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Update on TSCA, SNURs, and Nanomaterials

SCHC Fall Meeting

Arlington, VA

September 24, 2019

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The Frank R. Lautenberg Chemical Safety for the 21st Century Act

- Enacted June 22, 2016
- Lautenberg fundamentally changes U.S. federal approach to chemicals management
 - Introduces new concepts and approaches
 - Reflects careful balancing of interests
- Centralizing concept is *unreasonable risk*, the evaluation of which:
 - Excludes consideration of cost/benefit factors
 - Focuses on *conditions of use* (COU) as determined by the U.S. Environmental Protection Agency (EPA)
 - Includes consideration of *potentially exposed or susceptible subpopulations* (PESS) identified as relevant by EPA

Key Changes -- Definitions

- COUs
 - “... the circumstances, as determined by [EPA], under which a chemical is intended, known, or *reasonably foreseen* to be manufactured, processed...”
(emphasis added)
- EPA has specified “reasonably foreseen” is based on “information, knowledge, and experience”
- Early on, EPA was evaluating all possible COUs -- effectively making the determination a hazard-based decision

Safety Data Sheets (SDS) and EPA's Review of Premanufacture Notices (PMN)

- EPA will automatically accept hazards listed on the SDS
 - Be careful about “over classifying”
 - Consider Hazard Not Otherwise Classified (HNOC)
 - HNOC mechanical irritation
- SDSs are critical components of EPA's risk assessment for worker exposures
- SDSs may not be claimed as confidential business information (CBI)
 - Some information may be protected
 - Be careful to substantiate CBI claims on SDSs
- Always specify “impervious gloves”

Key Changes -- Determinations

- Requires EPA determination on all new chemicals
- Three alternative determinations at Section 5(a)(3):
 - (A) New chemical *presents* an unreasonable risk
 - (B)(i) Available information is *insufficient* to permit reasoned evaluation of health and environmental effects or
 - (ii)(I) new chemical *may present* unreasonable risk or
 - (ii)(II) it has *substantial production and exposure*, or
 - (C) New chemical *not likely* to present unreasonable risk

Key Changes -- Regulations

- If EPA determines:
 - (A) or (B), it is required to regulate under Section 5(f) or Section 5(e), respectively
 - Regulation must be “to the extent necessary” to protect against unreasonable risk
 - (C), it must publish/explain “not likely to present unreasonable risk” finding
- Section 5(e) or 5(f) determination, EPA must also issue a Significant New Use Rule (SNUR) or explain why not

Initial PMN Determinations

- “Not likely”
- Standard review (further, in-depth review)
- EPA identifies possible risks
 - “Not likely” with follow-on SNUR
 - “Not likely” based on SNUR
 - “May present” with consent order
 - “Insufficient information” with consent order for up-front testing
 - “Presents” with consent order
- SDS changes

“May Present” Cases

- Typically, consent order contains protective requirements such as the following:
 - Testing for toxicity, environmental fate, exposure (upfront, triggered, or pended)
 - Use of worker personal protective equipment (PPE)
 - New Chemical Exposure Limits (NCEL) for worker protection
 - Distribution and use restrictions
 - Restrictions on releases to water, air, and/or land
- If the risks cannot be mitigated, testing will be required prior to commercialization

What the Heck Is a SNUR?

- SNUR defines the impermissible COUs as Significant New Uses
- May be:
 - Specific use (“use other than...”)
 - Consumer use
 - Release to water
 - Absence of specific worker protection
 - Formation of respirable form (spray, dust, mist, aerosol)
 - Domestic manufacture
 - Production volume limit
- Which is better -- a consent order or SNUR?

SDS Changes from SNURs

- SNURs require supply chain communication
 - Existence of the SNUR
 - Section 12(b) export notice
 - Hazard communication statements (if specified in SNUR)
- Put SNUR and Section 12(b) statement in Section 15
- Use judgement about hazard communication statements, but include somewhere

Hazard Communication Requirements

- Workplace practices are a key consideration in what is “reasonably foreseeable”
 - Initially, EPA was foreseeing that workers might not use PPE and was issuing consent orders
 - The U.S. Occupational Safety and Health Administration (OSHA) violation database shows glove and goggle violations are rare
 - EPA revisited what is reasonably foreseeable for workers
 - EPA now requires “impervious gloves”
- EPA also requests additional hazard statements
 - Requests may conflict with Globally Harmonized System of Classification and Labeling of Chemicals (GHS) standards

Responding to EPA SDS Changes

- EPA identifies hazard concerns, often based on uncertainty
 - May lack specificity (specific target organ toxicity (STOT) without a target organ)
 - May conflict with classification standards
 - May conflict with known information
- Can engage with EPA or proactively revise SDS to address EPA's concerns

SDS Changes to Address EPA Concerns

- Evaluate whether EPA's concerns are valid
 - If you have a basis to refute, describe EPA's concerns and why you disagree
- Incorporate concerns somewhere
 - Can use Section 15
 - "EPA identified concerns for..."
- Interpret EPA's concerns in a GHS context
 - "Solvent neurotoxicity" -> STOT Single Exposure Category 3
 - "May cause eye irritation" -> Category 2B

New TSCA and Nanomaterials

- TSCA reform did not change EPA's January 2008 approach to chemical identity of nanomaterial
 - EPA does not use particle size to distinguish substance identity -- identity is based on molecular identity (the bonding arrangement of atoms)



History of PMN Submissions for Nano

- Since January 2005, EPA has received and reviewed more than 220 new chemical notices for nanoscale materials such as fullerenes, quantum dots, and carbon nanotubes
- EPA has issued consent orders and SNURs permitting manufacture under limited conditions, including:
 - Limiting the use of the nanoscale material
 - Requiring the use of PPE and engineering controls
 - Limiting environmental releases
 - Requiring testing to generate health and environmental effects data.
- More information is available in a forthcoming article, “Nanotechnology and Regulatory Certainty: Closer Now Than Ever,” written by Lynn L. Bergeson and Carla N. Hutton, that will be published in the American Bar Association’s (ABA) *The SciTech Lawyer*

Nanomaterials under New TSCA

- Like non-nanomaterials, except:
 - EPA may have more uncertainty, so more likely to receive an “insufficient information” determination
 - Submitters should spend additional time looking for analogs with data
 - Expect consent order and/or SNUR
 - Inhalation exposure is especially problematic

Summary

- TSCA reform has changed EPA's view towards new chemicals
- SDS plays a very important role
- Regulation is much more likely
 - Consent order and/or SNUR
 - SDS must be updated to reflect regulations
 - SDS has an important role in supply chain communication requirements
- Be responsive to EPA's concerns
 - Not necessarily verbatim
 - Use Section 15
- TSCA reform has not fundamentally changed EPA's approach to nanomaterials

THANK YOU

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