products that are likely to have potential expo
    - Use representative products from groupings where poss
    - Identify sources of potential product variability (multiple vendors, changing feedstocks)
    - Recognize that the more you test, the greater your certainty; you need to find the spot where your comfort lies
      - How many samples? No good guidance, your approach should be logical.

Case Example: Using Data to Develop Reasonable Testing Programs



What If There's No Existing Safe Harbor Value?

- Need to review the toxicity data
  - Prioritize data used for regulatory listing
  - e.g., studies cited by IARC for carcinogenicity classification
- Concern for consumers, workers, infants, others?
- For carcinogens:
  - Conduct benchmark dose modeling, adjust dosing
- For developmental toxicants:
  - Determine No Effect Level, divide by 1000
- 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

Final Points

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