Next Wave of Prioritization Candidates

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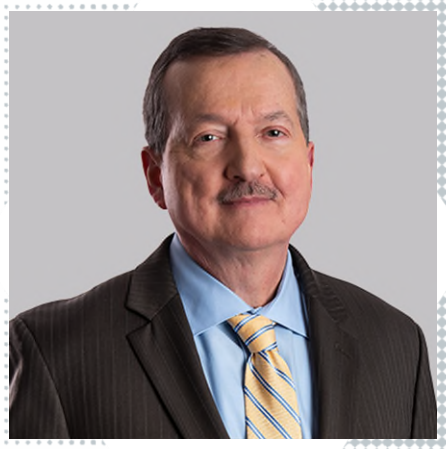
Herb Estreicher, Ph.D.

- 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 Toxic Substances Control Act (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.

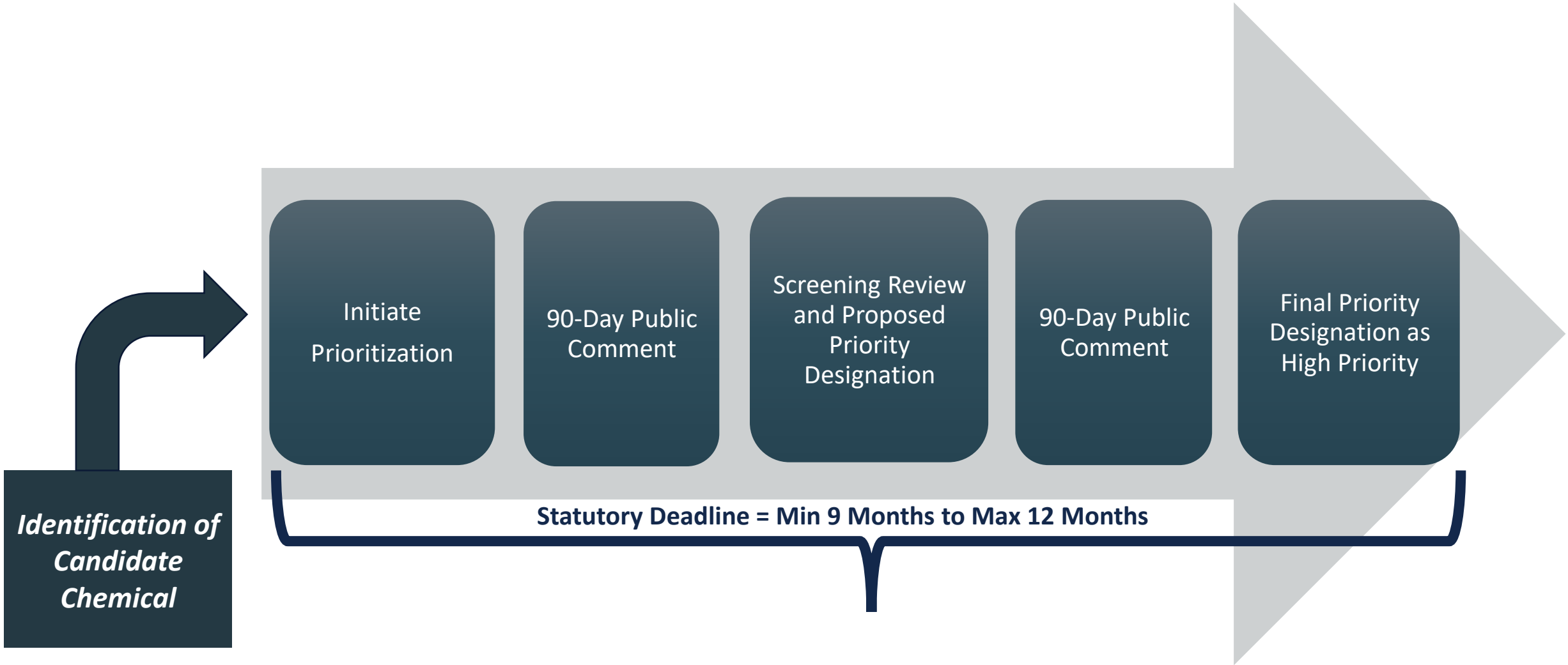
David B. Fischer

- David Fischer counsels clients on environmental, policy, and health and safety matters, with a concentration on 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.



Risk Evaluation Process

Chemical Prioritization Process



New Prioritization Candidates

- On December 18, 2023, EPA initiated the process of prioritizing five chemicals as candidates for high-priority designation and subsequent zrisk evaluation/ risk management:
  - Vinyl Chloride (CASRN 75–01–4),
  - Acetaldehyde (CASRN 75–07–0),
  - Acrylonitrile (CASRN 107–13–1),
  - Benzenamine (CASRN 62–53–3), and
  - 4,4’-Methylene bis(2-chloroaniline) (MBOCA) (CASRN 101–14–4)
- All five chemicals were selected from the **2014 TSCA Work Plan**, which is a list of chemicals identified by EPA for further assessment based on their hazards and potential for exposure
- **Comments are due March 18, 2024,** see 88 FR 87,423

Areas for Commenting

- The chemical substance's **hazard and exposure potential**;
- The chemical substance's **persistence and bioaccumulation**;
- **Potentially exposed or susceptible subpopulations** which the submitter believes are relevant to the prioritization;
- Whether there is **any storage of the chemical substance near significant sources of drinking water**, including the storage facility location and the nearby drinking water source(s);
- The chemical substance's **conditions of use or significant changes in conditions of use**, including information regarding trade names;
- The chemical substance's **production volume or significant changes in production volume**; and
- **Any other information relevant** to the potential risks of the chemical

Other Future Prioritization Candidates

- EPA has also requested comments on the following 10 chemicals:
  - 4-tert-Octylphenol(4-(1,1,3,3-Tetramethylbutyl)-phenol), CAS RN 140–66–9;
  - Benzene, CAS RN 71–43–2;
  - Bisphenol A, CAS RN 80–05–7;
  - Ethylbenzene, CAS RN 100–41–4;
  - Naphthalene, CAS RN 91–20–3;
  - Styrene, CAS RN 100–42–5;
  - Tribromomethane, CAS RN 75–25–2;
  - Triglycidyl isocyanurate, CAS RN 2451–62–9;
  - Hydrogen fluoride, CAS RN 7664–39–3; and,
  - N-(1,3-Dimethylbutyl)-N’-phenyl-p-phenylenediamine, CAS RN 793–24–8

Section 8 (c) Data Call-in for MBOCA

- EPA is requiring manufacturers (including importers) and processors of MBOCA to submit records of significant adverse human health and environmental effects reported to have been caused by this chemical
- Records must be submitted by **February 26, 2024**
- MBOCA is used in the manufacturing and processing of rubbers, plastics, resins and other chemicals
- It is a probable human carcinogen
- EPA believes there is also extensive data that demonstrate exposure to MBOCA may damage genetic material in cells

§ 8(c) Allegations of Significant Adverse Reactions (1)

- Manufacturers, importers, processors
- Must retain records of allegations of significant adverse reactions to human health or environment
- Central location
  - Must retain for five years
  - Must retain *any* employee allegations for 30 years!
- Allegation may be written/signed or oral
  - Transcribe or request reduction to writing
- 40 C.F.R. Part 717

§ 8(c) Allegations of Significant Adverse Reactions (2)

- Applies to allegations by any person
  - May be made without proof
  - But must identify source (product, mixture, process, effluent)
- Known/commonly-recognized effects exempt unless:
  - Significantly more severe
  - Significantly shorter exposure period/lower exposure level
  - Different exposure route

§ 8(d) Healthy and Safety Study Reporting

- Applicability Criteria:
  - Manufacturer/importer of listed substance (or proposed to) within last ten years
  - Company falls within certain NAICS (SIC) codes
    - NAICS 325 (chemical manufacturing and allied products)
    - NAICS 32411 (petroleum refiners)
- Submit or list unpublished health and safety studies
  - Broadly interpreted
  - Includes ongoing studies

§ 8(d) Reporting Exemptions (1)

- Studies published in the scientific literature
- Certain studies previously submitted to OCSPP (§8(e) submissions, § 4 filings, PMNs/SNUNs) or that will be under § 4
- Non-CBI studies previously submitted to any Federal agency (but include in list)
- Physchem and acute tox studies on mixtures
- Studies on substances you manufacture, import, or process only as an impurity

§ 8(d) Reporting Exemptions (2)

- Analyzed aggregations of monitoring data based on monitoring data acquired more than five years ago
- Analyzed aggregations of monitoring data on mixtures known to contain one or more listed substances, when the monitoring data are not analyzed to determine the exposure or concentration levels of the substances

Test Orders (1)

- For new data to be developed, reviewed, and then integrated into the risk evaluation process, test orders will need to be issued much earlier
  - The system needs to be “front loaded”
  - Data collection ideally should be started *before* the formal prioritization process begins, but that did not happen for any of the five chemicals to be prioritized
  - Nonetheless, EPA may still issue test orders for some if not all of the five chemicals

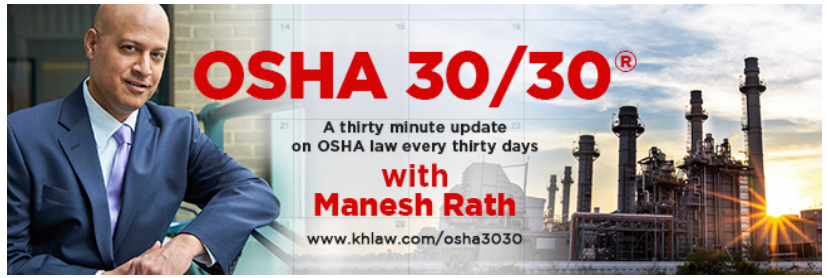
Test Orders (2)

- Take-aways from previous TSCA test orders:
  - Current test order litigation filed by the VI likely to be decided later this year, which will impact future test orders
  - Forming consortia can be a cost-effective means for impacted companies to implement test orders, but…
    - Keep in mind that the companies who have been issued test orders are ultimately responsible for satisfying all test order requirements
    - Thus, you must be vigilant in ensuring that the consortium manager is dutifully corresponding with EPA as needed and paying close attention to test order deadlines
    - Failure to abide by deadlines can lead to OECA enforcement action against the companies, not the consortium manager

Fees

- EPA proposed a fee rule in November 2022; expected to be finalized in 2024, currently under OMB review
- As proposed, fees for each EPA initiated risk evaluation would jump to $5,080,000
- Manufacturers otherwise subject to fees are exempt if they meet one or more of the following exemptions:
  - Import articles containing the chemical
  - Produce chemical as a by-product (that is not later commercialized)
  - Manufacture the chemical as an impurity
  - Manufacture the chemical as a non-isolated intermediate
  - Manufacture small quantities of the chemical for R&D
  - Manufacture the chemical in quantities below a 1,100 lbs. annual production volume
    - During the five years preceding and subsequent to EPA publishing a preliminary list of manufacturers subject to the fee

DISCUSSION



Please join us at 1:00 PM Eastern U.S.
Wednesday, January 24, 2024
www.khlaw.com/OSHA3030

Please join us at 10:00 AM Eastern U.S.
Wednesday, February 7, 2024
www.khlaw.com/REACH-3030

Please join us at 1:00 PM Eastern U.S.
Wednesday, February 14, 2024
www.khlaw.com/TSCA-3030

Thank You

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