TSCA INFORMATION GATHERING TOOLS IN SUPPORT OF SECTION 6 RISK EVALUATIONS

July 15, 2020

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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.

estreicher@khlaw.com • 202.434.4334

Thomas C. Berger

Tom Berger has a chemical engineering background and is a partner at Keller and Heckman. His practice focuses on the regulation and approval of new and existing chemicals under the Toxic Substances Control Act (TSCA) and its international counterparts in Australia, Canada, China, the European Union, Japan, Malaysia, New Zealand, the Philippines, South Korea, and Taiwan. Mr. Berger also counsels trade association clients on various matters, including environmental, and product disparagement and defense issues. Mr. Berger has been heavily involved in “reformed” TSCA, EPA's Chemical Data Reporting (CDR) rule, TSCA “Work Plan Chemicals,” and the TSCA Inventory “reset.”

berger@khlaw.com • 202.434.4285

Today's Topics

- **Context:** Need for more robust data to support risk evaluations
  - **Options:**
    - Expanded CDR Reporting
    - PAIR Rules
    - Bringing Back CAIR Reporting
    - Section 8(d) Data Call-ins
    - Section 4 Test Orders

Need for More Robust Data to Support Risk Evaluations

- NGOs have urged EPA to start work immediately to exercise its authorities under TSCA section 4 and 8 to mandate testing and require reporting to fill data gaps, particularly in view of perceived information adequacy shortcomings in the first 10 risk evaluations
- EDF has asserted relying on voluntary submission of data alone has "*proven wholly insufficient in the past*"
- NGOs and State Attorney Generals filed petitions to require EPA to amend the CDR to require more use information on asbestos, which EPA denied, and is now being litigated

Need for More Robust Data to Support Risk Evaluations (2)

- SACC has criticized EPA's first 10 risk evaluations for lacking data - particularly for environmental fate/effects
- AA Dunn has stated in a blogpost that EPA will focus on "gathering important, best available scientific evidence on the next 20 chemicals, and others on the 2014 TSCA work plan, so that when we begin work on a chemical, we have a complete set of information on exposure and hazards."
- Even industry concedes that better use and exposure data is needed, but believes that voluntary submissions will fill needed gaps

Section 8(a)

§2607. Reporting and retention of information

(a) Reports

(1) The Administrator shall promulgate rules under which—

(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii)) [R&D] shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require…

Expanded CDR Option

- The CDR rule could be amended to require more detailed use and exposure information on 2014 Workplan chemicals
- CDR is cyclical, with the next report due in 2024
- Manufacturers are not in the best position to report on downstream use and exposure
- Does processor reporting for Workplan chemicals make sense?

Section 8(a) Preliminary Assessment Information Rule (PAIR)

- 40 C.F.R. Part 712 Subpart A
- Manufacturers/importers only
- Specifically-listed substances
- Latest complete corporate fiscal year
- Two-page PAIR Form (7710-35)
  - Production volumes
  - Release information
  - Exposure information
- 60-day notification period

Recent use of PAIR rules

- Multi-chemical PAIR action = August 16, 2006
  - 243 unsponsored (“orphan”) HPV chemicals
  - Two chemicals later deleted (4/30/2007)
- Nanomaterials (under Part 704 Subpart B)
  - Final rule January 12, 2017
    - 82 FR 3,641

Section 8(a) PAIR Rules

- Subpart A PAIR rules = not particularly informative
- Subpart B Nanomaterial PAIR rule was more comprehensive, rulemaking on individual chemicals is labor and time consuming
- Should EPA bring back CAIR reporting (more to follow…) for potential high priority chemical candidates?

Spring 2020 Regulatory Agenda

"…EPA is developing a rulemaking under section 8(a) . .. to add certain chemicals that are on the TSCA Work Plan to . . . 40 CFR part 704, subpart B . . . EPA is developing this TSCA section 8(a) rule to obtain information about potential hazards and exposure pathways related to certain chemicals on the TSCA Work Plan, particularly occupational, environmental, and consumer exposure information. This information is needed to inform prioritization and risk evaluation of the chemical substances, as mandated under TSCA section 6. TSCA section 6 requires EPA to draw chemicals from the 2014 update of the TSCA Work Plan for Chemical Assessments to prioritize and/or evaluate those particular chemicals or chemical groups listed on the Work Plan for potential risks…"

Proposal: Nov. 2020

Section 8(a) Chemical-Specific and CAIR Reporting

- **Subpart B**
  - Nanomaterials (2017) plus eight other substances/categories
    - *e.g.*, chlorinated naphthalenes, hexafluoropropylene oxide
- **Subpart C**
  - CAIR model rule (40 C.F.R. Part 704, 1988), standard approach to gathering information on manufacture, import, and processing
  - Uniform reporting and recordkeeping requirements, standardized reporting form
    - ~100 page report!
  - Could be adapted to specific substances
  - Rescinded in 1995

Section 8(d) Data Call-ins

- Very powerful tool
- Requires submission of unpublished health and safety studies including monitoring data
- Last used in 2008
- Unless otherwise specified, limited to certain NAICS codes and to manufacturers and importers (not processors)

§4 – Testing

- EPA now provided flexibility to require testing by order or consent agreement
- Provided explicit authority to obtain exposure information
- EPA generally must "tier" testing, and reduce vertebrate testing to the extent practicable
- March 2020 - EPA issues §4(a)(2) order requiring BASF and Sun Chemical to conduct solubility testing and occupational exposure monitoring of PV29

Constraints on Section 4 Test Order Authority

- Testing must be “necessary” in most cases
- Agency must issue “Statement of Need”
- Identify the need–
  - How existing, reasonably available information was used to inform decision
  - Why a unilateral order is warranted (vs. rule or consent order on testing)
  - Identify protocols / methods to develop data
  - Consider relative costs of tests / methods selected
  - Consider availability of personnel / facilities to test
  - Justify forcing processors to test
  - Must use “best available science” (§26(h))
  - Agency must justify tests using vertebrate animals

Mandate to Reduce Animal Testing

- TSCA §4(h):“The Administrator shall reduce and replace, to the extent practicable, scientifically justified and consistent with the policies of this title, the use of vertebrate animals in the testing of chemicals substances [for TSCA] ...”
- EPA must first consider: Existing toxicity information–Read-across: grouping and analogue methods–QSAR and bioinformatics–High-throughput screening/ predictive methods
- EPA must encourage—Grouping; joint testing through consortia; Alt. methods that provide equivalent or better information

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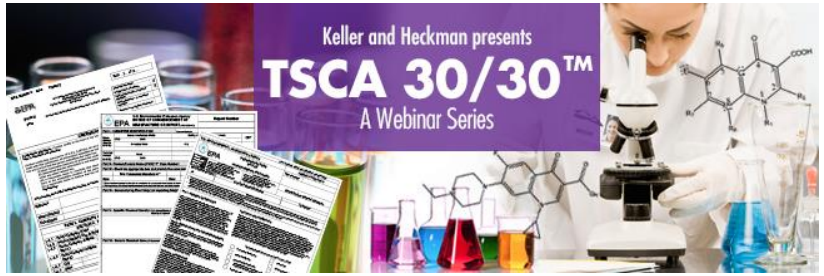

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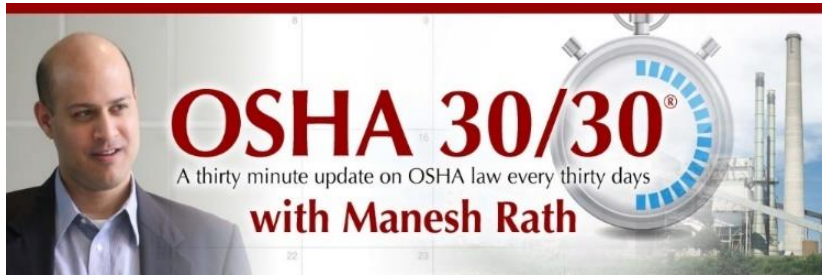

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