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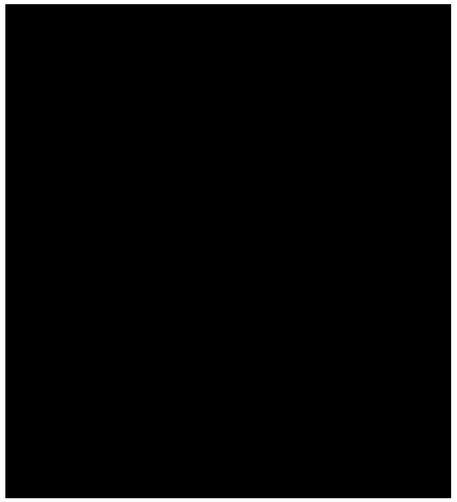
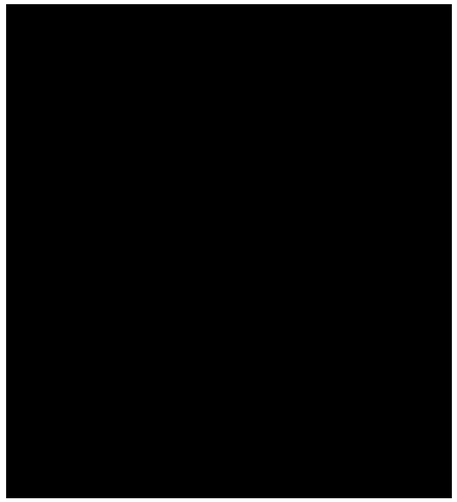
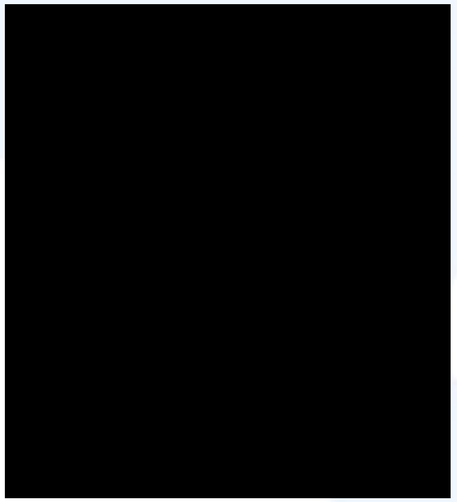
ICPHSO 2023 ANNUAL MEETING AND TRAINING SYMPOSIUM



Moderator Name
Moderator Organization
Moderator Position



Speaker Name
Speaker Organization
Speaker Position



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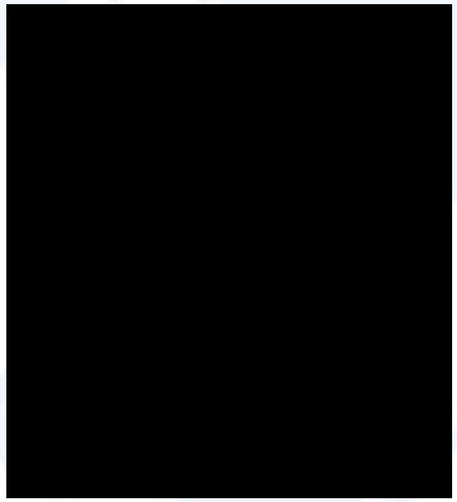

Phil Moffat
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Introduction

- Types of chemical regulations affecting product design
- Locus of regulatory activity
- Implications for product design
  - Regrettable substitutions
  - Product deselection / market backlash
  - Supporting more than one version of a product
  - Regulatory noncompliance
  - Legal liability
- Concluding thoughts

Types of Laws and Regulations Being Enacted

- **Product labeling / disclosure**
  - California Prop 65 - potential exposure to listed chemicals that may cause cancer, birth defects, or reproductive harm
  - California Cleaning Products Right-to-Know Act - presence of known hazardous chemicals
  - Colorado PFAS Consumer Protection Act - labeling cookware containing intentionally added PFAS
- **Bans / restrictions**
  - New York Environmental Conservation Law – bans specific flame retardants in certain electronic displays, furniture, and mattresses
  - U.S. CPSC – ban on eight ortho-phthalates used in children’s toys and child-care articles
  - U.S. EPA TSCA – ban on PIP 3:1
- **Reporting**
  - U.S. EPA TSCA – manufacturer and importer reporting on PFAS
  - Maine PFAS Pollution Law – reporting presence of intentionally added PFAS in products

Locus of Regulatory Activity

- Two agencies at the federal level are driving much of the activity.
  - EPA
  - CPSC
- The list of states is long, with leaders varying by the chemical targeted. Frequently at the forefront are:
  - California
  - Colorado
  - Maine
  - New York
  - Oregon
  - Vermont
  - Washington

Implications for Product Design

- Risk of regrettable substitutions
- Risk of product deselection/market backlash
- Risk of supporting multiple versions of a product on the market
- Risk of regulatory noncompliance
- Risk of legal liability

Risk of Regrettable Substitutions

- The replacement has different or unknown health and/or environmental hazards because it has not been broadly tested or only tested for the hazard that was of concern for the chemical being replaced.

  Alexandra Maertens, Emily Golden, and Thomas Hartung, “Avoiding Regrettable Substitutions: Green Toxicology for Sustainable Chemistry,” ACS Sustainable Chemistry & Engineering 2021 *9* (23), 7749-7758.

- Replacement results in a product that has a better chemical risk profile, but the product performs worse on other key metrics.

Risk of Regrettable Substitutions

Alexandra Maertens, Emily Golden, and Thomas Hartung, “Avoiding Regrettable Substitutions: Green Toxicology for Sustainable Chemistry,” ACS Sustainable Chemistry & Engineering 2021 *9* (23), 7749-7758.

Risk of Regrettable Substitutions

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Chemical(s)	Endpoint of Concern	Substitute	Endpoint of Concern
Phthalates (plasticizers)	Endocrine activity	DINCH	Endocrine activity
Bisphenol-A (BPA) (plasticizer)	Endocrine disruption	Bisphenol-S (BPS), Bisphenol-F (BSF)	Endocrine activity
Polybrominated diphenyl ethers (PBDEs) (flame retardant)	Persistence, Neurotoxicity, Reproductive toxicity, Carcinogenicity (penta and deca)	Tris (2,3-dibromopropyl) phosphate	Carcinogenic, aquatic toxicity

Risk of Regrettable Substitutions

Product Performance Impacts

- PFAS-free water-repellant clothing
- PFAS-free firefighting foam alternatives to AFFF

Risk of Regrettable Substitutions

- State processes are on a shorter time frame (e.g., proposed legislation) and less-defined than federal regulations; companies can be caught off guard, making it challenging to respond.
- Often a better-defined process at federal level (e.g., work plans, workshops, established hazard/risk review process, rulemaking).

Risk of Product Deselection / Market Backlash

- Minimal helpful guidance available to the public on how to interpret and apply information made available via:
  - a public database set up as part of a reporting rule; or
  - a product label compelling the disclosure of the presence of a substance and its associated hazards.
- The lack of context associated with publication creates confusion and fear, inviting market backlash, product deselection, and litigation.
- Consumers need information on risk, risk mitigation, performance benefits, trade-offs, etc. Links to company websites might help.

Risk of Supporting Multiple Versions of a Product

- Patchwork of regulations – one requirement at federal level, and one or more at the state level
- Potential for more than one version of a product in US commerce
- More regulatory tracking for legislative and regulatory proposals
- Consumer perception that one is “less safe”
- Defending the “less safe” product
- Increased risk of noncompliance

Risk of Regulatory Noncompliance

- Penalties
- Seizure
- Recall
- Market lockouts
- Other injunctive relief

Risk of Legal Liability

Compliance with regulatory and/or state statutory requirements is a floor and not a ceiling.

The Third Restatement of Torts: Product Liability, §4:

(a) a product's noncompliance with an applicable product safety statute or administrative regulation renders the product defective with respect to the risks sought to be reduced by the statute or regulation;

b) a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.

Concluding Thoughts

- Consumer products companies face a herculean task.
  - The number and complexity of regulatory requirements is increasing in the U.S.A. and abroad.
  - Tracking and engaging on legislative and regulatory developments is challenging.
  - Responding in a timely manner while protecting the brand, managing costs, and ensuring product longevity while minimizing the risks of legal and regulatory noncompliance is a significant undertaking.
  - A better system is needed.