Revamping TSCA Section 8(e)

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Herbert Estreicher, Ph.D.

- Herbert (Herb) Estreicher, Ph.D., has a broad practice in international environmental regulatory law, representing leading manufacturers of chemicals, pesticides, and consumer products. Clients in the chemical, nanotechnology, and biotechnology industries seek his in-depth legal and scientific knowledge of organic chemistry, risk assessment, and bioengineering stemming from his dual degrees – a Ph.D. in Chemistry and a J.D.
- Herb is recognized as a leading chemical regulations attorney with a particular emphasis on the Toxic Substances Control Act (TSCA), including EPA's implementation of the 2016 Lautenberg Amendments, and is one of the few United States (U.S.)-based lawyers with extensive knowledge of the European Union (EU) Registration, Evaluation and Authorization of Chemicals (REACH) regulation. In this capacity, he 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 counsels clients on product liability risk control and assists with crisis management for embattled products, including wood preservatives and persistent, bioaccumulative, and toxic (PBT) chemicals. He helps 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 REACH regulation, the Classification, Labelling and Packaging (CLP) regulation, and the Biocidal Products Regulation (BPR). He also represents clients in matters involving the Stockholm Convention on persistent organic pollutants (POPs) and has participated in the Canadian Strategic Options Process (SOP). In addition, he counsels clients on matters concerning sustainability and the circular economy.

Thomas C. Berger

- Thomas (Tom) Berger's practice is based on an in-depth understanding of and experience with the chemicals, plastics, and electronics industries. As a preeminent practitioner with over 30 years of experience, Tom helps clients commercialize new chemical products and preserve supply chains for existing chemical products utilizing an interdisciplinary team approach combining law and science, with an emphasis on emerging technologies in the industrial and consumer chemicals areas.
- Tom's practice focuses almost exclusively on the Toxic Substances Control Act (TSCA). Tom leads clients through the TSCA section 5 premanufacture notification (PMN) approval process and negotiates the terms of resulting section 5(e) orders and significant new use rules (SNURs). He provides counsel to clients on major U.S. Environmental Protection Agency (EPA) enforcement matters, assists companies in preparing for compliance inspections and responding to information requests and subpoenas, and defends Agency enforcement actions.
- As an active member of the environmental and chemical industries and legal community, Tom was extensively involved in efforts to "reform" TSCA, and has in-depth and day-to-day experience with all aspects of TSCA, including rulemaking/advocacy, test rule/order, section 5 PMN, TSCA Inventory, Chemical Data Reporting (CDR), and section 6, as well as confidential business information (CBI), section 8 recordkeeping and reporting, and import/export issues.
- Tom is a recognized leader in conducting extensive voluntary TSCA compliance audits, often conducted as part of corporate mergers or acquisitions. Since its inception in 1995, Tom has assisted hundreds of clients successfully utilize EPA's "Audit Policy" (as well as the "New Owner Policy") to disclose and obtain up to 100% gravity-based monetary penalty mitigation for a wide variety of TSCA violations.

TSCA Section 8(e)

- TSCA Section 8(e), 15 U.S.C. §2607(e), requires immediate reporting to EPA of information that "reasonably supports" a "substantial risk" of injury to health or the environment unless EPA is adequately informed
- Tom will discuss: EPA's 2026 Supporting Statement for an Information Collection Request (ICR) under the Paperwork Reduction Act (PRA)
  - EPA is aware that the current guidance is out-of-date
  - Draft reporting guidance in progress and will be made available for comment in 2026
  - EPA plans to address guidance on reporting results of New Approach Methodologies (NAMs) and hazard and exposure thresholds for reporting on non-emergency situations involving environmental contamination

Implementation of Section 8(e)

- No regulations, *per se*
- TSCA section 8(e) Policy Statement (issued March 16, 1978; 43 FR 11110 and amended several times).
  - Focus on:
    - Serious **human health** effects: cancer, birth defects, mutagenicity, neurotoxicity
    - Serious **environmental** effects: (1) emergency incidents of environmental contamination; (2) information pertaining to non-emergency environmental incidents, including those that involve "widespread and previously unsuspected distribution in environmental media"

The 8(e) Compliance Audit Program and Evolving Guidance

- In the 1980s EPA issued annual evaluations of 8(e) notices ("Status Reports"), showing that types of studies considered reportable were quite broad
- In the late 1980s EPA pursued enforcement against a company for failure to report a rodent study where the chemical caused benign tumors
  - Sent shock waves through industry
- EPA announced the §8(e) CAP in February 1991, with modifications in April and June 1991
  - One-time voluntary disclosure program designed to:
    - Encourage companies to audit past compliance with §8(e)
    - Promote late reporting ("amnesty-like") of previously unreported substantial risk information

CAP Program

- CMA (now ACC) submitted a number of hypotheticals to EPA
- Result was June 1991 TSCA section 8(e) *Reporting Guide*
  - Reportable information casts a wide net
- Precise total number of Section 8(e) submissions not readily ascertainable but clearly in the multiple thousands
  - EPA currently receives ~500 per year

What does EPA do with 8(e)submissions?

- **EPA Internal Processing and Data Structuring**
  - Initial data extraction and categorization, entering structured fields such as:
    - Endpoint/effect type
    - Test type
    - Dose and duration
    - Route of exposure
    - Species tested
  - **Where sufficient detail exists:** EPA may task contractors to summarize hazard information for use in assessments
  - Data may then be incorporated into:
    - Internal databases
    - Computational tools such as:
      - Analog Identification Methodology (AIM)
      - ECOSAR

How does EPA Use 8(e) Data

- **A. §5 New Chemicals Program**
  - §8(e) notices used as **analogs for read-across** in evaluating new chemicals lacking data
  - Data also integrated into **computational prediction tools** used in PMN review

- **B. Existing Chemicals (TSCA §6 Risk Evaluations)**
  - §8(e) data is part of the **Systematic Review process**, specifically within:
    - **Gray literature identification and evaluation workflows**
    - Inclusion in **literature inventories and evidence maps** for high-priority substances and MRREs

April 2026 Section 8(e) ICR

- **April 23, 2026:** EPA submits ICR for section 8(e) to OMB for approval under the PRA
  - 91 Fed. Reg. 21,809
  - This is a proposed ICR *extension*
- Public comments *previously* requested July 2, 2025
  - ACC, 3M, Syngenta (other stakeholders consulted)
- Comments on current ICR due **May 26, 2026**

What is an ICR

- Set of documents describing reporting, recordkeeping, survey, or other information collection requirements imposed on public by federal agency
  - Think IRS *Form 1040*
- PRA requires agency must obtain OMB approval before collecting same or similar information from ≥10 persons
- What is covered in an ICR?
  - Description of information to be collected
  - Reason information needed
  - Estimate of time/cost for public to respond

Common Comment Topics

- Whether information necessary for proper performance of agency functions
- Accuracy of the agency's time/cost estimates
- Comments on quality, utility, and clarity of information sought
- Suggestions on how to minimize burden
- Personal experiences with the requirement
  - Agencies actually consider this

What Could Be Improved

- Clarity of substantial risk requirements
  - Stakeholder input
- Consolidation of guidance
- Notice and comment rulemaking(?)

Substantive Issues

- Quantitative guidance provided only for certain types of tests/effects/endpoints
- Aquatic toxicity results depend heavily on exposure
  - Exposure can change
- “Foreign” data
- NAMs:
  - “.. use of and the interpretation of NAMs for substantial risk reporting will be considered…”
- CBI
  - “Health and safety studies … may not be protected as CBI under TSCA section 14(b)(2) … chemical identity is part of, or underlying data to, the health and safety study….”

More Specific Topics

- Acute toxicity
- Allergenicity
- Chemical/physical properties
- Chronic toxicity
- Environmental incidents/exposure
- Epidemiological information
- Immunotoxicity
- Mutagenicity – *in vivo* and *in vitro*
- Neurotoxicity
- Oncogenicity
- Reproductive/developmental toxicity
- Subacute and subchronic toxicity
- **General reporting issues** – e.g., subject persons, R&D, jurisdiction, "obtaining" information, "actual knowledge" by EPA, scientific literature, etc.

Where is EPA Right Now

- "…acknowledges that the TSCA section 8(e) webpage and the 2003 TSCA Section 8(e) Policy and Reporting Guidance are due for an update"
- Draft publication targeted for 2026
  - "plans to consolidate all relevant guidance resources into one uniform source … and edit language to further enhance clarity … stakeholders will receive an opportunity to review the draft guidance updates and provide feedback."
- "Although EPA's preferences regarding TSCA section 8(e) submissions could be codified in procedural rules under the [APA], EPA is not at this time adopting them as rules."
- K&H Coalition can address

Upcoming Webinars

Please join us at 1:00 PM Eastern U.S.
Wednesday, May 20, 2026
www.khlaw.com/OSHA3030

Please join us at 10:00 AM Eastern U.S.
Wednesday, 10 June 2026
www.khlaw.com/REACH-3030

Please join us at 1:00 PM Eastern U.S.
Wednesday, August 12, 2026
www.khlaw.com/TSCA-3030

Thank You

Any questions?

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