TSCA at 5: TSCA Litigation Update[1]

This update broadly summarizes Toxic Substances Control Act (TSCA) litigation since the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Chemical Safety Act) was signed into law on June 22, 2016.

On June 30, 2021, the Environmental Law Institute (ELI), Bergeson & Campbell, P.C. (B&C®), and the George Washington University Milken Institute School of Public Health will co-sponsor an annual conference, "TSCA Reform -- Five Years Later." During this event, Lynn L. Bergeson, Managing Partner, B&C, will moderate the TSCA Litigation Update discussion, with Martha E. Marrapese, Partner, Wiley Rein LLP, and Gavin McCabe, Special Assistant Attorney General, New York State Office of Attorney General, as panelists. The below summaries address the legal actions that have been brought in the past five years since Congress amended TSCA that may serve as points of discussion for the panel.

Closed Cases

TSCA Framework Rules Litigation

In 2017, several petitions for review were filed in U.S. Courts of Appeals challenging the U.S. Environmental Protection Agency's (EPA) final "framework rules" under amended TSCA: EPA's final prioritization of chemicals for risk evaluation, the final risk evaluation rule, and the TSCA Inventory Notification (Active-Inactive) Requirements rule. Several petitions for review were ultimately consolidated into two cases before the Ninth and Second Circuits.

- ***Safer Chemicals, Healthy Families et al. v. EPA*, 943 F.3d 397 (9th Cir. 2019)**
  - Filed August 10, 2017, Case Nos. 17-72260 (consolidated), the case involved challenges to EPA's final prioritization of chemicals for risk evaluation and risk evaluation rules.
  - On December 18, 2018, the court granted in part EPA's motion for partial voluntary remand of certain provisions of its final rule on Procedures for Chemical Risk Evaluations.
    - EPA sought remand with vacatur of 40 C.F.R. Section 702.31(d) (Penalty Provision) and remand without vacatur of 40 C.F.R. Sections 702.37(b)(4) (Relevancy Provision) and 702.37(b)(6) (Consistency Provision). The Ninth Circuit granted EPA's motion to remand and to vacate the Penalty Provision, but referred EPA's motion to remand without vacatur for the Relevancy and Consistency Provisions. The Penalty Provision states that "[s]ubmission to EPA of inaccurate, incomplete, or misleading information

[1] Prepared by Kelly N. Garson, Associate with Bergeson & Campbell, P.C., Washington, D.C.

pursuant to a risk evaluation … is a prohibited act … subject to penalties." (http://www.tscablog.com/blogs/tagged/framework+rules)

- The Ninth Circuit issued its decision on November 14, 2019.
  - Opinion: (http://cdn.ca9.uscourts.gov/datastore/opinions/2019/11/14/17-72260.pdf)

- Argument 1: TSCA requires EPA to evaluate the risks associated with a chemical's uses collectively before determining that the chemical is safe.
  - Holding: Court lacked Article III jurisdiction to review this challenge. The challengers' interpretation of what EPA intended to do and the resulting injury to the petitioners was too speculative. It was not yet clear how EPA would conduct its risk evaluations.
  - The court stated legal action could be pursued on a specific substance's "no unreasonable risk" determination if, in the future,:
    - EPA fails to consider all conditions of use together when completing a risk evaluation; and
  - The petitioners are harmed by that failure. EPA ended up conducting the risk evaluations on a "use-by-use" basis, making determinations for each condition of use instead of the substance as a whole. EPA is now reconsidering this decision and is requesting voluntary remand in its risk evaluation cases to revise the risk evaluations and make one binary finding of unreasonable risk or no unreasonable risk per substance.

- Argument 2: EPA must consider all of a chemical's conditions of use in that evaluation.
  - Holding: This argument failed on the merits because EPA may exclude certain conditions of use from the scope of the risk evaluation.

- Argument 3: When considering conditions of use, EPA must evaluate past disposals of all chemicals, as well as the use and subsequent disposal of chemicals not currently or prospectively manufactured or distributed in commerce for that use.
  - Holding: Granted in part (EPA needed to examine legacy uses, for example, for asbestos). EPA agreed that it needed to reconsider certain information-gathering provisions from the Risk Evaluation Rule and Prioritization Rule, requesting remand. The court reviewed these issues in a concurrently filed memorandum to the opinion.

■ ***Environmental Defense Fund (EDF) v. EPA*, 922 F.3d 446 (D.C. Cir.), Case No. 17-1201 (filed on September 1, 2017)**

- Challenge to EPA's TSCA framework rule: TSCA Inventory Notification (Active-Inactive) Requirements, published on August 11, 2017 (82 Fed. Reg. 37520).

- EDF filed its principal brief on March 6, 2018, arguing the following:
  - The Inventory Rule withholds information on chemical substances manufactured or processed in the United States from the public; this information is required to be disclosed under amended TSCA; EDF has been harmed by EPA's failure to disclose this information and to disclose unique identifiers for confidential chemicals; and the court can redress this harm.
  - The final rule illegally allows manufacturers and processors to assert certain new claims for nondisclosure of specific chemical identities based on other persons having asserted earlier claims, which is contrary to TSCA's plain text and the relevant precedent governing confidentiality claims; and EPA's rationale for its interpretation is arbitrary and capricious.
  - The final rule violates both the substantive and procedural requirements of TSCA Section 14, Confidential Information, specifically that: EPA refused to accept that TSCA Section 8, Reporting and Retention of Information, repeatedly incorporates Section 14 requirements for confidentiality claims; the final rule fails to implement one of the substantive requirements for confidentiality claims under Section 14; and the final rule fails to implement one of the substantive requirements for confidentiality claims under Section 14.
  - The final rule fails to implement the unique identifier and other public information requirements in TSCA Section 8(b)(7)(B).
  - The final rule exempts chemicals manufactured and processed solely for export from the reporting requirements, even though such chemicals are specifically not exempted from TSCA Section 8.
  - Finally, EDF requests the court to set aside the rule in part, stating that vacatur, along with remand, is the appropriate remedy for EPA's violations of the Administrative Procedure Act (APA). EDF does not seek a complete vacatur, however, stating that "a complete vacatur would postpone the release of some of the very information that EDF seeks, since it would allow EPA to postpone publishing the Inventory based on the information it has already collected. In addition, it would impose costs on the regulated community beyond those necessary to remedy EDF's harms [and] those manufacturers and processors who have already filed notices without claims of confidentiality should not need to refile the notices." The portions of the final rule that EDF requests the court to vacate are as follows: the exclusion for export-only manufacturers (40 C.F.R. § 710.27(a)(4)); Confidentiality

Claims (40 C.F.R. § 710.37); and certain portions of the preamble. EDF states specific instructions on how it would like the court to order EPA to promulgate the regulation on remand that include revisions to regulations on confidentiality claims, public information requirements, and notifications of activities during the lookback period. (http://www.tscablog.com/blogs/tagged/petition+for+review)

- On April 26, 2019, the court issued its opinion:
  - The court ordered a limited remand, without vacatur, for EPA to address its arbitrary elimination of substantiation questions regarding reverse engineering.
  - The court otherwise denied the petition for review and upheld significant aspects of EPA's final rule relating to the TSCA Inventory of chemicals and left the rule intact.
  - TSCA did not require EPA to develop and implement a unique-identifier system alongside its Inventory review process, established no deadline for EPA's development and implementation of unique identifiers, and it is not unreasonable for EPA to defer that process while it first determined how many and which chemical substances would be accorded confidential treatment. (https://www.govinfo.gov/content/pkg/USCOURTS-caDC-17-01201/pdf/USCOURTS-caDC-17-01201-0.pdf)

■ ***Natural Resources Defense Council v. Environmental Protection Agency,*** **No. 18-25 (2d Cir.) (July 31, 2018)**

- After being sued for violating TSCA and the APA's notice-and-comment requirements in issuing the Framework Rule, EPA filed a brief and affidavit in the case explaining that it was not following the Framework Rule. The National Resources Defense Council (NRDC) withdrew the petition on August 29, 2018.

Remand of EPA's 2019 Lead-Based Paint Hazard Standards

■ ***A Community Voice v. EPA*****, 997 F.3d 983 (9th Cir.) (May 14, 2021); Case No. 19-71930**

- This case was a petition for review of EPA's delay in promulgating a rulemaking on lead-based paint standards. EPA No. EPA-HQ-OPPT-2018-0166.

- In 2009, several organizations filed a rulemaking petition, requesting that EPA update its dust-lead hazard standards, dust-lead clearance levels, and the definition of lead-based paint. EPA granted the 2009 petition, but did not promulgate a rulemaking for eight years.

- Petitioners sought a directive in 2017 to require EPA to act. The Ninth Circuit issued a Writ of Mandamus to EPA in 2017.

- EPA promulgated a final rule in 2019. The Petitioners contended that EPA's 2019 Rule violated the Residential Lead-Based Paint Hazard Reduction Act (PHA), codified under TSCA Section 4 at 15 U.S.C. §§ 2683, 2681(10).

- Amending TSCA through the PHA required EPA to identify the level at which lead becomes dangerous to human health when contained in principal sources of lead poisoning, set hazard levels, and eliminate risks in housing from lead-based paint.
  - Congress requires EPA to first identify the hazards and take action to implement the standards second (similar to the Clean Air Act (CAA)).
  - Under the CAA: The Supreme Court in *Whitman v. Am. Trucking Associations*, 531 U.S. 457 (2001) held that EPA could not consider costs during the identification phase when setting standards -- other sections of the CAA explicitly stated when EPA was allowed to consider costs.
  - Same with the Resource Conservation and Recovery Act (RCRA): In *Utility Solid Waste Activities Group v. EPA*, 901 F.3d 414 (D.C. Cir. 2018), costs were not to be considered during classification phases because other sections of RCRA made clear when EPA was supposed to consider costs and *Utility Air Waste Activities Group v. EPA*, 573 U.S. 302 (2014) (EPA "may not rewrite clear statutory terms to suit its own sense of how the statute should operate").
  - EPA's 2019 rule does not set the hazard level at a level sufficient to protect health as Congress directed because EPA looked at factors in addition to health.
  - EPA has an ongoing duty to account for new information and modify initial standards when necessary to further Congress's intent to eliminate lead-based paint hazards.
  - If EPA states that there is scientific uncertainty regarding an issue, EPA must explain why the uncertainty justifies inaction.
  - EPA has more discretion in setting clearance levels because they concern the implementation of remedial measures than when identifying hazards, and can consider "reliability, effectiveness, and safety," whereas EPA may only consider health when identifying hazards. Despite this discretion, EPA must act when the hazard standard changes and amend the regulations to reconsider the effectiveness and safety of the associated abatement regulation.
  - The court remanded the rule on May 14, 2021, to EPA for revision.

Settlement in Case Regarding TSCA Section 8(a) Asbestos Reporting
TSCA Section 21 Petition

- ***Asbestos Disease Awareness Organization et al v. Wheeler et al.*, Case No. 3:19-CV-03807-EMC; 19-cv-00871-EMC, U.S. District Court for the Northern District of California**
  - On June 7, 2021, the parties agreed to settle in the case. EPA agreed to promulgate a rule requiring manufacturers, importers, and processors to report on their uses of asbestos and asbestos-containing articles, including as an impurity under TSCA Section 8(a). The rule is due by December 2022. (https://www.asbestosdiseaseawareness.org/wp-content/uploads/2021/06/ADAO-v-EPA-All-Settlement-Documents.pdf)

  - **Impact on TSCA Section 21 Petitions** -- Described by Counsel for Asbestos Disease Awareness Organization, Robert Sussman, the case is a milestone under the citizens' petition provision of TSCA Section 21.
    - This petition is the first case where EPA was compelled to initiate rulemaking. (https://chemicalwatch.com/277223/epa-agrees-to-create-tsca-reporting-rule-for-asbestos)

  - Other recent Section 21 petitions are pending or have been denied by EPA:
    - One petition calls on EPA to order Chemours to conduct testing on several dozen per- and polyfluoroalkyl substances (PFAS).
    - Another petition seeks a TSCA Section 6 rule to restrict the fluoridation of drinking water.
    - EPA denied a request for a TSCA Section 4 testing rule for phosphogypsum and process wastewater from phosphoric acid production, among other demands.
      - EPA denied the request because the petition does not demonstrate that existing information and experience on the effects of phosphogypsum and process wastewater are insufficient or that testing is necessary to determine whether disposal poses an unreasonable risk to public health or the environment. EPA also stated that the request for a risk evaluation and issuance of a significant new use rule (SNUR) for road building applications exceeded Section 21's boundaries.
      - Erik C. Baptist, Partner at Wiley Rein LLP, recommends that petitions are kept limited in scope and within the authority of Section 21 and reasonable in its request -- EPA will be more likely to grant a petition that is targeted, necessary, and reasonable, given

the limited resources of the agency. (https://chemicalwatch.com/270180/us-epa-denies-tsca-petition-for-phosphogypsum-testing)

➢ ***Case History***

- In 2018, six nongovernmental organizations (NGO)[2] petitioned EPA under TSCA Section 21 in a consolidated case to amend its TSCA Chemical Data Reporting (CDR) Rule under TSCA Section 8(a) and require reporting for asbestos and asbestos-containing products.
  - The case was consolidated with an action brought by the attorneys general from a coalition of several states -- State of California v. EPA, No. 19- CV-03807 ("AGs' Case");
- Arguments were that EPA must:
  - Require that asbestos be reported under the CDR Rule in order to collect information on its current import and use. The substance is currently exempted from reporting as it is "naturally occurring."
  - Lower the reporting threshold, eliminate exemptions for impurities and its presence in articles, and require processors to report "in order to assure that EPA has the information on asbestos necessary to meet its TSCA responsibilities."
  - Block such reports from being protected as confidential business information. (https://chemicalwatch.com/70621/ngos-petition-us-epa-to-require-asbestos-reporting)

➢ On December 22, 2020, the court issued an opinion granting summary judgment to the petitioners and ordering EPA to amend its TSCA CDR Rule to close "loopholes" in asbestos reporting. (https://chemicalwatch.com/196480/federal-court-orders-us-epa-to-close-loopholes-in-asbestos-reporting)

- EPA had asked the court to rescind the order and let EPA reconsider the original petition. EPA committed to initiating a rulemaking for asbestos reporting, but requested that the December order be amended to clarify that the authority to initiate a rulemaking resides with EPA.
- The court ordered EPA to amend its CDR Rule "to address the information-gathering deficiencies identified herein." The court specified that "the

[2] Asbestos Disease Awareness Organization (ADAO); American Public Health Association (APHA); the Center for Environmental Health (CEH); Environmental Working Group (EWG); Environmental Health Strategy Center (EHSC); and Safer Chemicals, Healthy Families (SCHF).

following loopholes in the CDR reporting scheme prevent EPA from receiving reasonably available information: (1) the asbestos-containing articles exemption; (2) the impurities exemption; and (3) the processors exemption." Judge Chen said he would maintain jurisdiction over the case to ensure compliance. (https://www.bloomberglaw.com/public/desktop/document/StateofCaliforniaetalvUnitedStatesEnvironmentalProtectionAgencyet/13?1624155109)

- The court had cited the following cases in support of its decision: *Cmty. Voice v. United States EPA (In re Cmty. Voice)*, 878 F.3d 779, 788 (9th Cir. 2017) (after EPA granted a petition from several organizations asking for a rulemaking to update lead-based and dust-lead hazard standards, the Ninth Circuit found that TSCA imposed a clear duty on EPA to conclude a rulemaking proceeding within a reasonable time, and it "order[ed] … that EPA issue a proposed rule within ninety days of the date that th[e] decision bec[ame] final … [and] retain[ed] jurisdiction for purposes of ensuring compliance").
- *NRDC v. United States EPA (In re NRDC)*, 956 F.3d 1134, 1143 (9th Cir. 2020) (finding that EPA's delay in responding to an environmental organization's administrative petition, which requested that it cancel the registration of a dangerous pesticide used in household pet products, merited mandamus relief because it delayed the performance of its statutory duties on a crucial matter of public health).

- [EPA and the Petitioners then began the settlement negotiations summarized above].

TSCA Reporting Rule (Exemptions for Mercury-Added Components)

- ***NRDC, Inc. v. EPA*, 961 F.3d 160 (2nd Cir. 2020), Case No. 18-02121**
  - The 2nd Circuit struck down exemptions for importers with mercury-added components from its mercury inventory reporting rule on June 5, 2020.
  - In a suit under TSCA Section 15(b)(10) (15 U.S.C. § 2607(b)(10)) and the CDR Rule, 40 C.F.R. Section 713.7, the exemption for importers of products containing mercury-added components was an unlawful interpretation of TSCA because EPA failed to provide a reasoned explanation for the exemption.
    - EPA argued that the exemption was intended to protect small "mom & pop" importers that might face a financial burden from compliance -- but EPA did not end up categorically exempting small businesses from reporting

requirements in its final rule. Therefore EPA did not explain reasonably why it exempted importers.

- EPA also argued that Congress did not intend for EPA to require reporting for importers because that are "too attenuated from the intentional addition of mercury into the products." The court said that Congress's instruction was to create and publish an inventory of mercury supply, use, and trade, which demonstrates that it was interested in mercury's use in the economy.

➢ The exemption for manufacturers of products with mercury-added components and for high-volume manufacturers were lawful in light of Congress's directive to not require reporting that was unnecessary or duplicative. EPA already collects reports from those that manufacture or import greater than or equal to 2,500 pounds of elemental mercury or 25,000 pounds of mercury compounds under the CDR Rule. (https://news.bloomberglaw.com/environment-and-energy/importer-exemption-to-epas-mercury-reporting-rule-struck-down?context=search&index=2)

Ongoing Cases

Impact of Incoming Biden Administration and Executive Order 13,990 on Current Cases

On January 20, 2021, the Biden Administration issued Executive Order (EO) 13,990, entitled "Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis." The Biden Administration issued an accompanying statement, "Fact Sheet: List of Agency Actions for Review," a "non-exclusive list of agency actions" to be used to implement the EO.

The Fact Sheet list includes the risk evaluations for methylene chloride and "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726 (July 20, 2017)." The Fact Sheet also lists other actions undergoing litigation, including:

➢ "Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a)," 84 Fed. Reg. 11420 (March 27, 2019);

➢ "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information," 86 Fed. Reg. 469 (January 6, 2021); and

➢ "Decabromodiphenyl Ether (DecaBDE); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h)," 86 Fed. Reg. 880 (January 6, 2021).

- "Phenol, Isopropylated Phosphate (3:1) (PIP 3:1); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h)," 86 Fed. Reg. 894 (Jan. 6, 2021).

EPA has cited EO 13,990 in several other reconsideration actions, citing the following paragraph:

> Where the Federal Government has failed to meet that commitment in the past, it must advance environmental justice. In carrying out this charge, the Federal Government must be guided by the best science and be protected by processes that ensure the integrity of Federal decision-making. It is, therefore, the policy of my Administration to listen to the science; to improve public health and protect our environment; to ensure access to clean air and water; to limit exposure to dangerous chemicals and pesticides; to hold polluters accountable, including those who disproportionately harm communities of color and low-income communities; to reduce greenhouse gas emissions; to bolster resilience to the impacts of climate change; to restore and expand our national treasures and monuments; and to prioritize both environmental justice and the creation of the well-paying union jobs necessary to deliver on these goals.

Challenges to Risk Evaluations the Ninth Circuit for the U.S. Court of Appeals

EPA completed risk evaluations for the first ten high-priority risk evaluations. EPA has announced plans to revisit or supplement risk evaluations while expeditiously moving to the risk management phase for these substances. Four of the ten final risk evaluations are the subject of petitions for review challenging EPA's determinations of unreasonable risk for certain conditions of use. As EPA has decided to supplement its past risk evaluations, EPA has requested voluntary remand for methylene chloride, 1,4-dioxane, and hexabromocyclododecane (HBCD) cases while it revisits the risk evaluation challenges described below.

Methylene Chloride Risk Evaluation

- ***Neighbors for Environmental Justice et al. v. EPA,* No. 20-72091; consolidated with *State* of *New York et al. v. Regan,* No. 20-73276**
  - Petition for review challenging EPA's six findings of unreasonable risk for methylene chloride, including assumptions EPA made regarding the use of personal protective equipment (PPE) and issues with underlying data. Petitioners also state that EPA impermissibly excluded review of exclusion of exposure pathways and risks to exposed communities or susceptible subpopulations in the evaluation.

Petitioners also argue that EPA's "use-by-use" risk determinations were unlawful and that EPA should make one finding of unreasonable risk for methylene chloride.

- Respondent-Intervenors: American Chemistry Council, NMP Producers Group, Halogenated Solvents Industry Alliance (HSIA).

- On May 13, 2021, EPA filed a motion for voluntary remand of the methylene chloride risk evaluation. EPA has committed to reconsidering the following:
  - Transition to a binary determination of unreasonable risk, or one finding that methylene chloride presents an unreasonable risk.
  - Reconsider assumptions relating to workers' use of PPE and wait to consider the use of PPE until risk management.
  - Review the impact of methylene chloride conditions of use on potentially exposed or susceptible subpopulations, and potential additional analysis on impacts on fence-line communities.
  - Potentially conduct additional analysis on exposure pathways previously excluded from the risk evaluation that are under the jurisdiction of other EPA-administered statutes (*e.g.* air and water exposure pathways).

- The Petitioners (environmental and labor advocacy groups and a coalition of states and municipalities) have opposed the motion for voluntary remand, or requested the following conditions. The Environmental Defense Fund filed an amicus curiae brief in support of these limitations.
  - Limit remand to one year;
  - Ask EPA to file status reports every 60 days; and
  - Require EPA to adhere to TSCA's timelines for completing the risk management rule.

- Projected outcome: It is likely that the court will grant EPA's motion for voluntary remand. EPA has committed to reconsidering several of its risk evaluations. EPA filed a reply to the Petitioners' responses in opposition, noting that EPA's request for remand is timely and in good faith, and that the court's review is limited to the case or controversy at hand (the determinations of no unreasonable risk). Therefore, the court does not have the jurisdiction to oversee risk management. EPA notes that its reconsideration follows Biden's EO, requiring a review of the risk evaluation.

■ This case addresses issues left unresolved by Safer Chemicals, Healthy Families et al. v. EPA, 943 F.3d 397 (9th Cir. 2019) (referenced above). In that case, the issue of whether EPA may make "use-by-use" determinations of unreasonable risk or one binary, holistic determination of unreasonable risk for the substance as a whole was not judicially

reviewable, stating that it was speculative whether EPA would conduct the risk evaluation "use-by-use." EPA has conducted its risk evaluations "use-by-use" and is reconsidering this procedure as it revisits is risk evaluations.

Hexabromocyclododecane (HBCD)

- ***Alaska Community Action on Toxics (ACAT) v. EPA*, No. 20-73099 (filed October 16, 2021); consolidated with *California Professional Firefighters et al. v. EPA* (filed Dec. 8, 2020)**
  - Petitioners and EPA requested that the court stay the case in order to allow time for additional discussion on May 5, 2021, after EPA noted its intention to file a motion for remand by May 28, 2021. The motion to stay the case referenced EO 13,990 as requiring EPA immediately to review and address actions that conflict with policies outlined in the EO, including limiting exposure to dangerous chemicals and pesticides and prioritizing environmental justice and protections for communities of color and low-income communities from environmental pollution.
  - On May 28, 2021, EPA filed a motion for voluntary remand.
  - On June 18, 2021, the Petitioners filed motions opposing EPA's motion.

1,4-Dioxane

- ***Environmental Defense Fund et al. v. EPA*, No. 21-70162 (filed January 27, 2021); consolidated with 21-70194; 21-70727; 21-70684; 21-70930**
  - On June 8, 2021, EPA requested voluntary remand without vacatur to allow EPA to revisit the risk evaluation:
    - Assumptions about PPE;
    - Decisions about certain exposure pathways and conditions of use that were excluded from the evaluation; and
    - Whether EPA should shift to making a single risk determination for a substance as a whole, rather than a use-by-use determination.
  - Petitioners' response to the motion to remand is due on or before July 9, 2021.

Asbestos

- ***Asbestos Disease Awareness Organization et al. v. EPA,* No. 21-70160 (filed January 26, 2021)**
  - The petition for review challenged Part 1 of the asbestos risk evaluation and does not contain ADAO's substantive arguments regarding the risk evaluation.
  - As of May 24, 2021, briefing in this case is scheduled to proceed. Petitioners' opening brief is due July 1, 2021. EPA's answering brief is due September 20, 2021. Intervenor -- The Chlorine Institute's brief is due October 4, 2021. The optional reply brief is due October 25, 2021.
  - EPA has not yet requested remand in this case. Because the opening brief has not yet been filed, and the complaint did not contain substantive arguments, it is unclear what arguments will be raised by Petitioners.

Challenge to March 2019 Methylene Chloride (MC) Rule Banning MC in Paint and Coating Strippers for Consumer Purchase

EPA promulgated a final rule entitled "Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use under TSCA Section 6(a)," 84 Fed. Reg. 11,420 (March 27, 2019) (to be codified at 40 C.F.R. Part 751). The rule banned the use of methylene chloride in consumer paint products and excluded commercial uses. This rule was subject to earlier law suits (*Vermont PIRG et al. v. EPA,* Case 2:19-cv-00009-jmc, U.S. District Court District of Vermont, January 14, 2019) to compel EPA to promulgate a final rule.

- ***Labor Council for Latin Am. Advancement v. EPA*, No. 19-1042 (2nd Cir.) (March 4, 2021)**
  - Three petitions for review challenging the rule were filed. The cases were consolidated, and arguments have been heard in the U.S. Court of Appeals for the Second Circuit.
  - Environmental petitioners (NRDC, Earthjustice, and the Labor Council for Latin American Advancement) argue that EPA should have banned the commercial uses of stripping products, in addition to consumer uses, due to fatalities when workers used methylene chloride.
    - Advocates argue that EPA should have issued a rule protecting workers in the 2019 rule. (https://news.bloomberglaw.com/environment-and-energy/methylene-chloride-rule-challenge-ripeness-focus-of-2nd-circuit?context=search&index=6)

- HSIA argues that barring retailers that sell any chemical products to consumers from selling methylene chloride paint removers was arbitrary and capricious and would prevent the majority of commercial uses still allowed by EPA.
  - HSIA also argued that EPA failed adequately to evaluate the economic costs of its decision and failed to comply with administrative requirements by announcing the retailer prohibition "at the last minute" and without adequate notice.

- EPA argues in response that there are other options EPA is exploring to protect workers that may not require a commercial ban of methylene chloride, and that EPA may also regulate methylene chloride based upon unreasonable risk findings in its risk evaluations.

- EPA argues that it is allowed to impose the ban as a logical outgrowth of earlier proposals and that it considered economic consequences of the ban to the extent allowed by reasonably available information. Furthermore, EPA argues that in addressing unreasonable risk from consumer use of methylene chloride paint and coating removers, EPA selected the less costly alternative.

- The parties each filed either a supplemental brief or post-argument letter on March 11, 2021.

Risk Management Rule for decaBDE

Decabromodiphenyl ether (decaBDE) is one of five persistent, bioaccumulative, and toxic (PBT) substances subject to a fast-tracked action under the 2016 amendments. EPA published a final rule that prohibits the manufacture, import, and processing of most uses of decaBDE and carve-outs, or delayed compliance dates or exclusions, for certain uses. "Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h)," 86 Fed. Reg. 880 (Jan. 6, 2021). The carve-outs include uses in replacement parts for the automotive and aerospace industry and certain uses in the hospitality industry.

Two cases filed in the U.S. Court of Appeals for the Ninth Circuit challenge the rule: *Alaska Community Action on Toxics v. EPA,* Case No. 21-70168 (Jan. 27, 2021) and *Yurok Tribe, et al. v. EPA,* Case No. 21-70670 (Mar. 19, 2021) were consolidated (order issued April 19, 2021).

ACAT is concerned about the exemptions for recycled products and decaBDE's use in replacement parts in automotive and aerospace vehicles, stating that TSCA requires EPA to eliminate exposure to the extent practical, and the exemptions and failure to regulate how products are disposed or recycled are unlawful. The proceedings in the consolidated cases are stayed until July 1, 2021, and the briefing schedule will be set at a future date.

Challenge to EPA's Science Transparency Rule

On January 6, 2021, EPA promulgated the final rule "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information," 86 Fed. Reg. 469 (Jan. 6, 2021) ("Final Rule"). This rule restricted the data EPA can use when taking regulatory action to protect human health and the environment.

The rule also:

- Requires EPA to identify, and make publicly available, any science underpinning "significant regulatory action" at the proposed or draft stage, to the extent practicable;
- "Reinforces the applicability" of peer review requirements for "pivotal science"; and
- Provides criteria for the EPA Administrator to exempt certain studies from the requirements in the rule. (https://chemicalwatch.com/198653/epa-publishes-final-rule-on-science-transparency)

On January 20, 2021, the Biden Administration's EO 13,990 impacted the two ongoing cases, *Environmental Defense Fund v. U.S. EPA*, No. 4:21-cv-00003-BMM, Docket No. 38 (D. Mont. Feb. 1, 2021); and *State of New York v. EPA*, Case No. 1 Civ. 462 (JPO), U.S. District Court for the Southern District of New York (filed Jan. 19, 2021).

In the latter case, a coalition of states and municipalities filed a complaint seeking a declaration that the final rule was in excess of EPA's statutory jurisdiction, not in accordance with law, and arbitrary and capricious, requesting vacatur of the Final Rule.

- On January 31, 2021, EPA filed an unopposed motion for vacatur and remand in the U.S. District Court for the District of Montana in the *Environmental Defense Fund* case.
- On February 1, 2021, the U.S. District Court for the District of Montana vacated and remanded to EPA's "strengthening transparency" rule ("Montana Order").
- On April 7, 2021, EPA submitted a proposed final rule: "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information; Vacatur Rule."
- Once the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget reviews the proposed rule, the court will reevaluate.

- As a result, on April 27, 2021, the state and municipal plaintiffs in *State of New York* filed a consent order with the U.S. District Court for the Southern District of New York staying the proceedings while EPA revises the rule in accordance with the Montana Order.

TSCA Section 21 Petition on Fluoride Chemicals in Drinking Water

On November 23, 2016, Food & Water Watch, Inc. and other citizens filed a TSCA Section 21 petition requesting that EPA issue a rule under TSCA Section 6(a) to "prohibit the purposeful addition of fluoridation chemicals to U.S. water supplies" on grounds that the ingestion of fluoride poses an unreasonable risk to humans.

On February 17, 2021, EPA denied the petition on the grounds that the petition failed to set forth a scientifically defensible basis to conclude that any person suffered neurotoxic harm as a result of exposure to fluoride through drinking water (or otherwise from fluoride exposure). EPA stated the Petition did not justify the regulation of fluoridation chemicals as a category and did not specify adequately the Section 6 rule. EPA also stated that the Petition failed to address conditions of use for the chemical substance as a whole and only requested EPA action on the fluoridation of drinking water. 82 Fed. Reg. 11878 (Feb. 27, 2017). (http://www.tscablog.com/epa-denies-tsca-section-21-petition-on-fluoride-chemicals-in-drinking-water?keywords=case)

- ***Food & Water Watch, Inc. v. EPA*, 291 F. pp. 3d 1033 (Dec. 21, 2017), Case No. 3:17-cv-02162-EMC**
  - The Petitioners challenged EPA's denial of the petition and filed suit in the U.S. District Court for the Northern District of California.
  - On December 21, 2017, the court denied EPA's motion to dismiss the judicial challenge and rejected EPA's interpretation that a Section 21 citizen petition must evaluate all conditions of use of a chemical substance in a TSCA Section 6(b) risk evaluation. Citizens are not obligated to address all conditions of use in a request for a risk evaluation. A manufacturer-requested risk evaluation may also be limited to particular conditions of use that are of interest to a manufacturer. 40 C.F.R. Section 702.37(b)(4). (http://www.tscablog.com/in-case-of-first-impression-court-rules-epa-wrongly-dismissed-citizen-group?keywords=case)
  - On June 8, 2020, the court held a Zoom trial.
    - The court heard expert testimony for the Plaintiffs that fluoride intake correlates with diminished thyroid productivity and discussed adverse effects on children's development, including lowered IQ. EPA's expert testimony argued that the data presented by plaintiffs suffers from inconsistencies, flawed methodologies, and biases.

(http://www.tscablog.com/entry/bench-trial-in-challenge-to-epas-denial-of-fluoride-petition-will-resume-on)

- The trial concluded on or about June 17, 2020. EPA's expert witnesses argued that there was a limited link between fluoride and adverse health outcomes and argued that EPA's decision to deny Plaintiff's Section 21 petition was correct because "robust science" warranted rejection of the petition.
  - Plaintiffs asserted in closing arguments that EPA failed to quantify what fluoride levels were dangerous to humans and argued for the necessity of developing additional data.
  - EPA responded that studies relied upon by Plaintiffs are limited by confounding variables, lack comparison groups and double-blind methodologies, and the reports cited contained inconsistencies. (http://www.tscablog.com/trial-concludes-in-challenge-to-epas-denial-of-fluoride-petition?keywords=case)

- On July 31, 2020, the Plaintiffs expressed their preference to file a new petition, stating that the petition will allow EPA to review all of the information presented at trial. EPA contended a new petition would be insufficient to reach a finding of unreasonable risk based upon the data presented at trial and requested a systematic review of the evidence, the raw data the Plaintiffs relied upon, and the data underlying certain risk calculations. The plaintiffs rejected these requests.

- Additional filings regarding EPA's March 18, 2020, supplemental notice of proposed rulemaking (SNPRM) regarding "Strengthening Transparency in Regulatory Science" were submitted to the court.

- On August 6, 2020, Judge Chen recommended that the Plaintiffs file a new Section 21. (http://www.tscablog.com/judge-suggests-new-tsca-section-21-petition-be-filed-regarding-fluoride-in?keywords=case)

- Since August 2020, the case has been held in abeyance, and hearings were scheduled for January 2021.

- EPA submitted a response to the Plaintiff's new administrative petition on January 19, 2021.

- On April 22, 2021, Judge Chen decided to put the case on hold while the court waits for additional scientific data to be released.

- This includes reports from the National Toxicology Program and the National Academy of Sciences, which will make final assessments of fluoride's potential toxicity to developing brains.
- The U.S. Public Health Service recommends communities add fluoride to drinking water to reduce tooth decay, but the decision to fluoridate water systems rests with state and local governments, according to EPA. (https://news.bloomberglaw.com/environment-and-energy/fluoride-toxicity-claims-on-hold-pending-research-court-decides?context=search&index=1)

➢ On May 11, 2021, the court granted Plaintiff's motion for leave to supplement their complaint/add supplemented pleadings.

EPA Failure to Disclose Information about New Chemical Substances

■ ***Environmental Defense Fund v. Wheeler*, No. 1:20-cv-762-EGS (D.D.C.)**

➢ EDF and a coalition of other NGOs filed suit in the U.S. District Court for the District of Columbia on March 18, 2020. EPA filed an answer on May 29, 2020. Plaintiffs filed an amended complaint on June 19, 2020.

➢ Brief statement of the case:

- This case is about TSCA and its implementing regulations. Plaintiffs allege that EPA did not comply with TSCA's various notice and disclosure requirements for more than 200 applications to manufacture chemicals, which establishes a pattern or practice of violation and failure to disclose.
- (1) Insufficient notice claims: EPA violated TSCA by not complying with requirements: (a) to publish notice of the receipt of certain applications in the *Federal Register* by the statutory deadline; and (b) to include specific information in the notices.
- (2) Incomplete Application Claims: EPA violated TSCA's mandate that EPA "ma[k]e available" all non-confidential information submitted with or in support of a new chemical application. (15 U.S.C. § 2604(d)(1); *see also* 40 C.F.R. § 720.95) Plaintiffs allege that in response to their requests, EPA provided applications that were unlawfully incomplete, as they did not include all the documents that Plaintiffs allege they are entitled to under TSCA.
- (3) EPA failed to comply with its own regulations (40 C.F.R. § 700.17(b)(1)) by failing to place the applications in an online docket at www.regulations.gov, as required.

- The parties are seeking to reach an agreement on some or all of the potential procedural issues in dispute and state that the issues in the case can be resolved by motions for summary judgment. (http://www.tscablog.com/suit-regarding-failure-to-disclose-information-about-new-chemicals-could-be?keywords=suit)

- They have been engaged in discussions since 2020 and propose to submit an updated case management statement following further discussions no later than **July 6, 2021**, though the parties may request an additional extension on this date.

Newly Filed

Request to Compel Chemours to Conduct Testing on Several Dozen Per- and Polyfluoroalkyl Substances (PFAS)

■ ***Center for Environmental Health et al v. EPA et al.***

- EPA denied a petition in January 2021 that would require Chemours to fund studies on 54 PFAS found in a watershed near its Fayetteville, North Carolina, facility.

- Petitioners, a coalition of six environmental groups, state that it is in EPA's authority under TSCA Section 4 to require Chemours to test these chemicals and fill in data gaps regarding potential adverse effects on communities in the watershed.

- Petitioners filed suit in the U.S. District Court of Appeals for the Northern District of California as a challenge to EPA's January 7, 2021, denial.

- Petitioners also filed a reconsideration request, which would resolve the issue outside of the court. (https://chemicalwatch.com/226309/ngos-ask-us-epa-to-reconsider-petition-for-pfas-tests)

Deadline for Part 2 of the Asbestos Risk Evaluation

■ ***Asbestos Disease Awareness Org. v. Regan*, U.S. District Court, Northern District of California, No. 21-03716, complaint filed May 18, 2021**

- Complaint filed by a coalition of health groups requesting that the court order EPA to complete the asbestos risk evaluation as required by TSCA and set enforceable deadlines for determining the scope of the risk evaluation, a draft and final evaluation, and award plaintiffs the cost of the suit and reasonable fees. (https://www.bloomberglaw.com/public/desktop/document/AsbestosDiseaseAwarenessOrganizationetalvReganetalDocketNo321cv03?1623780462)

- **Context:**
  - *Safer Chemicals, Healthy Families v. U.S. EPA*, 943 F.3d 397, 421 (9th Cir. 2019) held that EPA may not exclude legacy uses or associated disposal of substances from its risk evaluation. TSCA's "condition of use" definition includes future use of a substance and future disposals of a substance, regardless of whether substances are still manufactured for the particular use.
  - While asbestos is infrequently used for new insulation, EPA must consider the future disposal of asbestos insulation.
  - EPA divided the asbestos risk evaluation into two parts and reserved its review of legacy asbestos for Part 2 of its evaluation.
  - EPA issued Part 1 of its risk evaluation for asbestos on December 30, 2020.
    - EPA must propose a risk management rule for Part 1 of the risk evaluation by **early 2022** and a final rule in **early 2023**.
  - EPA stated its intent to conduct a Part 2 evaluation regarding legacy asbestos, but has not provided specifics on how it will be conducted or set a schedule for its completion.
  - In addition to the legacy uses of asbestos, EPA will look at the risks of legacy uses and associated disposals of chrysotile asbestos and uses of five other forms of the substance: crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite, and actinolite.

Petition for Review of the "Phenol, Isopropylated Phosphate (3:1) (PIP 3:1); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h)"

- ***Air-Conditioning, Heating, and Refrigeration Institute et al. v. EPA*, Case No. 21-1082 (filed Mar. 4, 2021) (D.C. Cir.)**
  - Several trade associations that represent heating, ventilation, air-conditioning, and refrigeration (HVACR), home-appliance, consumer technology industries, electrical equipment and medical imaging, and manufacturers from industrial sectors, have filed a Petition for review of EPA's adoption of the final rule, "Phenol, Isopropylated Phosphate (3:1) (PIP 3:1); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h)" on January 21, 2021. (https://www.epa.gov/sites/production/files/2021-03/documents/tsca_dc_cir._21-1082.pdf)

  - The rule prohibits the processing and distribution in commerce of PIP (3:1) -- a plasticizer, flame retardant, anti-wear additive, and anti-compressibility additive -- with exceptions for certain uses, including those in certain aeronautic and military applications. The final rule also requires that manufacturers, processors, and

distributors of PIP (3:1) and products containing PIP (3:1) notify customers of TSCA's restrictions. In addition, the final rule prohibits releases to water. This rule set a compliance date of **March 8, 2021,** to prohibit the use of PIP (3:1) in processing and distribution in articles.

- EPA announced on March 8, 2021, that it would re-examine the rule in accordance with EO 13,990, issued by the Biden Administration, and opened a 60-day public comment period regarding, among other issues, newly raised compliance issues associated with the final rule on PIP 3:1, including the compliance dates for certain regulated articles.

- On March 8, 2021, EPA also issued a temporary 180-day "No Action Assurance" that EPA will exercise its enforcement discretion regarding the prohibitions on processing and distribution of PIP (3:1) for use in articles, and articles to which PIP (3:1) is added under 40 C.F.R. Section (a)(1). EPA states its belief that this is sufficient time to begin finding suitable alternatives or replacing components in articles. The No Action Assurance also extends to the requirement under 40 C.F.R. 751.407(d)(2) that records required under 40 C.F.R. Section 751.407(d)(1) must include a statement that the PIP (3:1) or the PIP (3:1)-containing articles are in compliance with 40 C.F.R. Section 751.407(a)(1) for articles covered by the enforcement discretion pertaining to 40 C.F.R. Section 751.407(a)(1).
  - The No Action Assurance does not change compliance requirements on the following after March 8, 2021:
    - Releases to water under 40 C.F.R. Section 751.407(c).
    - Downstream notification requirements found at 40 C.F.R. Section 751.407(e), which provide immediate protection from water releases.
    - The recordkeeping requirements of 40 C.F.R. Section 751.407(d) apply to persons who process or distribute in commerce PIP (3:1) or PIP (3:1)-containing articles, including those persons who would otherwise be prohibited from processing or distributing PIP (3:1) under 40 C.F.R. Section 751.407(a)(1).

- Dr. Michal Freedhoff submitted a request to the Office of Enforcement and Compliance Assurance for No Action Assurance on these PIP (3:1) rules that outlined arguments and comments from the stakeholders that are also involved in the litigation.
  - Stakeholders informed EPA that the prohibitions on processing and distribution of PIP (3:1) could impact articles used in a wide variety of electronics, such as cell phones, robotics used to manufacture

semiconductors, and equipment used to move COVID-19 vaccines and keep them at appropriate temperatures.

- They note the complexity of international supply chains and issues with locating the presence of and finding alternatives to PIP (3:1). As articles containing PIP (3:1) may be imported, it is difficult for processors and distributors to determine whether they contain PIP (3:1).
- EPA notes that stakeholders did not engage sufficiently with EPA during the comment period before forming the final rule, stating that stakeholders were not aware of its presence in their supply chains or were unaware the articles could be regulated under TSCA.
- The extension of the compliance deadline will avoid significant disruption in the supply chain for a variety of articles and avoid a broad disruptive impact, as was not the intent of the rule. It would not benefit the general public for these entities to cease immediately the processing and distribution of articles. EPA established a compliance deadline that cannot be complied with feasibly as intended.

➢ During the comment period, EPA will assess the implementation deadlines for the prohibition of processing and distribution of PIP (3:1). EPA will also determine whether to make other revisions to the rule, in addition to deadlines, after the public comment period.

➢ As a result, on April 1, 2021, EPA filed an unopposed motion to hold the case in abeyance. The D.C. Circuit granted EPA's motion on April 6, 2021. Regarding the case, the Petition for Review did not include the trade group's potential arguments, though the delay of enforcement likely will delay in part the case pending EPA's review.

- The motion cites EO 13,990, noting EPA's intent to evaluate the rule, accept public comments, including from Petitioners, and the No Action Assurance.
- The court's order holding the case in abeyance directs parties to file motions to govern future proceedings by **October 7, 2021**.

Related Cases

TSCA Citizen's Suit

■ ***United States ex rel. Kasowitz Benson Torres LLP v. BASF Corp.*, 929 F.3d 721 (D.C. Cir. 2019)**

➢ The court upheld the dismissal of attorneys' claims that chemical manufacturers violated the False Claims Act (FCA). EPA assessed penalties under TSCA for

failing to report substantial risk information. There was no FCA obligation that the manufacturers avoided. EPA's interest in risk information is not a property interest; EPA's only interest in the information is regulatory. The payment of the penalty to EPA was proper.

EPA's "Delay Rule" in Implementing Formaldehyde Emissions Standards

- ***Sierra Club v. Pruitt*, 293 F. Supp. 3d 1050 (U.S. District Court for the Northern District of California) (Feb. 16, 2018)**
  - EPA promulgated a rule to delay its implementation of formaldehyde emission standards under the Formaldehyde Standards in Composite Wood Products Act, 15 U.S.C. Section 2697, 2010 law codified under TSCA by three months, and set the manufacturing and emission standards compliance dates for more than three years after the deadline required by the Formaldehyde Act. 82 Fed. Reg. 44533 (Sept. 25, 2017) (the "Delay Rule").

  - The year-long delay exceeded EPA's statutory authority under the act. The court vacated the delay rule, requiring EPA to determine an implementation schedule.