



TSCA Litigation Update – CBI Cases and EPA’s Appeal of the Water Fluoridation Case

August 13, 2025

Herb Estreicher

Partner

Washington, DC

202.434.4334

estreicher@khlaw.com

Allison Payne

Associate

Washington, DC

202.434.4484

payne@khlaw.com



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 US 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 US-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.



Allison Payne

- ◆ Allison Payne is an environmental law associate at Keller and Heckman focusing on regulatory and compliance matters under FIFRA, TSCA, and EPCRA. Prior to joining Keller and Heckman, Allison served as an attorney-advisor within the Pesticides and Toxic Substances Law Office for the U.S. Environmental Protection Agency's Office of General Counsel, where she advised EPA program offices on a wide variety of matters under chemical and pesticide laws.



CBI Litigation

CBI Statistics (1)

| CBI Review Statistics (cases received between June 22, 2016, and January 3, 2025) | |
|---|---------------|
| Cases in which the specific chemical identity is subject to CBI review | 9,660 |
| Cases in which information other than the specific chemical identity is subject to CBI review | 12,516 |
| Cases in which both the specific chemical identity and information other than the specific chemical identity is subject to CBI review | 2,479 |
| Total cases subject to CBI review | 24,655 |

CBI Statistics (2)

| Cases resulting in final CBI determinations | |
|--|---------------|
| Cases with all CBI claims subject to review, approved | 6,346 |
| Cases with all CBI claims subject to review, denied | 2,890 |
| Cases with CBI claims subject to review, approved-in-part/denied-in-part | 1,051 |
| Total cases resulting in final CBI determinations | 10,287 |

CBI Statistics (3)

| Cases reviewed with no final CBI determination necessary | |
|--|--------------|
| Cases with all CBI claims screened and found to be exempt from review | 3,334 |
| Cases with all CBI claims withdrawn by submitter | 571 |
| Cases identified for CBI review, for which no determination required (e.g., in some instances, older EPA information systems do not specifically identify which information is claimed as CBI and upon review, it is determined that no claims require review) | 2,198 |
| Total cases reviewed/screened with no final CBI determination necessary | 6,103 |

EPA Denial of CBI Claims

- ◆ Where EPA determines that a claim or part of a claim is not entitled to confidential treatment, EPA will provide notice of the denial to the person who made the claim and provide the reasons.
- ◆ EPA will disclose the information on the next business day following 30 days from the date the notice is made available to the submitter in their CDX account unless an appeal is brought.

Action to Restrain Disclosure

- ◆ Before the date on which the information is to be disclosed an aggrieved person may bring an action to restrain disclosure of the information in—
 - ◇ the United States district court of the district in which the complainant resides or has the principal place of business; or
 - ◇ the United States District Court for the District of Columbia.
- ◆ EPA will not disclose information that is the subject of an appeal until the court rules, with limited special exception.

Burgess Pigment Co. v. EPA

- ◆ *Burgess Pigment Co. v. EPA* filed in the U.S. District Court for the Middle District of Georgia
- ◆ First appeal of an EPA rejection of a CBI claim.
- ◆ Involved a claim asserted in connection with the 2016 CDR for the specific chemical identity of substances used to make “Kaolite Crudes,” a specialized kaolin for servicing specialty coating, plastics, rubber, and cement markets.
- ◆ EPA denied the CBI claim in 2020 because another company did not assert a CBI claim for the specific chemical identity in the 2016 CDR.
- ◆ The Company asserted that no other company disclosed the identity.
- ◆ In 2025 EPA raised a new ground for denial– failure to assert a CBI claim during the TSCA Inventory Reset.

Right to a Jury Trial in Civil Penalty Cases

SEC v. Jarkesy and Progeny

- ◆ The Supreme Court held that the Seventh Amendment entitles a defendant to a jury trial when the SEC seeks civil penalties for securities fraud.
- ◆ Some post-Jarkesy courts have required plaintiff's to exhaust the ALJ process, appeal an adverse decision to the US Court of Appeals, and then ask the Appellate Court to order a jury trial at the District Court level.

Wolferic, LLC v. FDA (N.D. Texas, Western Div.)



- ◆ Constitutional right to a jury trial in civil penalty cases unless a narrow public rights exemption applies.
- ◆ An agency acting in the public interest does not necessarily qualify for the public rights exemption.
- ◆ If upheld could eviscerate the ALJ adjudication process for civil penalty complaints.

Meaning of “*De Novo Proceeding*” Following Challenge of EPA Denial of TSCA §21 petition

TSCA §21 Citizens' Petitions Provision

- ◆ If EPA denies a §21 petition, petitioner can file suit in U.S. district court
- ◆ Petitioner is provided the opportunity to have ***such petition*** considered by the court in a ***de novo proceeding***
- ◆ If petition concerns a request for EPA to initiate a rule under §6(a), court will order EPA to act if petitioner shows by a preponderance of the evidence, substance presents unreasonable risk

FWW, et al. v. EPA (U.S. 9th Cir.) (1)

- ◆ EPA appeal of N.D. Cal. decision
- ◆ Court conducted two bench trials, considered evidence published after FWW petition
- ◆ Judge Chen found petitioners demonstrated artificially fluorinated water presents unreasonable risk, ordered EPA to issue TSCA §6(a) rule addressing risk

FWW, et al. v. EPA (U.S. 9th Cir.) (2)

- ◆ Issues before the 9th Circuit:
 - ◇ Whether plaintiffs properly established standing
 - ◇ Whether the court violated TSCA §21 by ruling on an evidentiary record different from that of the petition reviewed by EPA
 - ◇ Whether the court violated the party presentation principle
- ◆ Appeal concerns the meaning of “de novo proceeding” and “such petition” in TSCA §21(b)(4)(B)

EPA's Arguments

- ◆ The use of “such petition” in TSCA §21 limits a plaintiff to presenting facts, evidence presented **by the petition** in district court proceeding
- ◆ TSCA §21 “exhaustion requirement” means a court should decline to overturn EPA denial unless plaintiff raised relevant issues in petition before EPA
- ◆ “De novo proceeding” in TSCA §21 means a fresh proceeding that does not defer to EPA’s findings (not a continued investigation by the court)

Upcoming Events



Please join us at 10:00 AM Eastern U.S.
Wednesday, 27 August 2025

www.khlaw.com/REACH-3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, August 20, 2025

www.khlaw.com/OSHA3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, October 1, 2025

www.khlaw.com/TSCA-3030

Thank You

Any questions?



Herb Estreicher
Partner

Washington, DC
+1 202.434.4334
estreicher@khlaw.com



Allison Payne
Associate

Washington, DC
+1 202.434.4484
payne@khlaw.com

