The Seven Year Itch – Is it Time to Think of TSCA Reform (Again)?

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Thomas C. Berger

- Thomas (Tom) Berger has a combined chemical engineering and legal background and assists clients in commercializing new products and maintaining the ability to market them in a cost-effective manner with an emphasis on emerging technologies in the industrial chemicals area.
- He helps clients navigate the Toxic Substances Control Act (TSCA) premanufacture notification (PMN) review process and negotiates the terms and conditions of TSCA section 5(e) orders and significant new use rules (SNUR). Tom is a recognized leader in designing and conducting extensive voluntary TSCA compliance audits (often as part of corporate mergers and acquisitions) and assisting clients in managing liability under EPA's “Audit Policy” and other available penalty mitigation policies.
- Tom possesses a deep understanding of the chemicals, plastics, and electronics industries, with over 25 years of experience counseling clients on the regulation and approval of new and existing chemicals under TSCA and TSCA’s international counterparts in Australia, Canada, China, the European Union, Japan, Malaysia, New Zealand, the Philippines, South Korea, and Taiwan. His technical background allows him to undertake matters that involve polymers, inorganic chemistry, complex chemistry, and chemical nomenclature issues.

Gregory A. Clark

- Gregory (Greg) Clark counsels clients on regulatory and environmental issues, focusing on TSCA, the Clean Air Act (CAA), state volatile organic compound (VOC) regulations, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA).
- He assists clients needing approval of new chemical substances, genetically modified organisms (GMOs), and pesticides under TSCA, FIFRA, and similar laws abroad. Clients value his extensive experience guiding them through the PMN, Low Volume Exemption, Microbial Commercial Activity Notice (MCAN), and TSCA Environmental Release Application (TERA) review processes.
- Greg's extensive background enables him to provide guidance to companies and trade associations on the prioritization, risk evaluation, and risk management of existing chemicals, including chemicals on the 2014 TSCA Work Plan, following the Lautenberg Act amendments to TSCA. He assists companies with periodic reporting under the TSCA Chemical Data Reporting Rule and other agency reporting programs. He also designs, conducts, and coordinates comprehensive internal audits of TSCA compliance for existing operations under EPA's "Audit Policy," as well as under other penalty mitigation policies.

David B. Fischer

- 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 Clean Air Act (CAA), Clean Water Act (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.

§ 4 Test Rules, Orders, and Consent Agreements

- EPA can now require testing to develop information for:
  - PMNs or SNUNs
  - Risk evaluations under Section 6(b)
  - To implement a requirement imposed in a rule, order, or consent agreement under Section 5(e) or (f), or a rule under 6(a)
  - Upon request of a federal authority under another federal law
  - Prioritization
  - To determine if export-only substance presents unreasonable risk
- Old authority: large volumes + releases or exposures

§ 5(a) PMNs and SNUNs (1)

- "(1)(A) Except as provided in subparagraph (B) of this paragraph and subsection (h), no person may—
  - (i) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 2607(b) of this title, or
  - (ii) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use.

§ 5(a) PMNs and SNUNs (2)

- (B) A person may take the actions described in subparagraph (A) if—
  - (i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of, or imposed pursuant to, subsection (b), (e), or (f); and
  - (ii) the Administrator—
    - (I) conducts a review of the notice; and
    - (II) makes a determination under subparagraph (A), (B), or (C) of paragraph (3) and takes the actions required in association with that determination under such subparagraph within the applicable review period."

Review of New Chemical Notices

Determination	Related Action
The substance or significant new use is not likely to present an unreasonable risk	EPA notifies submitter of its decision and publishes its finding in the Federal Register
There is insufficient information to permit a reasoned evaluation of risk from the substance or significant new use	EPA must issue an order under section 5(e)
The substance is or will be produced in substantial quantities and there may be significant or substantial human and/or environmental exposure (exposure based).	EPA must issue an order under section 5(e)
In the absence of sufficient information to permit a reasoned evaluation of risk from the substance or significant new use, the substance or significant new use may present unreasonable risk	EPA must issue an order under section 5(e)
The substance or significant new use presents an unreasonable risk	EPA must take action under section 5(f)

*From EPA PFAS Framework webinar (September 6, 2023)

§ 5(e) Orders (1)

- If the Administrator determines that—
  - (i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); ~~and~~ or
  - (ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use; or
  - (II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

§ 5(e) Orders (2)

- The Administrator ~~may~~ shall issue ~~a proposed~~ an order, to take effect on the expiration of the ~~notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c)~~ applicable review period, to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, and the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, including while any required information is being developed, only in compliance with the order.

§ 5(h) Exemptions

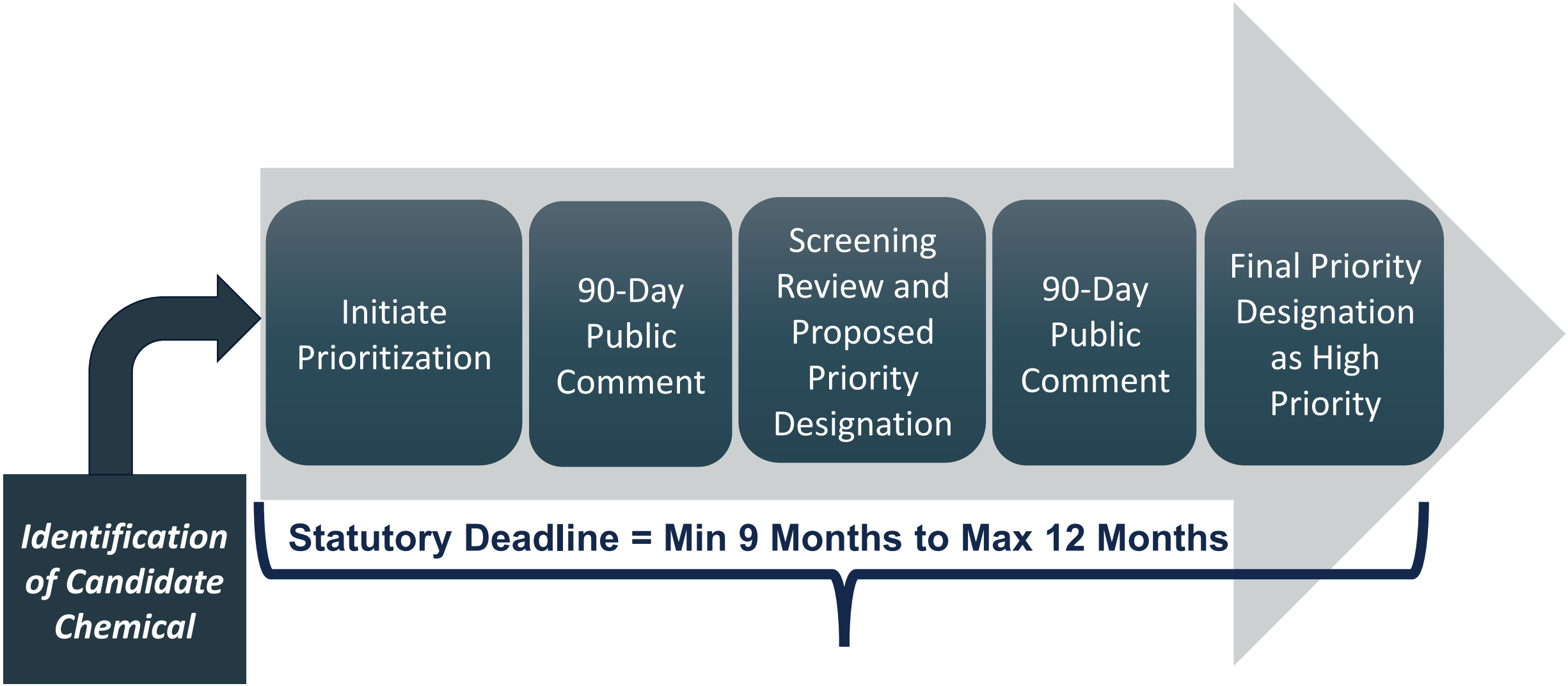
- 5(h)(1): Test marketing (discretionary)
- 5(h)(3): R&D (mandatory)
- 5(h)(4): Additional exemptions by rule
  - "…if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, ***will not present an unreasonable risk of injury*** to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use."
- 5(h)(5): Temporary substances, e.g., non-isolated intermediates (discretionary)

§ 18 Preemption

- Information Development Preemption (§§ 4, 5(e), or 6)
- Safety Finding Preemption (§ 6)
- Risk Management Preemption (§ 6)
- Notification Preemption (§ 5 SNUR)
- Pause Preemption (§ 6)

Process for Regulating Existing Chemicals

Prioritization Process



Section 8

- 8(a) – PAIR, CDR, *etc*.
- 8(b) – Inventory, reset, *etc*.
- 8(c) – Allegations of significant adverse reactions
- 8(d) – Unpublished H&S studies
- 8(e) – Submission of substantial risk information

Section 8(a)

- Statute requires reports/records "*only to the extent … necessary*"
- Statute should exempt export-only substances from at least some requirements
  - *E.g.*, CDR
  - See section 12 discussion

Section 8(b) (1)

- *(b) Inventory*
- *(1) The Administrator shall compile, keep current, and publish a list of each … substance … manufactured or processed in the United States.*
  - Not later than one year after [enactment], the Administrator shall promulgate rules to require the Administrator to receive, and approve or deny, requests to correct the specific chemical name of any chemical substance appearing on the list compiled under subsection (b)(1)
    - The Administrator shall approve or deny any such request within [120] days
      - If a request is approved, the corrected chemical name shall be deemed to appear on the list compiled under subsection (b)(1) as of the date the chemical substance was first added to the list compiled under subsection (b)(1) under any chemical name

Section 8(b) (2)

- Under subparagraph (3)(A) - in carrying out paragraph (1) (compilation of Inventory), the Administrator shall—
- (ii) "…maintain the use of the Soap and Detergent Association Nomenclature System"
  - Should be clarified/strengthened to apply to new chemicals
- (iii) "…treat the individual members of the categories…identified…as statutory mixtures, as defined in Inventory descriptions established by the Administrator, as being included on the [Inventory]…"
  - *Ahem*, what does this mean…?

Section 8(c), 8(d)

- Section 8(c)
  - Records of reactions “to the health of employees” must be retained for 30 years
    - Many persons are “employees”
- Section 8(d)
  - Ok…

Section 8(e)

- **§ 8(e) "guidance":**
  - March 16, 1978 "Statement of Interpretation and Enforcement Policy"
  - 1991 "Section 8(e) Reporting Guide"
  - July 13, 1993 proposed amendments
  - March 9, 1995 draft text
  - EPA § 8(e) "Status Reports"
  - June 3, 2003 FR notice
  - January 12, 2005 "corrections"
  - September 2006 "Frequent Questions"
- Administrator shall promulgate rules implementing this subsection [through a notice-and-comment rulemaking process]

Section 12(a) – Export-Only

- Should apply to certain § 8(a) rules
  - *E.g.*, CDR

Section 12(b) – Export Notification

- ~~***(b) Notice***~~
- ~~*"…(1) If any person exports or intends to export to a foreign country a chemical substance or mixture for which the submission of information is required under section 2603 or 2604(b) of this title, such person shall notify the Administrator of such exportation…"*~~
- Alternatively – "one-and-done" system

Please join us at 10:00 AM Eastern U.S.
Wednesday, October 11, 2023
https://www.khlaw.com/REACH-3030

Please join us at 1:00 PM Eastern U.S.
Wednesday, October 11, 2023
https://www.khlaw.com/TSCA-3030

Please join us at 1:00 PM Eastern U.S.
Wednesday, October 18, 2023
https://www.khlaw.com/OSHA3030

Keller and Heckman is hosting the seminar,
Navigating TSCA: Basics and Beyond on November 1-2, 2023, in Washington, DC!

More information at:

https://www.khlaw.com/events/navigating-tsca-basics-and-beyond-2023

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Thank You

Any questions?

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