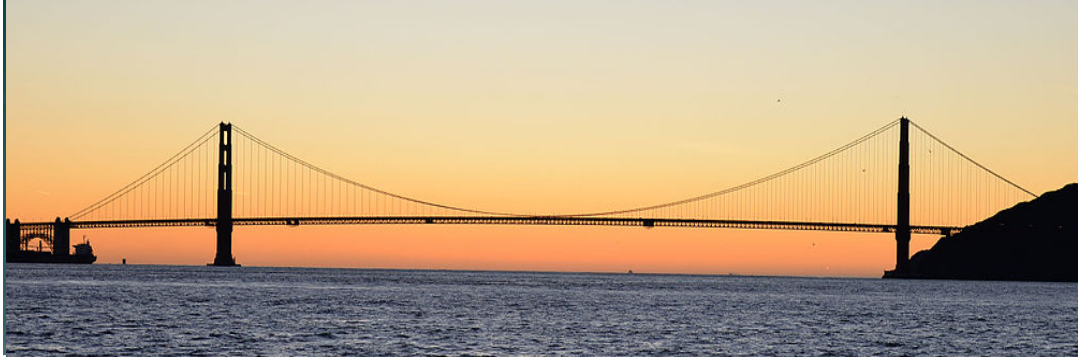


Exponent®



Proposition 65 A Scientist's Point of View

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Sacramento, California

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Today's Conference

- Updates on Current Status of Prop 65
 - What's Working – What's Not
 - New Listings
 - Safe Use Determinations (SUD)
- Legal and Process Consideration
 - Use of Previous Consent Judgement
 - When to Test Products
 - Responsibilities of Plaintiff and Defense Attorneys
- Compliance
 - Through the Chain of Commerce
 - TSCA – Intersections with Prop 65

“Science” Under Proposition 65

Three Areas for Science

- Listing and Delisting
- “Safe Harbor” Levels
 - No Significant Risk Levels (NSRL)
 - Maximum Acceptable Dose Levels (MADL)
- Exposure Assessments
 - Single products
 - Full product lines (>10,000 products)

“Science” Under Proposition 65

All “Science” is impacted by Proposition 65’s enforcement through litigation

- Different from any other jurisdiction
- Undertaken with “anticipation”

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Listing – 4 Mechanisms

- State's Qualified Experts
 - Cancer Identification Committee (CIC)
 - Developmental and Reproductive Toxicant Identification Committee (DART-IC)
- Authoritative Bodies Mechanism
 - EPA
 - FDA
 - IARC
 - NTP
 - NIOSH
- Labor Code Mechanism
 - Labor Code references IARC
- Formally Required to Be Labeled
 - e.g. Pharmaceutical labeling

Listing

- Reproductive Toxicity
 - Developmental toxicity
 - Male reproductive toxicity
 - Female reproductive toxicity
- Only bright-line for these endpoints, worldwide
- Takes a complex endpoint, impacted by many physiological factors and makes it into a yes/no decision
- Challenging to interpret and standardize for listing

Delisting

- Process for delisting clearly laid out
- Increasing sophistication of scientific data and understanding of mechanisms
- Rare – Time consuming
 - ≈ 26 out of ≈ 900

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Proposition 65 “Safe Harbor” Levels

- For carcinogens
 - “*No Significant Risk Level*” (NSRL)
 - a.k.a. – “Safe Harbor” level
 - Generally 1 in 100,000 risk level
- New Understandings
 - Mode of Action, Dose Response
 - Multistage Linear model default
 - Benchmark Dose alternate models
 - Need to predict approach to be used by OEHHA

Proposition 65 “Safe Harbor” Levels

- For reproductive toxicants
 - “*Maximum Allowable Dose Level*” (MADL)
 - a.k.a. – “Safe Harbor” level
 - 1000-fold lower than No Effect Level (NOEL)
- Challenges
 - Complex effects and databases
 - Methanol
 - Crystalline Silica of Respirable Size
 - Often unique to Proposition 65

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Exposure Assessments

- Should Cover Two Approaches:
 - Proposition 65 Guidelines
 - “Plaintiff” Presumptions

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What Have We Accomplished

- Attention to the presence of Proposition 65 chemicals in product design
- More predictable process
- Increasing reliance on Safe Use Determinations (SUD)