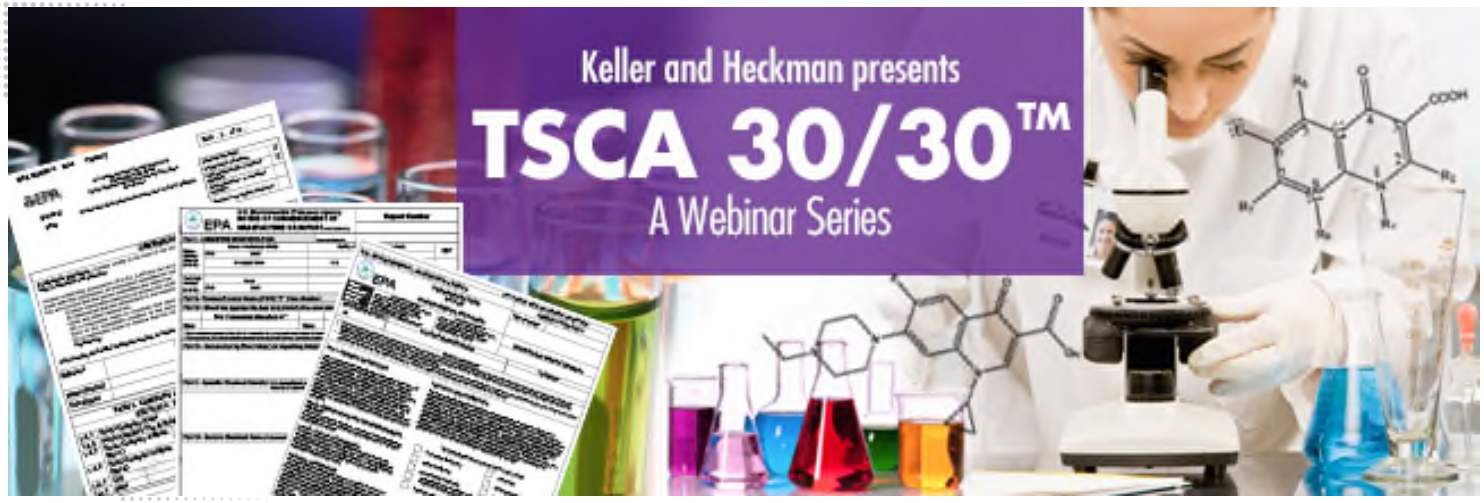


Section 8(d) Reporting Rule for High-priority Chemicals and Section 8(a) Proposal for PFAS Chemicals
July 14, 2021

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.

James Votaw

- James Votaw has an extensive practice focusing on environmental and health and safety regulation. Within that arena, he concentrates on the regulation of conventional and nanoscale chemicals, pesticides, consumer and industrial products, and industrial processes and wastes.

- For his clients, James obtains pre-market product approvals and exemptions, including the first U.S. approval of a nanoscale pesticide. He negotiates testing orders, defends enforcement actions, advises on restrictions and disclosures associated with the chemical content of products, counsels on release and other environmental reporting, and supports environmental regulatory and liability aspects of commercial transactions (including, but not limited to regulatory due diligence and private label distribution arrangements).Further, he participates in technical rulemaking proceedings, provides strategic and regulatory compliance counseling within existing and emerging industries, initiates compliance training, conducts internal investigations, performs compliance auditing, offers facility permitting services and develops product compliance plans and systems.

- James represents clients before State and Federal regulatory agencies and federal courts. He has extensive experience in compliance counseling on matters related to the Toxic Substances Control Act (TSCA); the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); the Clean Air (CAA) and Clean Water Acts (CWA); the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA); the Consumer Product Safety Commission (CPSC); California's Proposition 65; Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH); Restriction of Hazardous Substances (RoHS); and Waste Electrical and Electronics Equipment (WEEE).

- 8(d) Reporting of Unpublished Health and Safety Studies
- 8(a) Reporting on PFAS

Final TSCA § 8(d) Reporting Rule

- Federal Register June 29, 2021 (86 FR 34,147); automatic reporting for ITC-listed substances and mixtures
- Requires manufacturers (including importers) of 50 specified chemicals to report lists and copies of unpublished health and safety studies to EPA
- Chemicals subject to the rule consist of the 20 High-Priority Substances for Risk Eval and the 30 organohalogen flame retardants of interest to the CPSC
- Final rule is effective July 29, 2021; reporting period July 29-Sept 27, 2021
- Request to withdraw a chemical from the final rule for good cause must have been received on or before July 13, 2021

Health and Safety Studies and Exemptions

- The term "health and safety study" is **broadly interpreted** to mean any study of any effect of a chemical substance or mixture on health or the environment or both, including underlying data and **epidemiological studies**, studies of **occupational exposure**, toxicological, clinical, and **ecological,** or other studies including data on chemical and physical properties
- Trade Associations can submit the H&S studies
- Exempt H&S Studies
  - Studies published in the scientific literature
  - Certain studies previously submitted to the EPA OCSP. Limited to section 8(e) submissions, studies submitted during section 4 proceedings, studies submitted with premanufacture notices or significant new use notices, and studies submitted "for your information" (FYI submissions)
- Studies which have been initiated pursuant to a TSCA section 4(a) test rule, for which the person has submitted a letter of intent to conduct testing, are exempt from the list submission requirements

More Exemptions

- Studies previously submitted to any Federal agency with no claims of confidentiality are **exempt only from the copy submission requirements**, and must be listed
- Physchem and acute tox studies on mixtures
- Studies on substances that the person who is reporting has manufactured, imported, or processed or proposed to manufacture, import, or process **only as an impurity**
- **Analyzed aggregations of monitoring data** based on monitoring data acquired **more than five years** preceding July 29, 2021
- **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**
- See Q&A on reportability of monitoring data at https://www.complywithtsca.com/TSCAOnline/pdfs/vol1/chapterE/ChEdoc3.pdf

Who and What Needs to Be Reported

- Chemical manufacturers (including importers), (NAICS codes 325 (manufacturing) and 324110 (petroleum refineries)
- All persons or entities who, in the previous 10 years or presently, have either proposed to manufacture (including import) or have manufactured (including import) a listed chemical substance—even if that person or entity no longer does so
- § **716.25 Adequate file search –** Limited to records in the location(s) where the required information is typically kept and to records kept by the person or the person's individual employee(s) who is/are responsible for keeping such records or advising the person on the health and environmental effects of chemicals
- Persons are not required to search for reportable information dated before January 1, 1977

What Needs to be Reported (2)

- A **copy** of each health and safety study in their **possession**
- A **list** of the health and safety studies known to them, but **not in their possession**
- A **list** of the health and safety studies that are **ongoing and are conducted by or for them**
- A **list** of the health and safety studies that will be **initiated and will be conducted by or for them**
- A **copy** of each health and safety study **listed as ongoing or subsequently initiated, regardless of completion date**

TSCA Reporting by Per – and Polyfluoroalkyl Substance (PFAS) Manufacturers and Importers

TSCA § 8(a) Reporting for PFAS

- 2020 National Defense Authorization Act added a new subsection to TSCA: §8(a)(7)
- Requires extensive reporting by any person importing or manufacturing a "PFAS" since 2011:

  PFAS DATA – Not later than January 1, 2023, the Administrator shall promulgate a rule in accordance with this subsection requiring each person who has manufactured a chemical substance that is a perfluoroalkyl or polyfluoroalkyl substance in any year since January 1, 2011, to submit to the Administrator a report that includes, for each year since January 1, 2011, the information described in subparagraphs (A) through (G) of paragraph (2)
- Deadline: Final rule due January 2023; no statutory deadline for company reporting

EPA's Proposed PFAS Reporting Regulation

- Federal Register June 28, 2021 [86 FR 33,926] – *comments due Aug. 27*
- All manufacturers and importers of any "PFAS" substance to report on a wide range of endpoints
- **35+** individual data points, per chemical, per site, per year, for 10+ years (CDR-style reporting (format)
- Purpose of Collection:
  - Meet the new TSCA statutory requirement to collect
  - May be useful for TSCA decision-making; also SDWA, RCRA, CERCLA

Information Reporting Categories

A. Chemical Identity and Trade Name

B. Categories of Use

C. Amounts Manufactured or Processed, by Use and by Year

D. Description of Byproducts from Manufacture, Processing, Use, or Disposal

E. All Existing Environmental And Health Effects Information

F. Number of Workers Exposed and the Duration of Exposure

G. The Manner or Method of its Disposal

EPA Defines Reportable PFAS Very Broadly

- Any chemical substance or mixture that structurally contains the unit:

  R-(CF2)-C(F)(R')R'' WHERE BOTH THE CF2 AND CF MOIETIES ARE SATURATED CARBONS. NONE OF THE R GROUPS (R, R' OR R'') CAN BE HYDROGEN.

- Alkyl carbons on which the hydrogen atoms have been partially or completely replaced by fluorine atoms
- Class of reportable chemicals is defined by structure, *not by risk*
- Includes:
  - Long chain perfluoroalkyl substances regulated by TSCA SNURs (7-20 carbons)
  - Shorter chain perfluoroalkyls (< 6 carbons)
  - Essentially all fluoropolymers (large molecules; > 20 carbons)
- **Affects a wide range of products**: Considering only fluoropolymers, importers of an enormous range of products may be affected, including nearly all electronic devices, many fuel cells, hoses and gaskets, chemical and weather resistant coatings, container linings, piping, vessels, fluid-handling components, filters, vents, cable coatings, and water, heat and chemical resistant textiles

No TSCA Reporting Exemptions for PFAS

- No § 8(a)(1) small business exemption (!)
- No *de minimis* volume/concentration exemption
- No typical TSCA reporting exemptions for manufacturers and importers of:
  - Articles (e.g., components or coatings)
  - Impurities
  - Byproducts or wastes
  - Materials not on the TSCA Inventory
  - LVE, Test Marketing, LoRex, R&D materials
  - Non-isolated intermediates
  - Reactions incidental to use (e.g., curing)
  - Reactions incidental to storage or disposal
  - Reactions incidental to exposure to another substance, mixture or article, or to the environment (air, UV, etc.)

TSCA § 8 Due Diligence Standard

- Companies obligated to report to the extent the information is "**known or reasonably ascertainable**"
  - the CDR standard; CDR guidance will apply
- Information in company's possession or control or that a reasonable person similarly situated might be expected to possess, control, or know; e.g.,
  - A reasonable inquiry within the full scope of the organization, limited to those persons and files reasonably expected to contain responsive information
  - Available from **email/phone to upstream suppliers or downstream users** to fill gaps in knowledge
- The duty to inquire up and down the supply chain will involve many more companies and significantly expand the investigation and response time

Minimal Effort to Minimize Reporting Burden

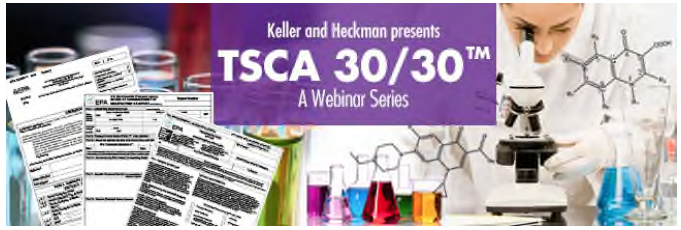
- New § 8(a)(7): "[EPA] shall promulgate a [PFAS] rule *in accordance with this subsection*" (i.e., §8(a))
- § 8(a)(5): To the extent feasible, EPA must tailor §8 rules to:
  - Avoid reporting this is unnecessary
  - Avoid reporting that is duplicative
  - Minimize compliance cost to small businesses
  - Apply reporting to obligations to those likely to have information relevant to implementing TSCA
- Proposed rule considers only possible duplication of past reporting (e.g., CDR)
  - Does not consider duplicative nature of the proposed reporting itself (e.g., 100 reports of the same published study)
  - Does not assess whether the information sought is necessary for its use
  - Does not tailor reporting to focus on sources most relevant to TSCA missions

Opportunities for Public Input

- **Comments to the OMB by July 28**: The Paperwork Reduction Act (ICR):
  - Focus on due regard for necessity for collecting the specific information sought (35+ endpoints) in light of EPA's limited purpose, avoidable duplication, compliance with law, impact on small business, and the sufficiency of EPA's estimates of the steps involved in achieving compliance, the necessary time involved at each step
- **Comments to EPA by August 27**:
  - Same topics as at OMB
  - Reasonable alternatives to avoid undue burden, duplication and burdening those not likely to have useful information, e.g.,
    1. Tiering reporting – most significant information sources first
    2. Recognize small business exemption, typical TSCA exemptions for incidental manufacture, articles, etc.
    3. Exclude polymers (large molecules, as in SNUR)
    4. Tailor information endpoints with actual data needs

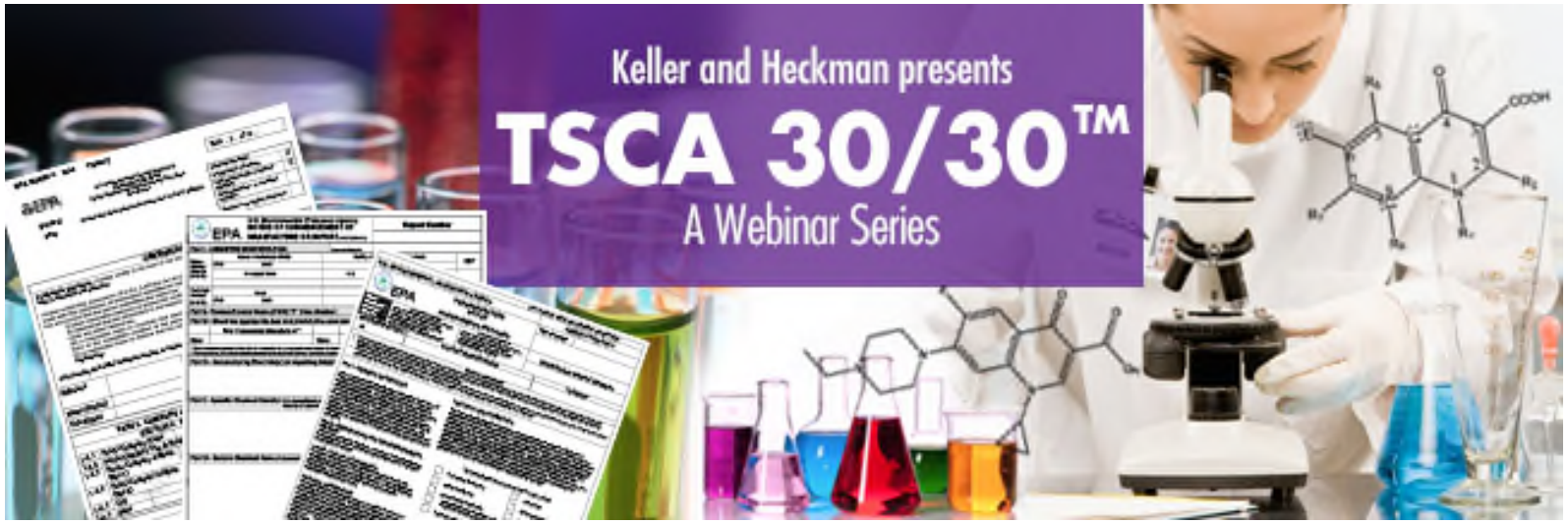
Final Thoughts

Please join us at 1:35 PM Eastern U.S.
Wednesday, July 14, 2021
www.khlaw.com/REACH-3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, August 18, 2021
www.khlaw.com/TSCA-3030

Please join us at 1:00 PM Eastern U.S.
Wednesday, July 21, 2021
www.khlaw.com/OSHA3030



Keller & Heckman

The Next TSCA 30/30:
Wednesday, August 18, 2021

For more information on past and future **TSCA 30/30** programs, please visit **www.khlaw.com/tsca3030** and **www.TSCAReformCenter.com** for the most up-to-date TSCA news

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