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New TSCA and Biobased Innovation

Advanced Bioeconomy Leadership Conference
March 1, 2018
Washington, D.C.

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Changes to Toxic Substances Control Act (TSCA)

- Frank R. Lautenberg Chemical Safety for the 21st Century Act enacted on June 22, 2016
- Changes to Section 5 effective immediately
  - EPA "reset" its review of all pending Section 5 notices
- Section 5(a)(3) requires EPA to make a determination on each new chemical (or significant new use)

Section 5(a)(3) Determinations

- EPA must determine if each case
  - (A) Will present
  - (B) May present (including insufficient information and exposure-based findings)
  - (C) Not likely to present

  unreasonable risk to health or environment under intended or reasonably foreseeable conditions of use
- If "will present" or "may present," the U.S. Environmental Protection Agency (EPA) must issue a consent order regulating "to the extent necessary" and issue a Significant New Use Rule (SNUR)
- New chemicals may not proceed to commercialization until EPA has made its determination and taken any necessary actions

Changes to TSCA New Chemicals -- Expected and Unexpected

Expected	Unexpected
More regulatory actions	Vast majority regulated
Reviews taking 90-180 days	Substantial delays
Risk-based "not likely" determinations	Hazard-based "not likely" determinations
	Insufficient information determinations for inhalation hazards

New Chemicals Review and Timing

Old TSCA	New TSCA
ca. 80% not regulated ("drop" cases)	<10% not regulated ("not likely" cases)
Drops and non-5e SNURs: 90 days	Not likely: probably less than 60 days
Standard consent orders: <180 days	Consent orders: at least 90 days, typically >120 days
Exemption notices: 30 days	Non-order SNURs: timeframe unknown
	Exemption notices: 30-60 days

Why the Changes?

- Regulating except in case of low hazard for health and low hazard for ecotoxicity ("low/lows")
  - EPA views this as necessary given what it views as "reasonably foreseen"
  - Often justifies action based on "somebody else might"
- Begs the questions:
  - What is "not likely"?
  - How is "reasonably foreseeable" different from "any conceivable"?

Results of Changes

- Protective conditions commonly include:
  - Required personal protective equipment (PPE)
  - Required hazard communication (that may deviate from the Globally Harmonized System of Classification and Labeling of Chemicals (GHS))
  - Surface water release limits
  - Import only
  - Use as specified in the premanufacture notice (PMN)
- Begs the question:
  - What is the “extent necessary”?

Open Questions

- EPA has not quantified "not likely"
- EPA has stated that "foreseeable" will be based on "evidence, knowledge, or experience"
- Many substances on the Safer Chemical Ingredient List would be heavily regulated if submitted as new chemicals under new TSCA

What Does This Mean for Innovators?

- Much worse new chemical bias
- If not low/lows
  - Plan for substantial delays
  - Be prepared to deal with restrictions
  - Little if any value in pollution prevention statements
- Sustainable Futures/Project XL no longer provides any relief to review time
  - Either “not likely” and shorter than 90 days or much longer than 90 days

Other Problems

- Errors in hazard, exposure, and risk assessments
  - Misinterpretation of no effect vs. no adverse effect levels in toxicity studies
  - Lack of understanding of substance properties or industry practices
  - Preference for modeled data over measured data
  - Improper use of EPA standard models
- Enormous workload
  - Reviews and re-reviews
- New employees unfamiliar with TSCA or "how things work"
- New, and hopefully temporary, process that requires Office Director review of all determinations

What Can Submitters Do Pre-Submission?

- Do not over-rely on your company's "good behavior"
- Build a robust PMN, which should include:
  - Detailed descriptions of all potential releases and exposures throughout the supply chain
  - Description of cleanout of equipment used for manufacturing, processing, or use
  - Disposition of empty containers
  - Disposition of rinsate from cleaning operations
  - Data on properties, toxicity
- Identify available measured data
- Identify analogs with measured data

What Can Submitters Do Post-Submission?

- Request new chemicals reports
- Review carefully
- Refute or respond to assumptions
- Be prepared for some restrictions
- Work with EPA to craft restriction to address EPA's concerns while minimizing burden on customer

Summary

- New chemicals review taking much longer
  - Unless EPA finds substance is low hazard to health and environment
- Very detailed PMNs are necessary for EPA to permit a substance to move to commercialization
- Submitters should generally expect EPA to regulate the substance
- Program is still in flux

Thank You

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