



# CBI in the Crosshairs

February 25, 2026

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# Thomas C. Berger

- ◆ Thomas (Tom) Berger’s practice is based on an in-depth understanding of and experience with the chemicals, plastics, and electronics industries. As a preeminent practitioner with over 30 years of experience, Tom helps clients commercialize new chemical products and preserve supply chains for existing chemical products utilizing an interdisciplinary team approach combining law and science, with an emphasis on emerging technologies in the industrial and consumer chemicals areas.
- ◆ Tom’s practice focuses almost exclusively on the Toxic Substances Control Act (TSCA). Tom leads clients through the TSCA section 5 premanufacture notification (PMN) approval process and negotiates the terms of resulting section 5(e) orders and significant new use rules (SNURs). He provides counsel to clients on major U.S. Environmental Protection Agency (EPA) enforcement matters, assists companies in preparing for compliance inspections and responding to information requests and subpoenas, and defends Agency enforcement actions.
- ◆ As an active member of the environmental and chemical industries and legal community, Tom was extensively involved in efforts to “reform” TSCA, and has in-depth and day-to-day experience with all aspects of TSCA, including rulemaking/advocacy, test rule/order, section 5 PMN, TSCA Inventory, Chemical Data Reporting (CDR), and section 6, as well as confidential business information (CBI), section 8 recordkeeping and reporting, and import/export issues.
- ◆ Tom is a recognized leader in conducting extensive voluntary TSCA compliance audits, often conducted as part of corporate mergers or acquisitions. Since its inception in 1995, Tom has assisted hundreds of clients successfully utilize EPA’s “Audit Policy” (as well as the “New Owner Policy”) to disclose and obtain up to 100% gravity-based monetary penalty mitigation for a wide variety of TSCA violations.



# Herbert Estreicher, Ph.D.

- ◆ Herbert (Herb) Estreicher, Ph.D., has a broad practice in international environmental regulatory law, representing leading manufacturers of chemicals, pesticides, and consumer products. Clients in the chemical, nanotechnology, and biotechnology industries seek his in-depth legal and scientific knowledge of organic chemistry, risk assessment, and bioengineering stemming from his dual degrees – a Ph.D. in Chemistry and a J.D.
- ◆ Herb is recognized as a leading chemical regulations attorney with a particular emphasis on the Toxic Substances Control Act (TSCA), including EPA’s implementation of the 2016 Lautenberg Amendments, and is one of the few United States (U.S.)-based lawyers with extensive knowledge of the European Union (EU) Registration, Evaluation and Authorization of Chemicals (REACH) regulation. In this capacity, he 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 counsels clients on product liability risk control and assists 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, advises clients on matters involving the Canadian Environmental Protection Act and on European chemical directives such as the REACH regulation, the Classification, Labelling and Packaging (CLP) regulation, and the Biocidal Products Regulation (BPR). He also represents clients in matters involving the Stockholm Convention on persistent organic pollutants (POPs) and has participated in the Canadian Strategic Options Process (SOP). In addition, he counsels clients on matters concerning sustainability and the circular economy.



# CBI Litigation

- ◆ NGOs have filed a number of lawsuits in an attempt to erode TSCA CBI protections in the name of the need for increased transparency.
- ◆ So far, the Courts have upheld the strong congressional mandate to preserve legitimate and documented CBI.

# EDF et al. v EPA Administrator (D.Ct DC, filed in 2020)

- ◆ One of earliest cases, EDF et al. v EPA Administrator filed in 2020 appears to be coming to a head.
- ◆ In that case the NGOs allege:
  - EPA does not timely notify the public when it receives a PMN, and the belated notices EPA provides are incomplete.
  - EPA fails to make the public files available online at [regulations.gov](https://www.regulations.gov).
  - EPA fails to turn over documents that must be in the public file.
  - EPA hides information from health and safety studies, including safety data sheets.

# More NGO Allegations and Prayer for Relief

- ◆ EPA also hides other information relevant to the potential risks presented by new chemicals.
- ◆ EPA withholds other information that does not meet the statutory standard for protection as confidential.

# Release of Unredacted PMNs Under Protective Order

- ◆ The NGOs have asked the Court to Order EPA to turn over several hundred unredacted PMNs and several thousand unredacted PMN attachments they claim will prove their case.
- ◆ On December 24, 2025, the Judge ordered EPA to turn over the unredacted PMNs and attachments by March 23, 2026.
- ◆ The Judge issued a Protective Order.

# What the Protective Order Accomplishes

- ◆ Disclosure of Protected Information (CBI and Copyrighted material) in the course of the case to persons other than EPA is not a waiver of any claim of confidentiality or a public disclosure of such information.
- ◆ No document containing or otherwise disclosing CBI shall be publicly filed with the Court.
- ◆ CBI shall be submitted to the Court only under seal.

# More Protective Order Terms

- ◆ Two sets of written pleadings/briefs needed (one sealed, one redacted) and all pages that include CBI to be filed only under seal.
- ◆ CBI discussed only in closed hearings
- ◆ CBI shall be received by and held in strict confidence by the Plaintiffs and their outside counsel.
- ◆ Any documents containing CBI produced to Plaintiffs to be returned to EPA or destroyed by counsel of record for Plaintiffs within 90 days of the conclusion of the case.

# EPA Notice to PMN Submitters

- ◆ On January 23, 2026, EPA notified the PMN submitters that they would release the unredacted PMNs.
- ◆ The notice advised of the right to bring a court challenge within 30 days of receiving the Notice.

# TSCA Section 14(e)

- ◆ Unless a claim is withdrawn or EPA becomes aware that the information does not qualify for protection ... The Administrator shall protect from disclosure information . . . for a period of **10 years from the date ... the person asserts the claim**
- ◆ Other than §14(c)(2), not later than ... **60 days** before the expiration of the [10 year period], the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period
- ◆ Not later than ... **30 days** before the expiration of the [10 year period], a person reasserting the relevant claim shall submit to the Administrator a request for extension substantiating ... the need to extend the period
- ◆ **Not later than** ... expiration of the [10 year period], the Administrator shall
  - ◆ review the request
  - ◆ make a determination whether claim continues to meet §14
  - ◆ grant a 10-yr extension or deny the request

# New CDX CBI Tool – Spring 2026

- ◆ In “April” EPA will post on website initial list of submissions with CBI claims set to expire beginning in June 2026
  - ◇ Will also send direct notices to submitters via CDX
- ◆ EPA expects to have newly-developed “simple” CDX tool implemented prior to June 2026
  - ◇ If implementation delayed, EPA will post estimated completion date
    - information will not be released until companies given opportunity to submit extension requests
- ◆ *“If EPA does not receive a request for extension at least 30 days prior to the claim expiration ... the information may be made public without further notice to the submitter.”*
- ◆ If EPA denies request, normal CBI denial procedures apply
  - ◇ i.e., file in federal court (“get one chance”)

# Timing Issues – Two “Buckets”

- ◆ Expiration date for **non-chemical identity** CBI claims → 10 years from date claim was asserted
  - ◇ Normally 10 years from date information submitted to EPA
- ◆ Expiration date for CBI claims for **specific chemical identity** → 10 years from submission of **first** approved CBI claim for specific chemical identity made by **any submitter** after 6/22/2016
  - ◇ Later submissions do not reset/extend expiration date – submitters should consult Inventory
    - Date flagged in Inventory in “EXP” field
  - ◇ Persons other than PMN submitter can request
- ◆ Cannot “preemptively” request extension

# TSCA Submissions to Consider

- ◆ Section 5 PMN/NOCs, SNUN, LVE, LoRex filings
- ◆ Section 8(a) CDR Submissions
  - ◇ Recall 2016 CDR reporting period 6/1 to 9/30/2016 → 10/31/2016
    - If report submitted after LCSEA enactment on 6/22/2016
- ◆ Section 8(e) reports
- ◆ Other – section 6 RA submissions, Inventory active/inactive “reset” submissions (begin expiring ~3Q 2027), inspection materials and subpoena responses, etc.

# Of course, Need to Substantiate...

- ◆ Substantiation requirements appear at 40 C.F.R. §703.5(a) and (b) - certification re:
  - ◆ Submitter has taken reasonable measures to protect the CBI
  - ◆ CBI is not required to be disclosed under federal law
  - ◆ Disclosure of CBI would cause substantial harm to company's competitive position
  - ◆ CBI not readily discoverable via reverse engineering
- ◆ Claims cannot be modified, new claims cannot be added, withdrawn/denied claims cannot be revived

# So....

- ◆ Be prepared to act quickly in June and later
  - ◇ Check Inventory “EXP” field
- ◆ This would be a prudent time to:
  - ◇ Update company contact information
  - ◇ Review company organization ID numbers
  - ◇ Preserve CDX passphrases
    - Re-establish lapsed/inaccessible CDX accounts by working with CDX helpdesk
  - ◇ Consider whether information submitted in paper TSCA/electronic filing pre-dating CDX filing requirement for that submission type
- ◆ Perhaps even begin to map out entirety of company’s renewal schedule

# Some of the first CBI claims coming up



<b>PMNNO</b>	<b>ACCNO</b>	<b>UID</b>	<b>EXP</b>
P160250	221160	UID-2016-00143	20260624
P160222	183096	UID-2016-00144	20260627
P050722	236090	UID-2016-00002	20260705
P060004	277895	UID-2016-00003	20260705
P060007	238267	UID-2016-00004	20260705
P060070	242650	UID-2016-00005	20260705
P130162	226563	UID-2016-00146	20260706
P160042	215135	UID-2016-00145	20260706
P160270	189721	UID-2016-00008	20260708
P890872	113747	UID-2016-00009	20260711
P950342	157223	UID-2016-00010	20260711

# DISCUSSION

# Upcoming Webinars



Please join us at 1:00 PM Eastern U.S.  
Wednesday, March 25, 2026  
[www.khlaw.com/OSHA3030](http://www.khlaw.com/OSHA3030)



Please join us at 10:00 AM Eastern U.S.  
Wednesday, 8 April 2026  
[www.khlaw.com/REACH-3030](http://www.khlaw.com/REACH-3030)



Please join us at 1:00 PM Eastern U.S.  
Wednesday, TBD, 2026  
[www.khlaw.com/TSCA-3030](http://www.khlaw.com/TSCA-3030)



# Thank You

Any questions?

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