



EPA's Final Rule to Require Reporting of PFAS Data Under TSCA

October 11, 2023

Herb Estreicher
Partner

Washington, DC

+1 202.434.4334

estreicher@khlaw.com

Gregory A. Clark
Partner

Washington, DC

+1 202.434.4302

clarkg@khlaw.com

James G. Votaw
Partner

Washington, DC

+1 202.434.4227

votaw@khlaw.com

David B. Fischer
Counsel

Washington, DC

+1 202.434.4224

fischer@khlaw.com

Legal Disclaimer



This presentation provides information about the law. Legal information is not the same as legal advice, which involves the application of law to an individual's specific circumstances. The interpretation and application of the law to an individual's specific circumstance depends on many factors. This presentation is not intended to provide legal advice.

The information provided in this presentation is drawn entirely from public information. The views expressed in this presentation are the authors' alone and not those of the authors' clients.

Gregory A. Clark

- ◆ Gregory (Greg) Clark counsels clients on regulatory and environmental issues, focusing on the Toxic Substances Control Act (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.



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.



James G. Votaw

- ◆ James Votaw has an extensive practice focusing on environmental and health and safety regulation, concentrating on regulating chemicals, pesticides, consumer and industrial products, and industrial processes and wastes.
- ◆ James obtains pre-market product approvals and exemptions for his clients, 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 TSCA, the Federal Insecticide, FIFRA, CAA, and CWA.



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 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.



Rule Overview (1)

- ◆ Applies to all manufacturers or importers of a **PFAS*** at any time from 2011 to 2022
 - ◆ **As defined in the rule*
 - ◆ Covers 1,462+ PFAS
 - ◆ Neat, mixtures, articles, impurities, byproducts
- ◆ **Dozens** of data elements, per chemical, per site, per year
- ◆ Mandated by Congress
- ◆ Estimated cost to industry: **\$843 million**

Rule Overview (2)

- ◆ Scope includes fluoropolymers
- ◆ Under EPA's 8(a) authority
- ◆ One-year "information collection" period
- ◆ Six-month reporting period (Nov. 12, 2024 - May 8, 2025)
 - ◇ 12 months for certain small article importers (to Nov. 10, 2025)
- ◆ Joint submissions
- ◆ CBI substantiation burdens

Rule Overview (3) – Required Information



- ◆ Company and plant site information
 - ◇ Parent company
 - ◇ Authorized official
 - ◇ Technical contact
 - ◇ Company name, address, NAICS code
- ◆ Substance information
 - ◇ Common or trade name
 - ◇ Chemical identity (CA Index name and CASRN, Accession No., LVE No.)
 - ◇ Representative molecular structure (if not Class-1)
 - ◇ Physical form

Rule Overview (4) – Required Information



- ◆ Categories of use
 - ◇ Type of industrial processing or use
 - ◇ Industrial sector (e.g., paper manufacturing, petroleum refineries)
 - ◇ Industrial function categories (e.g., surfactant, flux agent)
 - ◇ Consumer and commercial product categories (e.g., textile finishing, solder)
 - ◇ Consumer and commercial function categories (e.g., surfactant, flux agent)
 - ◇ Whether consumer or commercial
 - ◇ If consumer product(s), whether intended for use by children age 14 or younger
 - ◇ Maximum concentration of the PFAS (range)

Rule Overview (5) – Required Information



- ◆ Manufactured amounts
 - ◆ Volume manufactured or imported
 - ◆ Presence at site
 - ◆ Volume exported
 - ◆ Percentage of production for each industrial category of use
 - ◆ Percentage of production for each consumer and commercial product category
 - ◆ Whether site-limited
 - ◆ Volume recycled
- ◆ Byproducts resulting from the manufacture, processing, use, or disposal of each PFAS
 - ◆ Identity, volume, and releases to the environment

Rule Overview (6) – Required Information



- ◆ Environmental and health effects
 - ◇ All existing information in manufacturer's possession or control
 - ◇ Must submit an OECD Harmonized Template
 - ◇ Preliminary studies with human health data
 - ◇ Identify analytical or test methods used to detect the PFAS
- ◆ Worker exposure data
 - ◇ Number of workers and duration of exposure
 - ◇ Activities
 - ◇ If a commercial product, information on commercial workers required
- ◆ Disposal
 - ◇ Methods and volumes

Rule Overview (7) – Reduced Reporting

- ◆ *No small business exemption*
- ◆ *No de minimis threshold*
- ◆ Certain imported MSW streams
- ◆ Duplicative reporting (CDR, 8(d), 8(e), GHG Reporting, TRI)
- ◆ Streamlined reporting form available for:
 - ◆ Articles
 - ◆ R&D substances <10 kg/year



PFAS Definition



Proposed Rule Definition

- ◆ Defined PFAS as a substance that includes the following structure: $R-(CF_2)-C(F)(R')R''$, where both the CF_2 and CF groups are saturated carbons and none of the R groups (R , R' , or R'') can be hydrogen
- ◆ EPA found that at least 1,364 substances from both the TSCA Inventory (Inventory) and Low-Volume Exemption (LVE) list would meet the proposed structural definition
- ◆ Separately, a count of chemicals meeting the proposed definition on EPA's CompTox Chemicals Dashboard found approximately 9,400 structures

Final Rule Definition

- ◆ PFAS is defined as including at least one of these three structures:
 - ◇ $R-(CF_2)-CF(R')R''$, where both the CF_2 and CF moieties are saturated carbons;
 - ◇ $R-CF_2OCF_2-R'$, where R and R' can either be F , O , or saturated carbons; and
 - ◇ $CF_3C(CF_3)R'R''$, where R' and R'' can either be F or saturated carbons
- ◆ EPA will provide a list of substances that meet this definition, gathered from the Inventory, LVEs, and the CompTox Chemicals Dashboard <https://comptox.epa.gov/dashboard>
- ◆ A substance not on this list but still falling under the definition of a “chemical substance” under TSCA is subject to this rule if the substance has been manufactured or imported for a commercial purpose since 2011

What Changed? (1)

- ◆ EPA modified the proposed definition allow the R groups to be hydrogen
- ◆ This includes substances that are only “lightly” fluorinated (i.e., the molecule only contains unconnected CF₂ or CF₃ moieties)
- ◆ The final definition does not include substances that only have a single fluorinated carbon, or unsaturated fluorinated moieties (e.g., fluorinated aromatic rings and olefins)
- ◆ The second sub-structure (RCF₂OCF₂-R', where R and R' can either be F, O, or saturated carbons) aims to capture certain fluorinated ethers

What Changed? (2)

- ◆ The second sub-structure ($\text{RCF}_2\text{OCF}_2\text{-R}'$, where R and R' can either be F, O, or saturated carbons) aims to capture certain fluorinated ethers
- ◆ EPA believes that these ethers are likely to be found in water; for example, PFMOAA (CASRN 674-13-5) and other chemicals with structures similar to GenX
- ◆ The third sub-structure ($\text{CF}_3\text{C}(\text{CF}_3)\text{R}'\text{R}''$, where R' and R'' can either be F or saturated carbons) aims to capture a different type of branching for highly fluorinated substances that would not meet the proposed definition due to their non-adjacent fluorinated carbons

U.S. State and EU PFAS Definitions

- ◆ Any substance that contains at least one fully fluorinated methyl
- ◆ (CF₃-) or methylene (-CF₂-) carbon atom (without any H/Cl/Br/I attached to it)
- ◆ The EU definition has a few exceptions

Articles

- ◆ In the final rule, EPA asserts its authority to collect information on certain PFAS that are manufactured through articles
- ◆ EPA notes, in particular, that TSCA “does not define ‘chemical substance’ to exclude articles.”
 - ◇ “[T]here is no definitional distinction for a chemical substance depending on whether it is incorporated into an article; nothing says that an ‘article’ is exclusive or distinct from a ‘chemical substance.’”
- ◆ Manufacture = “to import into the customs territory of the United States [...] produce, or manufacture for commercial purposes.” (40 CFR 705.3)
 - ◇ EPA clarifies that the rule **does not apply** to you if you “solely process, distribute, and/or use PFAS, and do not manufacture (including import) PFAS for a commercial purpose.”

Articles (1)

- ◆ 40 CFR section 704.3 (emphasis added)
 - ◇ *Article* means a manufactured item
 - (1) which is formed to a specific shape or design during manufacture,
 - (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and
 - (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles;
except that fluids and particles are not considered articles regardless of shape or design.

Articles (2)

- ◆ Accommodations for article importers:
 - ◆ Reference 14 in the final rule provides compliance guidance for small entities and for article importers
 - ◆ Importers have the option to use a shorter, streamlined reporting form, but only “if they do not know nor can reasonably ascertain information requested” in the longer form
 - “EPA is not requiring or enabling joint submissions for article importers when they do not know the CAS name, CASRN, Accession number, or LVE number of the PFAS.”

Articles (3)

- ◆ Accommodations for article importers:
 - ◇ EPA will provide guidance on the reporting standard for article importers
 - “EPA also acknowledges that it may not be within the scope of ‘reasonably ascertainable’ to survey all articles and products, especially for article importers.”
 - ◇ Small article importers (as defined in 40 CFR 704.3) have **24 months** following the effective date of the final rule to submit reporting forms



PFAS Reporting: *Investigation Due Diligence Standard*

How Hard Do You Have to Look for Information?

- ◆ **“... to the extent known to or reasonably ascertainable by” submitter**
 - ◇ Both a ‘sword and a shield’
 - ◇ Sets both *minimum* and *maximum* required level of effort
 - ◇ Reporting that requested information is “NKRA” is an *affirmative representation* that the minimum required level of investigation was completed
- ◆ **Critical to understanding the stringency/burden imposed by the rule**
- ◆ **Established by TSCA § 8(a)(2) and addressed in Preamble**
 - ◇ Lots of existing guidance on “NKRA” from other TSCA contexts
 - ◇ Same standard as applicable to CDR, TSCA Inventory Reset, PAIR rules
 - ◇ ‘Small business compliance guide’ reportedly coming to docket

What Information is Considered KRA? (1)

◆ **Two-prong definition:**

1. All information in a person's "possession or control"
2. All information that a reasonable *person similarly situated might be expected* to possess, control, or know" [40 CFR 704.3]

◆ **Includes information ...**

- ◆ In the reporting company's own files (including employee files)
 - Monitoring data, job hazard analysis
 - Marketing studies, sales reports, or customer surveys
 - SDS
- ◆ In commercially available databases to which the person has purchased access
 - Also, standard reference works; available SDS...

What Information is Considered KRA? (2)

- ◆ **Includes information held by *certain* Affiliates and Agents:**
 - ◇ A corporate subsidiary or parent company
 - ◇ A sister corporation controlled by common parent
 - ◇ A partnership in which the person is a general partner
 - ◇ Agents of the company (e.g., brokers, consultants) (files related to submitter)
 - ◇ Includes *foreign* affiliates ! [51 Fed. Reg. 15,096 (1986)]
- ◆ **But - search limited to those affiliates and agents associated with the reporting company in the *R&D or marketing* of the PFAS chemical**

What Information is Considered KRA? (3)



◆ **Extent of required search:**

- ◆ Not just managerial or supervisory employees
- ◆ Reasonable inquiry within *full scope of the organization*
- ◆ Limited to persons reasonably likely to have responsive information, if it exists
- ◆ Search at reporting company *and relevant affiliates*

◆ **Objective standard: as extensive a search as a reasonable person, similarly situated, might be expected to perform**

What Information is Considered KRA? (4)

- ◆ **Uncertainty after investigation is not grounds to claim “NKRA”**
 - ◇ Certification: “All information submitted is true and correct”
 - ◇ Uncertainty alone is not enough to avoid reporting

- ◆ **Rule requires submitting *reasonable estimates (where possible) if actual data unknown***
 - ◇ Based on existing knowledge or past experience and, for example, mass balance equations, emission factors, engineering judgments
 - ◇ E.g., extent of worker exposure; extent of environmental release
 - ◇ Not clear that there will be a way to indicate reported data is estimated, or the basis for the estimate
 - *Potential future compliance and liability concern if submitted estimates are treated as admitted facts*

Are Queries to Customers/Suppliers Required? (1)

- ◆ **Generally, not required to fill data gaps**
- ◆ **Exception: Required when (1) the missing information is information usually possessed by *similarly situated companies* and (2) there is a reasonably likely source of the information**
 - ◇ E.g., Ask vendor for chemical identity of PFAS known to be in a formulation
 - ◇ E.g., Customer “use” information could be obtained by asking one customer (not a wide survey) or looking at the customer’s website
 - ◇ CDR guidance has more examples; more guidance from EPA coming?
- ◆ **The diligence standard requires reporting companies to “ask” in these circumstances, but does not require the reporting company to get the answer**
 - ◇ If the supplier or customer does not provide the information, can internally document the request and report “NKRA”

Are Queries to Customers/Suppliers Required? (2)

- ◆ **Changes in facility ownership during reporting period** – former owner need to ask new owner for old exposure, release, production records?
 - ◇ Generally, no – 2020 CDR guidance addresses the approach
- ◆ **Imported formulations:** If an imported formulation is not known to contain a PFAS, is the importer obligated to ask the supplier whether any are present?
 - ◇ Would similarly situated importers know?
 - ◇ EPA should address in small entity compliance guide

Joint Submissions for Unknown Chemical Identity

- ◆ **The rule *requires* requesting information from a supplier in limited circumstances:**
 1. Where an imported formulation (not article) is known to contain a PFAS, (e.g., a fluoropolymer) and
 2. The specific chemical identity of the PFAS is not known to the importer; and,
 3. A person that would have the information ("Secondary Submitter") is known
- ◆ **Process: CDX system generates an email request to the identified secondary submitter to provide the information directly to EPA**
 - ◇ Not clear that Secondary Submitter has to respond to EPA
 - ◇ Not the primary submitter's responsibility to assure a response
- ◆ **This is only circumstance where the "joint submission" tool can be used**
 - ◇ Cannot be used by importers to determine whether a formulation contains *any PFAS*

Investigation Recordkeeping (1)

- ◆ **Only required to keep records that substantiate the information submitted to EPA**
 - ◇ Factual matters
 - ◇ Basis for estimates
- ◆ **EPA recommends documenting (1) the extent of the overall investigation (sufficient under KRA standard?) and (2) investigations supporting “NKRA” certifications in particular**
 - ◇ EPA encourages [a reporting company] to document its activities to provide evidence of due diligence. Additionally, consistent with their own business practices, companies may elect to retain documentation of their conclusion that they were not subject to reporting requirements. [88 F.R. 70,516, -21 (Oct. 11, 2023)]

Investigation Recordkeeping (2)

- ◆ **BMP: plan the investigation scope and process from the beginning to generate documentation substantiating its sufficiency in all respects (differ by endpoint)**
 - ◆ Look back at “TSCA reset” investigation approach (2017-18)



Keller and Heckman is hosting
Navigating TSCA: Basics and Beyond

on November 1-2, 2023, in
Washington, DC!

View more information at:

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

or [Click Here to Register](#)



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



Please join us at 10:00 AM Eastern U.S.
Wednesday, December 6, 2023
<https://www.khlaw.com/REACH-3030>



Please join us at 1:00 PM Eastern U.S.
Wednesday, December 6, 2023
<https://www.khlaw.com/TSCA-3030>

Thank You

Any questions?



Gregory A. Clark
Partner

Washington, DC
+1 202.434.4302
clarkg@khlaw.com

James G. Votaw
Partner

Washington, DC
+1 202.434.4227
votaw@khlaw.com



Herb Estreicher
Partner

Washington, DC
+1 202.434.4334
estreicher@khlaw.com

David B. Fischer
Counsel

Washington, DC
+1 202.434.4224
fischer@khlaw.com

