



Bypassing EPA: Citizens Use of the Courts to Regulate Existing Chemicals and Enforce TSCA (TSCA §§ 20 and 21)

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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.



TSCA Section 20 – “Citizens’ Civil Actions”



- ◆ **§20(a) - Any person may commence a civil action ...**
 - ◇ (1) against any person [including the government]... alleged to be in violation of [TSCA, or certain TSCA rules/orders] ... to **restrain** such **violation**, or
 - ◇ (2) against Administrator to **compel** Administrator to perform any **act** or duty ... which is not discretionary
- ◆ **Can bring action:**
 - ◇ **§20(a)(1):** in U.S. district court where alleged violation has occurred or defendant resides, or location of defendant’s PPOB
 - ◇ **§20(a)(2):** in U.S. district court of D.C. (“DDC”), or U.S. district court for judicial district where plaintiff domiciled

Limitations

- ◆ **No civil action may be commenced—**
- ◆ **§20(a)(1) (“restrain”):**
 - ◇ before expiration of 60 days after plaintiff provides notice to EPA Administrator and alleged violator, or
 - ◇ if EPA has commenced and diligently prosecuting proceeding for issuance of §16(a)(2) order to require compliance, or Attorney General has commenced and diligently prosecuting civil action in court to require compliance
 - “diligent-prosecution bar”
- ◆ **§20(a)(2) (“compel”)**
 - ◇ before expiration of 60 days (different for §7/18 actions) after plaintiff has given notice to Administrator of alleged failure to act

Other

- ◆ If not a party, EPA may intervene as a matter of right
 - ◇ *e.g.*, §20(a)(1) action
- ◆ In issuing final order, court allowed to award costs of suit and reasonable fees for attorneys and expert witnesses if determines appropriate
 - ◇ Reviewing court also can award costs of suit and reasonable attorneys fees if appropriate
- ◆ Other envt'l statutes contain substantially similar provisions
 - ◇ *e.g.*, CAA §304(a)(2), §CWA 505(a)(2), *etc.*
 - ◇ Materially unchanged by LCSA

How has §20 been used?

- ◆ Center for Environmental Health (CEH) used §20(a)(1) several times
 - ◇ Used publicly-available commercial databases to search companies' chemical import records
 - *e.g.*, “Panjiva,” “Import Genius”
- ◆ Compared records against 2016/2020 TSCA §8(a) CDR reports to ascertain where non-reporting appeared to have occurred
 - ◇ Typically focused on “toxic” chemicals
- ◆ Sent 60-day letters
- ◆ Filed complaints if no response

CEH-Type §20(a)(1) Actions

- ◆ Can create “War on two fronts”
 - ◆ NGO - Potential settlement, attorneys fees, auditing, Form U submission
 - ◆ EPA - Enforcement action, subpoena, inspection
 - ◆ Press coverage
- ◆ Commercial database limitations and data interpretation can create issues
 - ◆ “Importer” definition
 - ◆ CBP Automated Commercial Environment “ACE” system
 - See <https://www.cbp.gov/trade/automated>

How else has §20 been used?

- ◆ May 17, 2024 - CEH/Public Employees for Environmental Responsibility (PEER) allege EPA failed to perform non-discretionary duty under §4(f) to initiate action under §5/6/7 to prevent/reduce risks from PFOA allegedly formed when **fluorinating plastic containers**
- ◆ Followed 5th Circuit decision in *Inhance Technologies L.L.C. v. EPA*
- ◆ July 25, 2024 filed complaint in DDC for declaratory and injunctive relief
 - ◇ Sep. 27, 2024: EPA files motion to dismiss on basis that it “initiated” §6 proceedings
- ◆ Court earlier used “diligent prosecution bar” to dismiss action filed a week or so after DOJ initially filed suit

Other §20(a)(2) actions

- ◆ To compel EPA to disclose **PMN-related** information (“transparency”) (EDF *et al.*, 2019)
- ◆ To compel EPA to finalize ban on **methylene chloride** (NRDC *et al.*, 2019)
- ◆ To compel EPA to perform non-discretionary duty to address use/disposal of “legacy” §6(b) **asbestos** risk evaluation (ADAO *et al.*, 2021)
- ◆ To compel EPA to complete 22 overdue §6(b) **risk evaluations** (CIDA *et al.*, 2023)

Section 21 – Citizen Petitions

- ◆ Allows any person to petition EPA...
- ◆ ...to initiate a proceeding for issuance, amendment, or repeal of:
 - ◇ a rule under sections 4, 6, or 8
 - ◇ an order under sections 4, 5(e), or 5(f)
- ◆ Must set forth the facts to establish it is necessary to issue, amend or repeal the rule or order

Section 21 – Procedure

- ◆ EPA may hold a public hearing or conduct an investigation or proceeding
- ◆ EPA must grant or deny the petition **within 90 days**
- ◆ EPA denial or delay can be challenged in district court
- ◆ District court considers the petition in a *de novo* proceeding
- ◆ Petitioner needs to show by a preponderance of the evidence that:
 - ◇ Section 4/section 5 original standard is met (sections 4, 5(e)); or
 - ◇ Substance presents an unreasonable risk (sections 5(f), 6(a), 8)

Food & Water Watch v. EPA (N.D. Cal) (1)



- ◆ Food & Water Watch group filed a section 21 petition in November 2016 asking EPA to regulate fluoridation of drinking water under section 6(a)
- ◆ EPA denied the petition in February 2017
- ◆ Petitioners filed suit in California
- ◆ Case stayed after an initial 7-day bench trial in June 2020
- ◆ Petitioners filed a supplemental petition for reconsideration in November 2020
- ◆ EPA denied the supplemental petition in January 2021
- ◆ Second 10-day bench trial in January-February 2024

Food & Water Watch v. EPA (2)

- ◆ Key holdings
 - ◆ Water fluoridation at the level of 0.7 mg/L presents an unreasonable risk of injury to health
 - ◆ “initiate a proceeding” = issue a risk management rule
 - ◆ Record for the *de novo* court proceeding includes information not included in the petition
 - ◆ Chemical at issue need not be found hazardous at the exposure level to establish that an unreasonable risk is present under TSCA
 - ◆ Severity of the hazard, exposure-related considerations, and exposure of susceptible populations weigh strongly towards finding the risk unreasonable; confidence in hazard data and overall strength of the evidence and uncertainties, are largely neutral.

Food & Water Watch v. EPA (3)

- ◆ Scientific determinations by the Court
 - ◇ Fluoride is associated with lower IQ in children at the level of 4 mg/L
 - Or 1.5 mg/L (NTP Monograph finding of “association”)
 - Or 1.536 mg/L, or 0.768 mg/L, or 0.28 mg/L...
 - ◇ Insufficient margin of exposure between 4 mg/L and the 0.7 mg/L optimal level for drinking water fluoridation
 - ◇ Exposure exceeds other points of departure

Food & Water Watch v. EPA (4)

- ◆ Significant issues
 - ◆ Scope of the record
 - ◆ Reliance on post-petition studies, in particular pooled BMCL analyses used in the Court's dose-response assessment
 - ◆ Conflation of “safe” and “no unreasonable risk”
 - ◆ Elevation of EPA Guidelines and other policies
 - ◆ Conflation of exposure through drinking water concentration vs. maternal urinary fluoride
 - ◆ Margin of exposure requirement
 - ◆ Hazard without a tested or established mechanism of action

Food & Water Watch v. EPA (5)

- ◆ Other issues of note
 - ◆ Court cites methylene chloride risk evaluation and its low evidentiary standard as effectively providing carte blanche
 - ◆ What unreasonable risk does EPA have to address?
 - ◆ “It is inherently more difficult to observe an adverse effect of a chemical at lower exposure levels because of reduced exposure contrast” vs. “dosage matters”

Food & Water Watch v. EPA (6)

- ◆ Lessons for industry
 - ◆ Are comments on a petition significant?
 - ◆ Need to engage in toxicological reviews conducted by other bodies (NTP, IRIS, IARC, states, etc.)
 - ◆ Can stakeholders intervene?
 - ◆ Importance of the challenge to the methylene chloride risk management rule and risk evaluation



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Thank You

Any questions?

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