(1) TSCA CBI Litigation
(2) Section 21 Petitions: An end-run around Section 6(b)?

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Herb Estreicher, Ph.D.

- Herb Estreicher is a prominent environmental lawyer who holds a Ph.D. in Chemistry from Harvard University in addition to his U.S. law degree. Herb is an expert on the TSCA and is frequently quoted in Inside EPA, Chemical Watch, and BNA Environmental Law Reporter. He has successfully argued many cases before the European Chemicals Agency 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 clients secure and maintain chemical approvals and pesticide registrations in Canada and Europe and advises clients on matters involving the Canadian Environmental Protection Act and on European chemical directive.

David B. Fischer, M.P.H.

- David Fischer counsels clients on environmental, policy, and health and safety matters, with a concentration on the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Having served as the Deputy Assistant Administrator for EPA's Office of Chemical Safety and Pollution Prevention as well as having held senior level positions at the American Chemistry Council, David advocates for clients before the U.S. EPA and provides strategic advice to them regarding issues before Congress.
- In addition, he has experience with numerous other statutes including the CAA, CWA, Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), Safe Drinking Water Act (SDWA), Emergency Planning and Community Right-to-Know Act (EPCRA), and the Food Quality Protection Act (FQPA).
- David's clients include domestic and international industrial and specialty chemical manufacturers and the trade associations that represent them. Clients seek his assistance on new chemical approvals, chemical and pesticide risk evaluations, and risk management rulemaking because of his deep understanding of EPA, its internal science policy apparatus, and its many organizational pieces, responsible for all aspects of TSCA and FIFRA.

Definition of Health and Safety Study

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- Health and safety (H&S) studies can not be claimed CBI.
- Not everything in a study report is part of an H&S study.
- 40 C.F.R. 703.3 clarifies what is NOT part of an H&S study, namely:

  (1) The name, address, or other identifying information for the submitting company, including identification of the laboratory that conducted the study in cases where the laboratory is part of or closely affiliated with the submitting company.

Not Part of an H&S Study (Cont.)

(2) Internal product codes

(3) Names and contact details for testing laboratory personnel and names and other private information for health and safety study participants or persons involved in chemical incidents such as would typically be withheld under 5 U.S.C. 552(b)(6) or under other privacy laws.

(4) Information pertaining to test substance product development, advertising, or marketing plans, or to cost and other financial data.

- Why is this important?
- Has to do with Data Compensation under REACH and REACH-Like programs and possession of full study reports.
- Also has to do with EPA long-standing pre-Lautenberg practice.

EDF v EPA, Case No. 23-1166 (D.C. Cir.)

- Challenges EPA's authority to carve out certain information in study reports from the definition of Health and Safety Study.
- EDF argues that the statutory definition of H&S study is very broad and covers with limited explicit exception "any health and safety study" along with "any information…from a health and safety study."
- Information on the identity of the submitter and/or linked lab needs to be disclosed because that information is useful.

EDF also alleges

- EPA’s violates TSCA because, after a company brings a new chemical onto the market, the Rule does not require the company to substantiate or EPA to review the company's earlier CBI claims, in particular, the chemical identity.
- EDF argues that chemical identity can only be claimed CBI pre-commercialization unless substantiated.
- Section 14 (c)(2)(G) is clear -- the chemical identity may only be claimed CBI without substantiation "prior to the date on which a chemical substance is first offered for commercial distribution."

EPA's Defense

- Only those parts of a study report that evaluate the effect of a substance on health or environment are part of an H&S study.
- That certain information contained in a study report be considered useful by someone examining the study does not mean that such information constitutes information bearing on the effects of the chemical substance on human health or the environment.
- Statute does not require post-commercialization CBI substantiation.

Section 21 Petitions (1)

- TSCA section 21(b)(1) states the petition "shall set forth the facts which it is **claimed establish that it is necessary** to issue, amend, or repeal a rule under section 4, 6, or 8 …."
- Under the previous administration this language was interpreted to mean that the petition had to demonstrate that it fully comported with the statutory standards that apply to the petition's request.
  - If a petition, for example, requested a 6(a) rulemaking on a chemical, then the petition would need to include a risk evaluation on that chemical.

Section 21 Petitions (2)

- The current administration has expressed a similar interpretation.
- The burden rested with the petitioners, not the agency to "set forth the facts which it is **claimed establish that it is necessary…**."
- But in practice, EPA has abandoned this interpretation and now asserts its "discretion" to consider information that is reasonably available to the agency.

Section 21 Petitions (3)

- The 6PPD petition focused exclusively on “the unreasonable risk 6PPD in in tires presents to the environment.”
- EPA admits that the petition fails to meet the section 21 standard.
- Nonetheless, EPA granted the petition and “will promptly commence an appropriate proceeding under TSCA Section 6(a).”
  - ANPRM to be published in the Fall of 2024.
  - Meanwhile, EPA plans to use its TSCA authorities to gather human health effects data on 6PPD and to issue test orders.

Section 21 Petitions (4)

- The petition process stands in stark contrast to the section 6 prioritization, risk evaluation, and risk management paradigm for existing chemicals. Although EPA must seek public comment for any rule issued pursuant to section 21, EPA does not need to request either public comment or scientific peer review on a section 21 petition itself or on EPA's basis for granting the petition.
- And with respect to 6PPD, EPA granted the petition with respect to a single condition of use, 6PPD's use in tires.
- But for section 6 risk evaluations, EPA recently changed its regulations to mandate a whole chemical approach in which EPA reviews all conditions of use (COU) for a chemical and renders a single unreasonable risk determination for the whole chemical, rather than for any COU.

Section 21 Petitions (5)

- Perhaps inadvertently, EPA has now created an end run around section 6, especially at a time when EPA's refrain is a plea for more funds to implement sections 5 and 6.
- By granting section 21 petitions EPA diverts resources away from its statutory obligations under sections 5 and 6.
- EPA doesn't collect fees from section 21 petitioners, but it does from new chemical submissions and section 6 risk evaluations.

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Thank You

Any questions?

