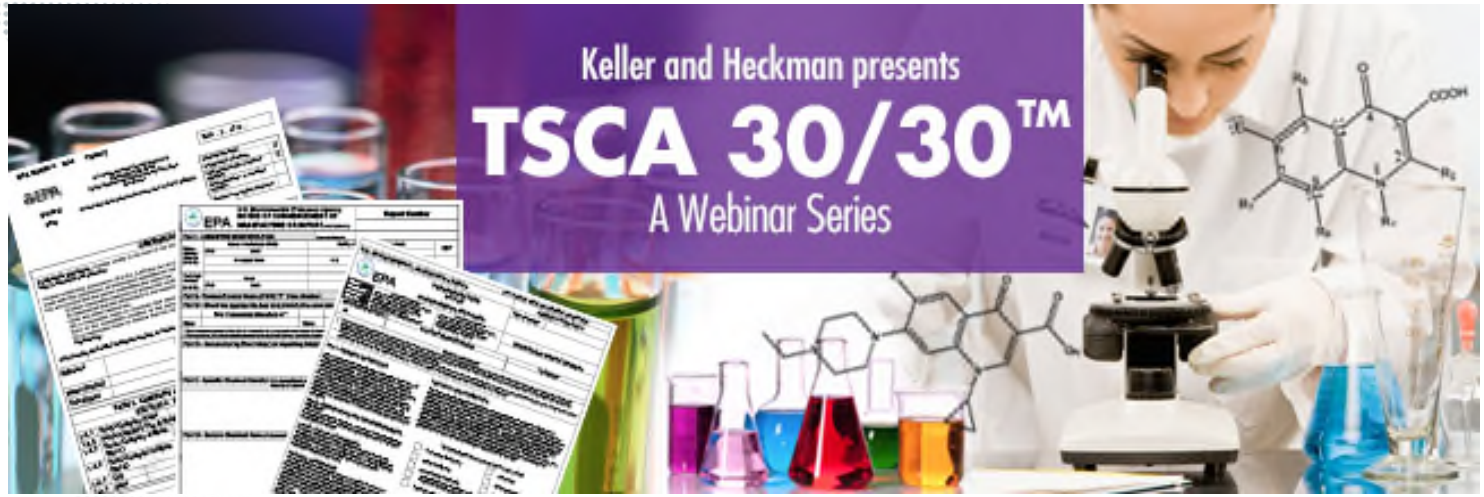


# Chickens Come Home to Roost – Biden EPA's Implementation of TSCA

## June 9, 2021

 

# Herb Estreicher

- Herbert (Herb) Estreicher is a prominent environmental lawyer who is listed in Who's Who Legal: Environment and in Marquis Who's Who in America. Herb holds a PhD in Chemistry from Harvard University (1980) in addition to his U.S. law degree (1988). He is also listed as a foreign lawyer (B List) with the Brussels legal bar. Herb is recognized as a leading expert on the Toxic Substances Control Act (TSCA) and is frequently quoted in Inside EPA, Chemical Watch, and BNA Environmental Law Reporter. He is one of the few U.S.-based lawyers that is expert on the EU REACH regulation and has successfully argued a number of cases before the European Chemicals Agency (ECHA) Board of Appeal and has briefed cases before the EU General Court and the European Court of Justice.

- Herb represents leading manufacturers of chemicals, pesticides, and consumer products. His broad practice in international environmental regulatory law allows him to take an interdisciplinary approach with his clients and their needs. His extensive background in organic chemistry, risk assessment, and bioengineering is valued highly by his clients in the chemical, nanotechnology, and biotechnology industries.

- Herb provides advice on product liability risk control and assists his clients with crisis management for embattled products, including wood preservatives and persistent, bioaccumulative, and toxic (PBT) chemicals. He helps his clients secure and maintain chemical approvals and pesticide registrations in Canada and Europe, advises clients on matters involving the Canadian Environmental Protection Act and on European chemical directives such as the EU Registration, Evaluation and Authorization of Chemicals (REACH) regulation, the Classification, Labelling and Packaging (CLP) regulation, and the Biocidal Products Regulation. Herb also represents clients in matters involving the Stockholm Convention on persistent organic pollutants (POPs) and has participated in the Canadian Strategic Options Process (SOP). He counsels clients on matters concerning sustainability and the circular economy.

# James Votaw

- James Votaw has an extensive practice focusing on environmental and health and safety regulation. Within that arena, he concentrates on the regulation of conventional and nanoscale chemicals, pesticides, consumer and industrial products, and industrial processes and wastes.

- For his clients, James obtains pre-market product approvals and exemptions, including the first U.S. approval of a nanoscale pesticide. He negotiates testing orders, defends enforcement actions, advises on restrictions and disclosures associated with the chemical content of products, counsels on release and other environmental reporting, and supports environmental regulatory and liability aspects of commercial transactions (including, but not limited to regulatory due diligence and private label distribution arrangements).Further, he participates in technical rulemaking proceedings, provides strategic and regulatory compliance counseling within existing and emerging industries, initiates compliance training, conducts internal investigations, performs compliance auditing, offers facility permitting services and develops product compliance plans and systems.

- James represents clients before State and Federal regulatory agencies and federal courts. He has extensive experience in compliance counseling on matters related to the Toxic Substances Control Act (TSCA); the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); the Clean Air (CAA) and Clean Water Acts (CWA); the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA); the Consumer Product Safety Commission (CPSC); California's Proposition 65; Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH); Restriction of Hazardous Substances (RoHS); and Waste Electrical and Electronics Equipment (WEEE).

# Section 5
# New Chemical Review

 

# Key §5 Changes by Lautenberg Act

1. **EPA must make an *affirmative* safety determination:**
   - ◊ NCS presents an unreasonable risk → "A" finding
   - ◊ NCS may present an unreasonable risk
   - ◊ There is insufficient info to determine NCS risk
   - ◊ Substantial quantities + significant release or exposure

   → "B" findings

   - ◊ NCS not likely to present an unreasonable risk → "C" finding
2. **Expressly consider risks of "reasonably foreseeable" uses**
3. **Requirements For "B" findings**
   - ◊ 1976 TSCA: EPA *may* issue an order to limit manufacture, processing, use
   - ◊ 2016 TSCA: EPA *shall* issue an order … *to the extent necessary* to protect against unreasonable risk

# Key issue: Response to "Foreseeable Use" Risks

- Response to "B" Finding for use described in PMN:
  - ✓ 5(e) Order to PMN submitter + SNUR (standard) (40 CFR 721.160)
- Response to "B" Finding for uses not in PMN but "reasonably foreseeable"?
  - Order to submitter + SNUR?
  - SNUR only?
  - To what extent should EPA rely on PMN submitter's workplace controls and SDS guidance to others to mitigate exposure assumptions?

# Response to "B" findings – Clinton EPA Interpretation

- Issue SNUR and no Order ("non 5(e)-SNUR")
  - PMN submitter allowed to proceed with PMN uses without delay
  - SNUR subsequently proposed/issued to control non-PMN uses
    - E.g., When manufacture commences (NOC filed)
- Codified at 40 CFR § 721.170 (expedited SNUR procedure)
- Theoretical risk someone would commence the "foreseeable use" before SNUR proposed

# Response to "B" findings – Obama EPA Interpretation

- Initially: Any "B" finding required EPA to issue a 5(e) Order + SNUR
  - Slows PMN review and processing while Orders and SNURs prepared
  - SNUR/Order to be issued in most cases
  - Very long delays beyond 90 days
  - Huge backlog of PMNs/Exemption applications
- Floated idea for more flexible/practical approach

# Response to "B" findings – Trump EPA Interpretation

- EPA may rely on SDS to estimate risks from PMN uses (workplace controls)
- EPA may propose/issue a SNUR during the PMN review period to control potential uses that might otherwise generate "B" findings
- EPA relies on this new SNUR as basis for a "C" finding ("not likely to present an unreasonable risk")
  - No "B" finding, No 5(e) order required
  - Essentially reorders the pre-Lautenberg process
  - But SNURs still required in most cases (evolving approach to timing)
  - **Delay/backlog improve but remain**

# Response to "B" findings – Biden EPA Interpretation

- **Statements by OCSPP Deputy Asst. Administrator Freedhoff:**
  1. EPA will no longer rely on SNURs/intended SNURs during the PMN review process to avoid "B" finding for non-PMN uses
  2. EPA may not rely on SDS/other law to control exposure assumptions for PMN uses ("no guarantee" that they will be implemented)
  3. Where "B" findings are made, EPA will issue 5(e) orders to submitters
     - Control risk from non-PMN uses (?)
     - Develop data to support risk assessment of uncertain future uses?
- **Implications for companies**
  - Orders + SNURs in most cases; permit-like system
  - Long delays in processing and deep backlogs

# Amended Section 5 Procedural Rules

- **Update PMN/SNUR rules to reflect Lautenberg Act Changes**
  - 40 CFR Parts 720 & 721
  - Delayed - NPRM expected May 2021 (Unified agenda in Spring/Fall 2020)
- **EPA's Stated Objectives/Means:**
  - Align EPA's PMN review processes/procedures with new LSCA requirements
  - Improve EPA PMN review efficiency
  - Increase quality of information in PMNs when submitted
  - Improve EPA's processes to reduce unnecessary rework in the risk assessment and ∴ reduce length of new chemical review period
- **Implications for companies:**
  - Codify new Biden-era review procedures
  - Expand/detail PMN information requirements
  - Potentially – create disincentives for late information

 

# Section 6
# Risk Evaluation

 

# Conditions of Use – Obama EPA Interpretation

- Risk Eval Proposed Rule Federal Register of January 19, 2017 [82 FR 7562]
- Risk evaluations must encompass all manufacture, processing, distribution in commerce, use, and disposal activities that constitute the conditions of use within the meaning of TSCA section 3
- A risk evaluation must encompass all known, intended, and reasonably foreseen activities associated with the subject chemical substance
- The components of its risk evaluations will be "fit for purpose." All conditions of use will not warrant the same level of evaluation, and EPA expects it may be able to reach conclusions without extensive or quantitative evaluations of risk
- For example, lower-volume or less dispersive uses might receive less quantitative, data-driven evaluations than uses with more extensive or complicated exposure patterns

# Conditions of Use – Trump EPA Interpretation

- Federal Register for Thursday, July 20, 2017 [82 FR 33726]
- Risk determinations to be made on individual conditions of use or categories of conditions of use
- Legislative history of the amended TSCA explicitly states that EPA has discretion to determine the conditions of use that it will address in its risk evaluations, in order to ensure that the Agency's focus is on the conditions of use that raise the greatest potential for risk
- EPA intends to exercise discretion in addressing circumstances where the chemical is unintentionally present as an impurity in another chemical substance
- Discretion to consider uses where other agencies hold jurisdiction, misuse, illegal use, speculative future conditions of use, uses that are inconsistent with labeling requirements or PPE requirements, chemicals used in articles or replacement parts, uses that are inconsistent with manufacturers' instructions, accidental conditions of use, or uses where residuals from an industrial process are completely destroyed

 

# The 2019 case Safer Chemicals Healthy Families (SCHF), et al., v. EPA

- Interpretation of conditions of use at the heart of the case
- But the U.S. Court of Appeals for the 9th Circuit declined to rule on that aspect of the case because it was not ripe for review
- What the Court did was overturn the agency's policy of generally excluding legacy uses from TSCA evaluations
- ENGO's have raised the issue of conditions of use in litigation on the various no unreasonable risk determinations made in the context of the first 10 chemicals to undergo risk eval

# HBCD and Methylene Chloride Cases (9th Circuit)

- EPA has requested a voluntary remand without vacatur in both cases
- Trump EPA determined that HBCD does not present such unreasonable risk under six of 12 conditions of use
- Remand to allow EPA to revisit:
  - The decision to make risk determinations on a condition-of-use by condition-of-use basis rather than a determination for the chemical as a whole
  - Assumptions regarding workers' use of personal protective equipment ("PPE") when exposed to HBCD in an occupational setting
  - And to consider whether to conduct additional analyses involving tribal or environmental justice communities
- Remand will also allow EPA to seek public comment
- EPA presently expects its reconsideration process to be complete in 12-18 months
- Similar request in the Methylene Chloride litigation but also EPA plans to assess exposure from pathways that fall under the Agency's Clean Air Act jurisdiction

# What Does This Mean?

- No more no unreasonable risk determinations
- No preemption for such uses after the risk eval issues
- Aggregate exposure will likely be considered
- Legacy uses by themselves may in many cases result in unreasonable risk findings for the chemical as a whole
- Manufacturer-requested risk evaluations will need to include complete information on all conditions of use
- This was already proposed in the Obama-era risk eval proposal

 

# Does EPA Need To Repropose Its Risk Eval Rule?

- § 702.47 Unreasonable risk determination
  - As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment **under each condition of uses within the scope of the risk evaluation, either in a single decision document or in multiple decision documents**
- § 702.37 Submission of manufacturer requests for risk evaluations
  - (3) The manufacturer must identify the circumstances on which they are requesting that EPA conduct a risk evaluation and include a rationale for why these circumstances constitute conditions of use under § 702.33

# More TSCA Testing

- April 2021 Interagency Testing Committee (ITC) report recommends the addition of 15 high-priority substances to the Priority Testing List, as well as 24 flame retardant chemicals
- The flame retardants are recommended for addition based on a requests by the CPSC
- The ITC report also requests that EPA add these chemicals to the TSCA section 8(d) Health and Safety Data Reporting rule

# Final Thoughts

 


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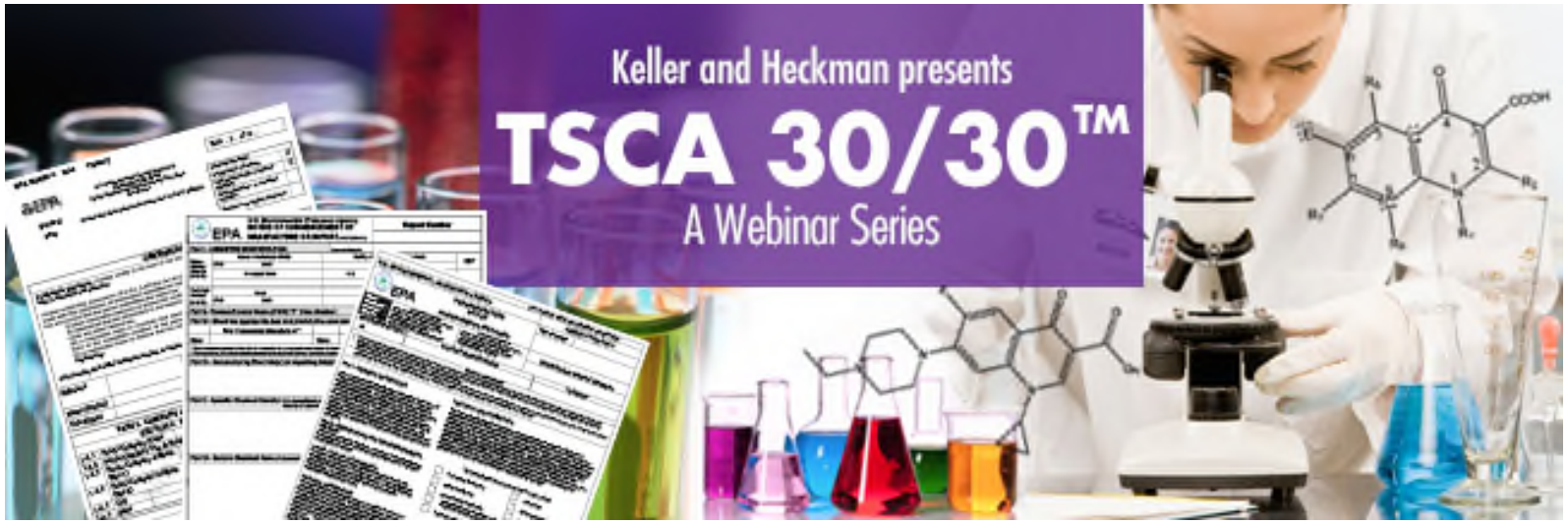


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