

*Section of Environment, Energy, and Resources
American Bar Association*

Environment, Energy, and Resources Law: The Year in Review 2022

Chapter H · Pesticides, Chemical Regulation, and Right-to-Know

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Chapter H: PESTICIDES, CHEMICAL REGULATION, AND RIGHT-TO-KNOW 2022 Annual Report¹

In 2022 the Environmental Protection Agency (EPA) made progress in addressing some of its most challenging responsibilities under the Toxic Substances Control Act (TSCA) and the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). This includes completing its rework of TSCA risk evaluations conducted under the Trump Administration and its first proposed risk management rule under the amended statute, acknowledging and starting to address the delays in reviewing new chemicals, developing a strategy to address the backlog of endangered species impact review obligations for pesticides, and nearing the end of the first cycle of pesticide registration reviews. EPA's chemicals office also pursued a range of actions addressing per- and polyfluoroalkyl substances (PFAS), consistent with the Agency's 2021 *PFAS Strategic Roadmap*² and updated *Roadmap* goals.³

I. TOXIC SUBSTANCES CONTROL ACT (TSCA)

A. *New Chemicals Program and Significant New Use Rules*

1. New Chemical Review

The longstanding backlog of TSCA section 5 premanufacture notice (PMN) reviews continued to grow in 2022.⁴ EPA cited inadequate funding and resources to meet the expanded new chemical review requirements of the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act)⁵ as the main reasons for the backlog.⁶ The number of new PMNs and Low Volume Exemptions (LVE) submitted was down to 514, continuing a significant downward trend since the Lautenberg Amendments.⁷

¹L. Margaret Barry, Lawrence Culleen, Arnold & Porter; Lynn Bergeson, Richard Engler, Ph.D., Carla Hutton, and Todd Stedeford, Ph.D., Bergeson & Campbell, P.C.; Sarah A. Kettenmann, Beveridge & Diamond, P.C.; Michael Boucher, Amy Symonds, and Siyi Shen, Crowell & Moring LLP; Tom Berger and James Votaw, Keller and Heckman LLP; Allison In, Andrew Stewart and Joseph Zaleski, Sidley Austin LLP; Sara Beth Watson, Steptoe & Johnson LLP; Ariel Neumann, Verdant Law, PLLC.; and Keith Matthews, Wiley Rein LLP.

²U.S. ENVTL. PROT. AGENCY, [PFAS STRATEGIC ROADMAP: EPA'S COMMITMENTS TO ACTION 2021-2024](#) (2021).

³U.S. ENVTL. PROT. AGENCY, [EPA'S PFAS STRATEGIC ROADMAP: A YEAR OF PROGRESS](#) (2022)

⁴[Statistics for the New Chemicals Review Program under TSCA](#), U.S. ENVTL. PROT. AGENCY (last updated Jan. 6, 2023) (showing 398 pending notices at year end).

⁵Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016).

⁶*See, e.g.*, U.S. ENVTL. PROT. AGENCY, [TSCA NEW CHEMICAL ENGINEERING OUTREACH INITIATIVE TO INCREASE TRANSPARENCY AND REDUCE PAPERWORK](#), (2022); The Honorable Michal Freedhoff, Ph.D., Assistant Admin., Off. Of Chem. Safety and Pollution Prevention, U.S. Env'tl. Prot. Agency, Statement Before the U.S. Senate Committee on Environment and Public Works 17 (June 22, 2022) (transcript available at [epw.senate.gov](#)).

⁷[Statistics for the New Chemicals Review Program under TSCA](#), U.S. ENVTL. PROT. AGENCY (last visited Mar. 18, 2023) (describing a 50% drop in new submissions).

EPA took a number of program implementation actions to help address the backlog, including public webinars highlighting common submitter errors that require EPA to rework risk assessments,⁸ and initiatives to streamline review of PMNs for bio-based or waste-derived chemicals,⁹ and mixed-metal oxides (MMOs), which are commonly used in the manufacture of electrical vehicle batteries.¹⁰ The Agency also launched a long term research initiative to modernize EPA’s approach to new chemical risk assessments.¹¹ It is intended to include developing and implementing New Approach Methodologies (NAMs), updating approaches to using structural activity relationships (read-across) in risk assessment, and augmenting the range of models used in risk assessment to predict physical-chemical properties, fate, transport, exposure, and toxicokinetics of new chemicals.

The Agency made a number of policy changes that will impact new chemical review. EPA expanded the scope of individual risk assessments by discontinuing an historic policy of omitting small quantities of chemicals released to air or from landfills from its exposure and risk modeling.¹² EPA revoked a 1980 policy that has allowed manufacturers (and their successors) to correct their submissions made to identify chemicals in commerce for the initial TSCA Inventory in certain excusable circumstances, such as correcting chemical identities based on information obtained by new technology.¹³

EPA also issued two compliance advisories changing or clarifying interpretation of TSCA requirements. First, EPA issued a series of statements clarifying that chemical species incidentally produced in connection with fluorinating high density polyethylene (HDPE) barrels and not separated from the barrels were “byproducts,”¹⁴ and were not exempt as “impurities” or on any other basis under the Significant New Use Rule (SNUR) general provisions.¹⁵ Indeed, EPA commenced an administrative and later a civil enforcement action against a fluorinated barrel manufacturer for violating the principal PFAS categorical SNUR, seeking an injunction from further manufacture of the PFAS

⁸See [TSCA New Chemical Engineering Initiative to Increase Transparency and Reduce Rework](#), U.S. ENVTL. PROT. AGENCY (last visited Mar. 18, 2023).

⁹[Integrated Approach for Biofuel Premanufacture Notices](#), U.S. ENVTL. PROT. AGENCY (last visited Mar. 18, 2023).

¹⁰Press Release, U.S. Env’tl. Prot. Agency, [EPA Announces Innovative Effort to Bring New Chemicals Used in Electric Vehicle, Semiconductor, Clean Energy Sectors to Market](#) (Oct. 5, 2022); see also [Integrated Approach for Mixed Metal Oxides New Chemicals Review](#), U.S. Env’tl. Prot. Agency (last visited Mar. 18, 2023).

¹¹Toxic Substances Control Act (TSCA) Collaborative Research Program to Support New Chemical Reviews; Notice of Public Meeting and Request for Comments, [87 Fed. Reg. 10,784](#) (Feb. 25, 2022).

¹²Press Release, U.S. Env’tl. Prot. Agency, [EPA Updates Policy to Include All Exposures in Review of New Chemicals Under TSCA](#) (Aug. 22, 2022).

¹³Revocation of 1980 Guidelines and Final Opportunity To Submit a Request To Correct the Initial Report Filed for the Original Toxic Substances Control Act (TSCA) Inventory of Chemical Substances, [87 Fed. Reg. 10,781](#) (May 31, 2022).

¹⁴[Memorandum from Tala Henry, Ph.D., Dpty. Dir., Off. of Pollution Prevention and Toxics, U.S. Env’tl. Prot. Agency, to Manufacturers, Processors, Distributors, Users, and Those that Dispose of Fluorinated Polyolefin Containers](#) (Mar. 24, 2022); see also, Press Release, U.S. Env’tl. Prot. Agency, [EPA Releases Data on Leaching of PFAS in Fluorinated Packaging](#) (Sep. 8, 2022).

¹⁵40 C.F.R. § 721.45(e) (2022).

“byproducts.”¹⁶ EPA’s enforcement actions were followed by a citizen suit by environmental organizations under TSCA section 20(a)¹⁷ seeking similar injunctive relief against the barrel manufacturer.¹⁸ While this issue arose in the context of a specific PFAS SNUR, the general principle that such coincidentally produced substances may trigger SNUR notification requirements may have broader implications for a wide range of companies incidentally manufacturing or processing SNUR chemicals.

Without acknowledging any change in position, EPA also issued a compliance advisory confirming its current view that mixed metal oxides are viewed as single chemical entities and not mixtures for TSCA Inventory purposes.¹⁹ This statement of enforcement position arises from a longstanding controversy over the proper TSCA Inventory nomenclature for ceramics (such as many MMOs), and whether they may be represented on the Inventory as mixtures of individual metal oxides under a categorical Chemical Abstracts Service registration number (CASRN) as suggested by past EPA guidance, or must be listed individually on the Inventory.²⁰

Under EPA’s 2021 PFAS LVE Stewardship Program, companies voluntarily withdrew an additional twenty-two LVEs for short chain PFAS substances.²¹ A coalition of environmental organizations petitioned EPA to revoke approximately 600 remaining PFAS LVEs and low release and low exposure exemptions (LoREX).²²

Litigation continues between environmental NGOs and the Agency concerning the sufficiency and timing of EPA’s public disclosure of non-confidential section 5 new chemical notices.²³ EPA’s motion for judgment on the pleadings for lack of standing remains pending.²⁴ However, in the interim, EPA reported that it gathered and published non-confidential versions of all section 5 notices submitted in 2014 or later, and 3,900

¹⁶See Complaint, U.S. v. Inhance Technologies LLC, No. 2:22-cv-05055 (E.D. Pa. Dec. 19, 2022).

¹⁷15 U.S.C. § 2619(a).

¹⁸Complaint, Ctr. for Envntl. Health v. Inhance Technologies USA, No. 1:22-cv-03819, (D.D.C. Dec. 27, 2022).

¹⁹U.S. ENVTL. PROT. AGENCY, [COMPLIANCE ADVISORY: APPLICABILITY OF THE TOXIC SUBSTANCES CONTROL ACT TO MIXED METAL OXIDES, WHICH INCLUDE CATHODE ACTIVE MATERIALS \(CAMS\) AND MODIFIED CAMS](#) (2022); see also [Integrated Approach for Mixed Metal Oxides New Chemicals Review](#), U.S. ENVTL. PROT. AGENCY (last visited Mar. 18, 2022).

²⁰Compare, e.g., Inventory Reporting Regulations, [42 Fed. Reg. 64,572](#), 64,585 (Dec. 23, 1977) (“The Administrator agrees ceramics, frits, and cements ... are mixtures under TSCA”), with [TSCA Inventory; Clarification for Chemical Identification Describing Statutory Mixtures, Including Ceramic Materials, Cements, and Frits for TSCA Inventory Purposes](#), OFF. OF CHEM. SAFETY AND POLLUTION PREVENTION (last visited Mar. 18, 2023).

²¹[PFAS Low Volume Exemption Stewardship Program](#), U.S. ENVTL. PROT. AGENCY (last visited Mar. 18, 2023).

²²[Pet. to the U.S. EPA to revoke the approval of approximately 600 per- and polyfluoroalkyl substances \(PFAS\) that were granted through low-volume or low-release and low-exposure exemptions to the premanufacture notice requirements of the Toxic Substances Control Act](#), Earthjustice (submitted Oct. 13, 2022).

²³Complaint, [Envntl. Defense Fund v. Wheeler](#), No. 1:20-cv-762-EGS (D.D.C. Mar. 18, 2020).

²⁴Defendants’ Motion for Judgment on the Pleadings, [Envntl. Defense Fund v. Regan](#), No. 1:20-cv-762 (EGS) (D.C. Cir. June 14, 2022).

section 8(e) substantial risk notices submitted in the period 2019 through late 2021 in its web-based [ChemView application](#).²⁵

An industry coalition filed a petition under the Administrative Procedure Act seeking specific revisions to the 40 C.F.R. Part 720 Premanufacture Notice regulations intended to streamline and improve the PMN review process, and to conform those rules to the requirements of the Lautenberg Act amendments to section 5 of TSCA.²⁶

2. Significant New Use Rules

EPA finalized long-pending changes to the SNUR general provisions.²⁷ Among other things, the amendments require employers to establish and use all feasible engineering and administrative controls to prevent occupational dermal and inhalation exposures before using personal protective equipment (PPE), update the Part B hazard communication requirements to align with current OSHA regulations and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), and update SNUR respirator selection procedures to align with current OSHA and NIOSH regulations. The rule and preamble also address control of releases to water. Industry now may consider the effect of wastewater treatment to meet SNUR discharge concentration limitations in some cases. And the preamble clarifies EPA's enforcement position concerning which inadvertent chemical releases are nevertheless deemed to be "predictable or purposeful" and therefore may trigger Significant New Use Notice (SNUN) requirements. EPA explained its view that "non-routine releases to water that are not due to emergency conditions are deemed "predictable or purposeful"²⁸ and not exempt.

The Agency initiated a series of SNURs to support other TSCA actions. First, complementing the development of risk management rules under section 6 for High-priority chemicals completing the risk evaluation process,²⁹ EPA signaled that it was preparing SNURs that would require submission of a SNUN before one could engage in any use of a High-priority chemical that had not been evaluated during the corresponding risk evaluation process.³⁰ EPA plans to propose these SNURs for groups of High-priority

²⁵Press Release, U.S. Env'tl. Prot. Agency, [EPA Publishes Thousands of Additional TSCA Risk, New Chemicals Submissions, Commits to Near Real-Time Publication Going Forward](#) (Nov 21, 2022).

²⁶Pet. for Rulemaking Pursuant to Section 553 of the Administrative Procedure Act Concerning Revisions to the Premanufacture Notice Regulations Under Section 5 of the Toxic Substances Control Act (submitted Nov. 11, 2022).

²⁷Significant New Uses of Chemical Substances; Updates to the Hazard Communication Program and Regulatory Framework; Minor Amendments to Reporting Requirements for Premanufacture Notices, [87 Fed. Reg. 39,756](#) (Jul. 5, 2022) (to be codified at 40 C.F.R. pts. 720, 721, 723).

²⁸*Id.* at 39,756, 39,761 (citing 40 C.F.R. § 721.90).

²⁹See [40 C.F.R. § 702.49\(c\)](#) (2022).

³⁰See [Other Chemical Substances Undergoing TSCA Section 6 Risk Evaluation; Significant New Use Rule for Certain Non-ongoing Uses](#), OFF. OF CHEM. SAFETY AND POLLUTION PREVENTION (last visited Mar. 18, 2023).

substances, including for phthalates,³¹ flame retardants,³² and certain solvents.³³ Complementing EPA’s broader PFAS Strategic Roadmap, EPA initiated development of SNURs for certain PFAS no longer in active commerce and listed as “Inactive” on the TSCA Inventory.³⁴ EPA proposed SNURs for thirty-five PFAS for which TSCA section 5 consent orders had been issued following PMN review, but for which EPA had never issued a corresponding SNUR.³⁵ The SNURs would designate as a significant new use any use not described in the corresponding PMN or 2020 Chemical Data Reporting (CDR) report and, where not contraindicated by CDR reporting, annual manufacturing greater than 2,500 pounds.³⁶ In an atypical move, EPA also effectively proposed the addition of more protective exposure control requirements to chemicals already subject to a consent order by adding control terms in the SNURs that are not specified in the underlying orders, and making inapplicable the [standard SNUR notification exemption for persons operating under a consent order](#).³⁷

B. *Regulation of Existing Chemicals: Prioritization, Risk Evaluation, and Risk Management*

1. EPA-Initiated and Manufacturer-Requested Risk Evaluations

EPA’s existing chemicals regulatory efforts in 2022 continued to be focused on addressing the perceived shortcomings of risk evaluation decision-making completed during the Trump administration. Key features of a new approach were announced in 2021³⁸ and included assuming no personal protective equipment is used when assessing exposure (the “baseline scenario”), conducting a screening assessment of general population exposures to air and water emissions in fenceline communities using modeling,³⁹ and making single risk determinations for High-priority chemicals covering all uses rather than the use-by-use risk determinations used by the Trump Administration. EPA reopened the first ten risk evaluations completed by the Trump administration in 2020 and 2021 to make new risk determinations using these new principles. EPA issued a draft

³¹See [Phthalates; Significant New Use Rule for Certain Non-Ongoing Uses](#), OFF. OF CHEM. SAFETY AND POLLUTION PREVENTION (last visited Mar. 18, 2023).

³²See [Flame Retardants; Significant New Use Rule for Certain Non-Ongoing Uses](#), OFF. OF CHEM. SAFETY AND POLLUTION PREVENTION (last visited Mar. 18, 2023).

³³See [Certain Solvents; Significant New Use Rule for Certain Non-Ongoing Uses](#), OFF. OF CHEM. SAFETY AND POLLUTION PREVENTION (last visited Mar. 18, 2023).

³⁴[Inactive Inventory Per- and Polyfluoro Alkyl Substances \(PFAS\) Significant New Use Rule](#), OFF. OF CHEM. SAFETY AND POLLUTION PREVENTION (last visited Mar. 18, 2023).

³⁵Significant New Use Rules on Certain Chemical Substances (22-1.5e), [87 Fed. Reg. 74,072](#) (proposed Dec. 2, 2022) (to be codified at 40 C.F.R. pt. 721).

³⁶*Id.* at 74,074.

³⁷*Id.* (citing [40 C.F.R. § 721.45\(i\)](#) (2022)).

³⁸Press Release, U.S. Env’tl. Prot. Agency, [EPA Announces Path Forward for TSCA Chemical Risk Evaluations](#) (June 30, 2021).

³⁹U.S. ENVTL. PROT. AGENCY, [DRAFT TSCA SCREENING LEVEL APPROACH FOR ASSESSING AMBIENT AIR AND WATER EXPOSURES TO FENCELINE COMMUNITIES: VERSION 1.0](#) (2022); Press Release, U.S. Env’tl. Prot. Agency, [EPA Releases Screening Methodology to Evaluate Chemical Exposures and Risks to Fenceline Communities](#) (Jan. 21, 2022).

revised risk determinations for trichloroethylene (TCE)⁴⁰ and completed revised risk evaluations for methylene chloride,⁴¹ cyclic aliphatic bromide cluster (HBCD),⁴² Pigment Violet 29,⁴³ carbon tetrachloride,⁴⁴ perchloroethylene (PCE),⁴⁵ 1-Bromopropane,⁴⁶ and n-Methylpyrrolidone (NMP).⁴⁷ Final risk evaluations were due in December 2022 for each of the twenty chemicals designated as High-priority in December 2019, but EPA did not issue a draft risk evaluation for any of these. Work on these twenty evaluations continued to be significantly delayed while EPA focused resources on reworking risk evaluations for the first ten chemicals.

EPA for the first time proposed a section 6(a) risk management rule for a High-priority chemical that had been determined to present an unreasonable risk through the section 6(b) risk evaluation process – chrysotile asbestos.⁴⁸ EPA proposed to address risks from the few remaining uses of chrysotile asbestos with a ban phased in over six months to two years, depending on the use. EPA considered and rejected controlling risk with new occupational exposure limits established under TSCA authority (Existing Chemical Exposure Limits or ECELs). Notably, EPA’s ECELs for asbestos would have been far more stringent than the Occupational Safety and Health Administration’s (OSHA) corresponding permissible exposure limit (PEL). As required by TSCA section 9, EPA also considered whether chrysotile asbestos risks could be adequately addressed by other federal agencies or under other statutes administered by EPA. EPA concluded that OSHA standards would be inadequate because they must be technologically and economically feasible, while TSCA standards do not. Similarly, EPA determined that other EPA authorities outside of TSCA would not be adequate because they do not address occupational exposure.⁴⁹ Development of the proposed rule also was notable because EPA conducted environmental justice consultations in compliance with Executive Orders 12898

⁴⁰Trichloroethylene (TCE); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment, [87 Fed. Reg. 40,520](#) (July 7, 2022).

⁴¹Methylene Chloride; Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability, [87 Fed. Reg. 67,901](#) (Nov. 10, 2022).

⁴²Cyclic Aliphatic Bromide Cluster (HBCD); Revision to the Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability, [87 Fed. Reg. 38,747](#) (June 29, 2022).

⁴³Colour Index Pigment Violet 29 (PV29); Revision to the Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability, [87 Fed. Reg. 54,491](#) (Sept. 8, 2022).

⁴⁴Carbon Tetrachloride; Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability, [87 Fed. Reg. 79,303](#) (Dec. 27, 2022).

⁴⁵Perchloroethylene (PCE); Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability, [87 Fed. Reg. 76,481](#) (Dec. 14, 2022).

⁴⁶1-Bromopropane (1-BP); Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability, [87 Fed. Reg. 77,603](#) (Dec. 19, 2022).

⁴⁷n-Methylpyrrolidone (NMP); Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability, [87 Fed. Reg. 77,596](#) (Dec. 19, 2022).

⁴⁸Asbestos Part 1: Chrysotile Asbestos; Regulation of Certain Conditions of Use Under Section 6(a) of the Toxic Substances Control Act (TSCA), [87 Fed. Reg. 21,706](#) (proposed Apr. 12, 2022) (to be codified at 40 C.F.R. pt. 751).

⁴⁹*See id.* at 21,733.

and 14008,⁵⁰ including outreach to communities deemed to face greater risk of exposure to asbestos.

The proposed chrysotile asbestos rule and underlying risk determination did not address potential risks associated with ongoing use (and future disposal) of asbestos and asbestos impurities in products, such as construction materials. As required by the 2019 decision in *Safer Chemicals, Healthy Families v. EPA*,⁵¹ EPA initiated a separate risk evaluation for asbestos focused only on these legacy uses, including publishing a [final risk evaluation scope](#).⁵²

EPA also published the final risk evaluation scope for the manufacturer-requested risk evaluation of octamethylcyclotetra-siloxane (D4).⁵³ The final scope includes additional conditions of use identified by EPA and not by the manufacturers, and reflects EPA's intent to assess risk without considering PPE and consider general population exposures for fence-line communities arising from facility air emissions and water discharges.⁵⁴

2. Persistent, Bioaccumulative, and Toxic (PBT) Chemicals

Similar to the concerns with Trump Administration risk evaluation decisions for High-priority chemicals, the Biden administration also is concerned with perceived shortcomings with of the Trump Administration's risk management decisions under TSCA section 6(h) for five chemicals deemed to be persistent, bioaccumulative, and toxic (PBTs). The EPA confirmed its intent to revise the current partial bans for each of the five PBTs to further reduce exposures to the extent practicable.⁵⁵ EPA also further extended the compliance date to October 31, 2024 for the ban on manufacture and distribution of phenol, isopropylated phosphate (PIP) (3:1) for use in articles and PIP (3:1)-containing articles. The further extension was deemed necessary to give manufacturers additional time to transition to substitute materials (or demonstrate the need for even further extensions), and to avoid significant disruption in supply chains in the interim.⁵⁶

C. Test Order Activity and Litigation

EPA issued a second round of TSCA section 4(a)(2) test orders for eight chemicals undergoing section 6(b) EPA-initiated risk evaluation, focused primarily on toxicity testing

⁵⁰Exec. Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, [59 Fed. Reg. 7629](#) (Feb. 16, 1994); Exec. Order 14008, Tackling the Climate Crisis at Home and Abroad, [86 Fed. Reg. 7619](#) (Feb. 1, 2021).

⁵¹[943 F.3d 397, 406 \(9th Cir. 2019\)](#).

⁵²Asbestos Part 2 Supplemental Evaluation Including Legacy Uses and Associated Disposals of Asbestos; Final Scope of the Risk Evaluation To Be Conducted Under the Toxic Substances Control Act; Notice of Availability, [87 Fed. Reg. 38,746](#) (June 29, 2022).

⁵³See [Supporting Documents for Manufacturer Requested Risk Evaluation for Octamethylcyclotetra-siloxane \(D4\)](#), U.S. ENVTL. PROT. AGENCY (last visited Mar. 18, 2023).

⁵⁴U.S. ENVTL. PROT. AGENCY, [FINAL SCOPE OF THE RISK EVALUATION FOR OCTAMETHYLCYCLOTETRA-SILOXANE \(CYCLOTETRASILOXANE, 2,2,4,4,6,6,8,8-OCTAMETHYL-\)](#) 9, 52 (2022).

⁵⁵Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Phenol, Isopropylated Phosphate (3:1); Further Compliance Date Extension, [87 Fed. Reg. 12,875](#) (Mar. 8, 2022) (to be codified at 40 C.F.R. pt. 751).

⁵⁶*Id.* at 12,876, 12,884.

on sediment-dwelling organisms (*i.e.*, chironomids) and terrestrial organisms (*i.e.*, earthworms and birds).⁵⁷ EPA has issued no test orders for eleven of the twenty substances currently under review.

Three of the new orders were challenged. The Vinyl Institute, Inc. filed suit in the U.S. Court of Appeals for the District of Columbia Circuit for review of the test order for 1,1,2-trichloroethane, challenging the sufficiency of the Agency's assessment of need, required by TSCA section 4(a)(3), for an avian reproduction test.⁵⁸ An industry consortium's challenge to the trans-1,2-dichloroethylene (TDCE) test order also centered on the sufficiency of EPA's demonstration of need for the order. In that case, the consortium had proposed to submit existing data in lieu of new testing to address a data gap identified by EPA. It filed suit to preserve its right to judicial review when EPA was unable to reach a conclusion about the adequacy of that data within the 60-day period for filing a petition for review.⁵⁹ Lanxess sought review of EPA's second test order for o-dichlorobenzene (ODCB), in part because it was not subject to the Order because TSCA section 4(b)(3)(C) limited EPA's authority to require testing to persons currently manufacturing or processing a substance or intending to do so, and the petitioner had ceased manufacture and processing ODCB before the order was issued.⁶⁰ EPA subsequently agreed to withdraw the order as against Lanxess on other grounds,⁶¹ and the case was dismissed without a decision on the legal defense. Subsequent to the suit, the Agency issued guidance explicitly confirming its legal position, reflected in the several orders, that it may properly issue TSCA section 4 orders to *former* manufacturers and processors of a substance.⁶²

In connection with its 2021 National PFAS Testing Strategy,⁶³ EPA issued the first of twenty-four anticipated TSCA section 4(a)(2)⁶⁴ test orders for certain PFAS chemicals selected as representative of a category of PFAS chemicals with similar structure and physical properties.⁶⁵ The first order was directed to EPA-identified manufacturers of 6:2 fluorotelomer sulfonamide betaine (6:2 FTSB) and requires respondents to conduct a series of tests over seven years, including tests establishing certain physical properties,

⁵⁷Press Release, U.S. Env'tl. Prot. Agency, [EPA Issues Additional Test Orders to Support Risk Evaluations of Eight Chemicals under TSCA](#) (Mar. 24, 2022).

⁵⁸Petitioner's Statement of Issues, *The Vinyl Institute v. EPA*, No. 22-1089 (D.C. Cir. June 23, 2022).

⁵⁹TDCE Consortium v. EPA, No. 22-1216 (D.C. Cir.); *see also* Press Release, TDCE Consortium, Public Statement of TDCE Consortium Regarding Filing of Lawsuit Challenging TSCA Section 4 Test Order (Aug. 24, 2022).

⁶⁰Petitioner's Concise Summary of the Case, *Lanxess Corp. v. EPA*, No. 22-2036, at 2 (3d Cir. Jun. 14, 2022).

⁶¹*See* MICHAL FREEDHOFF, ASSISTANT ADMIN., OFF. OF CHEM. SAFETY AND POLLUTION PREVENTION, U.S. ENVTL. PROT. AGENCY, [REMOVAL OF CERTAIN COMPANIES FROM SEVEN TSCA SECTION 4\(A\)\(2\) ORDERS ISSUED IN 2022 \(CLARIFICATION\)](#) (2022).

⁶²MICHAL FREEDHOFF, ASSISTANTT ADMIN., OFF. OF CHEM. SAFETY AND POLLUTION PREVENTION, U.S. ENVTL. PROT. AGENCY, [POLICIES REGARDING MANUFACTURERS AND PROCESSORS SUBJECT TO TSCA SECTION 4\(A\) TESTING](#) (2022).

⁶³U.S. ENVTL. PROT. AGENCY, [NATIONAL PFAS TESTING STRATEGY: IDENTIFICATION OF CANDIDATE PER- AND POLY-FLUOROALKYL SUBSTANCES \(PFAS\) FOR TESTING](#) (2021).

⁶⁴15 U.S.C. § 2603(a)(2).

⁶⁵[Order Under Section 4\(a\)\(2\) of the Toxic Substances Control Act](#), EPA-HQ-OPPT-2021-0897 (U.S. Env'tl. Prot. Agency Jun. 6, 2022) (requiring testing of 6:2 Fluorotelomer sulfonamide betaine).

biosolubility, toxicokinetics, and inhalation toxicity.⁶⁶ One of the respondents, National Foam, Inc., petitioned for review of the order in the U.S. Court of Appeals for the District of Columbia Circuit on the novel grounds that it processed the chemical only as part of a mixture and never processed 6:2 FTSB as a separate substance.⁶⁷

D. TSCA Section 8 Information Collection Rules

EPA proposed a TSCA section 8(a) one-time reporting rule for asbestos covering manufacture, import and processing over the prior four years, including asbestos in the form of an impurity, in mixtures and in articles.⁶⁸

The Agency convened a Small Business Advocacy Review Panel and prepared an Initial Regulatory Flexibility Analysis (IRFA) more fully assessing the likely costs of implementing its 2021 proposed TSCA section 8(a)(7) PFAS reporting rule.⁶⁹ That rule, required by the National Defense Authorization Act for Fiscal Year 2020 (FY2020 NDAA),⁷⁰ would require all manufacturers and importers of PFAS in any amount, at any concentration, in any product, in any year since 2011, to report a wide range of information on chemical identity, manufacture, processing, use, disposal, environmental and health effects, and worker exposure, by site, and by year back to 2011.⁷¹ EPA's revised cost estimate for the program, as reflected in the IRFA, rose dramatically from \$10.8 million to \$875 million.⁷²

E. Other TSCA Regulatory Developments

EPA issued a supplemental proposed rule to increase fees for industry and EPA actions under TSCA sections 4, 5, 6, and 14.⁷³ EPA proposed TSCA fee increases significantly greater than increases proposed in the last days of the Trump Administration. The large increase is derived from a new, much higher estimate of the total annual cost to EPA administering TSCA sections 4, 5, 6, and 14: \$181 million, which is more than twice the \$87.5 million estimated by EPA in 2021.⁷⁴ If the proposed rule is adopted, fees for submitting a PMN, for example, would increase from \$19,020 to \$45,000, while fees

⁶⁶*Id.*

⁶⁷Petition for Review, Nat'l Foam v. EPA, No. 22-1208 (D.C. Cir. Aug. 15, 2022).

⁶⁸Asbestos; Reporting and Recordkeeping Requirements Under the Toxic Substances Control Act (TSCA), [87 Fed. Reg. 27,060](#) (proposed May 6, 2022) (to be codified at 40 C.F.R. pt. 704).

⁶⁹TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Notice of Data Availability and Request for Comment, [87 Fed. Reg. 72,439](#) (proposed Nov. 25, 2022) (to be codified at 40 C.F.R. pt. 705).

⁷⁰[National Defense Authorization Act for Fiscal Year 2020](#), Pub. L. 116-92, § 7351, 133 Stat. 1198, 2289 (2019).

⁷¹TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, [86 Fed. Reg. 33,926](#) (proposed Jun. 28, 2021) (to be codified at 40 C.F.R. pt. 705).

⁷²TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances; Notice of Data Availability and Request for Comment, [87 Fed. Reg. at 72,440](#).

⁷³Fees for the Administration of the Toxic Substances Control Act (TSCA); Supplemental notice of proposed rulemaking, [87 Fed. Reg. 68,647](#) (proposed Nov. 16, 2022) (to be codified at 40 C.F.R. pt. 700).

⁷⁴*Id.* at 68,651, 68,654.

shared among manufacturers for an EPA-initiated risk evaluation under section 6(b) would increase from \$2,560,000 to \$5,081,000.

EPA proposed new procedures for asserting and substantiating Confidential Business Information (CBI) claims in TSCA submissions, including expanding electronic reporting requirements, procedures for maintenance and withdrawal of CBI claims, and internal procedures for reviewing and communicating with TSCA submitters about confidentiality claims.⁷⁵ The proposal also would require companies to submit health and safety information to EPA using the Organisation for Economic Co-operation and Development ([OECD templates](#)), if available. The Agency explained that using the templates should make CBI claims clearer and make it easier for EPA to share data across the Agency.

EPA addressed a number of rulemaking and other petitions. A coalition petitioned EPA under TSCA section 21 to perform human and environmental health and safety testing for polyvinyl alcohol (PVA/PVOH) as it is used in consumer-packaged goods.⁷⁶ Among other things, PVA is used to make laundry and dishwasher detergent pods and sheets.

EPA denied a citizen petition requesting that EPA determine that the manufacture, processing, distribution in commerce, use, or disposal of greenhouse gas emissions, fossil fuels, and fossil fuel emissions presents an unreasonable risk of injury to health or the environment and initiated a TSCA section 6(a) risk management rulemaking.⁷⁷ EPA found that the petition was insufficiently specific and that the petitioners did not meet their burden of establishing that it is necessary to issue a rule under TSCA section 6(a).

The U.S. District Court for the Northern District of California partially lifted its stay⁷⁸ of a long-running suit challenging EPA's 2017 denial of a TSCA section 21 petition seeking a TSCA section 6(a) risk management rule prohibiting the addition of fluoridation chemicals to drinking water.⁷⁹ The stay was lifted to give plaintiffs access to draft National Toxicology Program (NTP) review studies of fluorine hazards and epidemiology that might be used in a new trial.⁸⁰ EPA in turn moved to hold the case in abeyance until the NTP studies are in final form.⁸¹

EPA [initially denied](#) the section 21 petition of a coalition of environmental organizations seeking a TSCA section 4 test rule for fifty-four PFAS “manufactured by The Chemours Company [] at its chemical production facility in Fayetteville, North

⁷⁵Confidential Business Information Claims Under the Toxic Substances Control Act (TSCA), [87 Fed. Reg. 29,078](#) (proposed May 12, 2022) (to be codified at 40 C.F.R. pts. 2, 702, 703, 704, 707, 716, 717, 720, 723, 725, and 790).

⁷⁶[Pet. to Require Health and Environmental Testing and Regulation on Polyvinyl Alcohol Under the Toxic Substances Control Act and the Removal of Polyvinyl Alcohol from the EPA's Safer Choice and Safer Chemical Ingredients Lists](#), Blueland, et al.(submitted Nov. 15, 2022).

⁷⁷Toxic Substances Control Act (TSCA) Section 21 Petition for Rulemaking Under TSCA Section 6; Reasons for Agency Response; Denial of Requested Rulemaking, [87 Fed. Reg. 57,665](#) (Sept. 21, 2022).

⁷⁸Order Granting Plaintiff's Motion to Lift the Stay and Take Case Out of Abeyance, *Food & Water Watch, Inc. v. EPA*, 3:17-cv-02162-EMC, 2022 WL 16528140, at *2-4, *10 (N.D. Cal. Oct. 28, 2022).

⁷⁹Fluoride Chemicals in Drinking Water; TSCA Section 21 Petition; Reasons for Agency Response, [82 Fed. Reg. 11,878](#) (Feb. 27, 2017).

⁸⁰*Food & Water Watch, Inc.*, 2022 WL 16528140, at *10.

⁸¹Defendants' Administrative Motion to Govern Future Proceedings, *Food & Water Watch, Inc. v. EPA*, (N.D. Cal. Dec. 22, 2022).

Carolina.”⁸² The coalition filed suit in the U.S. District Court challenging the denial of the petition. EPA (under the Biden Administration) later reversed itself and granted the petition.⁸³ However, EPA proposed to implement only a portion of the requested testing, following the path presented in its National PFAS Testing Strategy. The coalition viewed this as a partial grant and partial denial of its petition and filed an amended complaint seeking judicial review of both the original denial and EPA’s subsequent grant.⁸⁴ EPA then moved to dismiss the suit on the grounds that the court has no jurisdiction to review the grant of a petition.⁸⁵

F. *National Program Chemicals*

EPA issued new guidance outlining suggested content for petitions to exempt particular laminated composite wood products from the formaldehyde emission standards scheduled to take effect in 2024.⁸⁶ EPA also proposed to update references in the composite wood products regulation to the most current versions of several voluntary consensus standards concerning composite wood products.⁸⁷

II. FEDERAL INSECTICIDE FUNGICIDE AND RODENTICIDE ACT (FIFRA)

A. *Endangered Species Act (ESA) Consultations on Pesticide Registrations*

In a significant change of approach, EPA [announced](#) that, going forward, before registering any new conventional pesticide active ingredient (AI), EPA first will make an effects determination for species listed or habitats designated under the ESA.⁸⁸ EPA will seek the Fish and Wildlife Service’s (FWS) or the National Marine Fisheries Service’s (NMFS) (collectively, the Services) concurrence or initiate consultation before issuing a new AI registration. If a new AI could jeopardize listed species or adversely modify critical habitat (J/AM), EPA will require mitigation from the registrant.⁸⁹ EPA also developed and released a [workplan](#) outlining its strategies for successfully implementing this approach

⁸²TSCA Section 21 Petition for Rulemaking; Reasons for Agency Response; Denial of Requested Rulemaking, [86 Fed. Reg. 6602](#) (Jan. 22, 2021).

⁸³Press Release, U.S. Env’tl. Prot. Agency, [EPA Grants Petition to Order Testing on Human Health Hazards of PFAS](#) (Dec. 28, 2021).

⁸⁴Amended Complaint for Declaratory and Injunctive Relief, Center for Environmental Health v. Regan, No. 4:21-cv-01535-PJH (N.D. Cal. Feb. 1, 2022).

⁸⁵Mot. To Dismiss, Center for Environmental Health v. Regan, No. 7:22-cv-00073-M, (E.D.N.C. Jun. 23, 2022).

⁸⁶[Guidance on Petitions to Exempt Additional Laminated Products Under the Formaldehyde Emissions Standards for Composite Wood Products Rule](#), U.S. ENVTL. PROT. AGENCY (last visited Mar. 18, 2023).

⁸⁷Voluntary Consensus Standards Update; Formaldehyde Emission Standards for Composite Wood Products, [87 Fed. Reg. 17,963](#) (proposed Mar. 29, 2022) (to be codified at 40 C.F.R. pt. 770); Voluntary Consensus Standards Update; Formaldehyde Emission Standards for Composite Wood Products, [87 Fed. Reg. 57,432](#) (proposed Sept. 20, 2022) (to be codified at 40 C.F.R. pt. 770).

⁸⁸[Assessing Effects of New Pesticides on Listed Species](#), U.S. ENVTL. PROT. AGENCY (last visited Mar. 18, 2023).

⁸⁹*Id.*

going forward, including addressing the current backlog.⁹⁰ EPA subsequently updated the workplan to address endangered species determinations in connection with registration review.⁹¹

The Ninth Circuit partially vacated EPA's interim registration review decision (IRRD) for glyphosate.⁹² The court found that the human health portion was not supported by substantial evidence, and, significantly, found the IRRD violated the ESA because it did not include a biological evaluation (BE). The court granted EPA's request for voluntary remand without vacatur of the ecological portion of the risk assessment, but EPA was unable to meet the court's deadline to complete a new analysis and withdrew the IRRD.⁹³

The Ninth Circuit [partially granted](#) a petition challenging EPA's approval of new uses of sulfoxaflor, finding that EPA failed to make a required effects determination under the ESA and failed to provide the notice and comment required by FIFRA. The court declined to vacate the registrations, however, because doing so could harm the environment and would disrupt agriculture. Instead, the court directed EPA to fulfill its obligations within 180 days.⁹⁴

The D.C. Circuit [issued a writ of mandamus](#) ordering EPA to complete an ESA effects determination for cyantraniliprole within 180 days.⁹⁵ EPA had been ordered by the court in 2017 to complete the analysis, but had failed to take significant action.

Other ESA-FIFRA cases were resolved by settlement. In a set of cases brought after EPA approved five new AIs without completing BEs, the parties reached a settlement in which the court will hold the cases in abeyance until agreed-upon deadlines for EPA to complete BEs.⁹⁶ The parties to a lawsuit regarding EPA's failure to consult the Services prior to registering the new AI trifludimoxazin also reached a [settlement](#).⁹⁷ The registrant voluntarily canceled the trifludimoxazin registrations with plans to reapply, and EPA will evaluate the applications as applications for a new AI, subject to EPA's new [workplan](#).⁹⁸ Finally, EPA settled a dispute surrounding its FIFRA registrations of acetamiprid, dinotefuran, and imidacloprid products without ESA reviews. In 2021, the parties reached a [partial settlement](#) regarding imidacloprid.⁹⁹ Consistent with that agreement, EPA

⁹⁰Press Release, U.S. Env'tl. Prot. Agency, [EPA Announces Plan to Protect Endangered Species and Support Sustainable Agriculture](#) (Apr. 12, 2022); U.S. ENVTL. PROT. AGENCY, [BALANCING WILDLIFE PROTECTION AND RESPONSIBLE PESTICIDE USE: HOW EPA'S PESTICIDE PROGRAM WILL MEET ITS ENDANGERED SPECIES ACT OBLIGATIONS](#) (2022).

⁹¹[EPA's Workplan and Progress Toward Better Protections for Endangered Species](#), U.S. ENVTL. PROT. AGENCY (last visited Mar. 18, 2023); U.S. ENVTL. PROT. AGENCY, [ESA WORKPLAN UPDATE: NONTARGET SPECIES MITIGATION FOR REGISTRATION REVIEW AND OTHER FIFRA ACTIONS](#) (2022).

⁹²Natural Res. Def. Council v. EPA, [38 F.4th 34](#) (9th Cir. 2022).

⁹³[Memorandum](#) from Cathryn Britton, Branch Chief, Risk Mgmt. and Implementation Branch V, Pesticide Re-evaluation Div., U.S. Env'tl. Prot. Agency, to Glyphosate Registration Review Docket (EPA-HQ-OPP-2009-0361) (Sept. 21, 2022), at 5.

⁹⁴[Center for Food Safety v. EPA](#), Nos. 19-72109, 19-72280, 2022 WL 17826872 (9th Cir. Dec. 21, 2022).

⁹⁵In re Center for Biological Diversity, [53 F.4th 665](#), 673 (D.C. Cir. 2022).

⁹⁶[Center for Biological Diversity v. EPA](#), 56 F.4th 55, 77 (D.C. Cir. 2022).

⁹⁷Center for Food Safety v. EPA, Case [No. 21-71180](#), at *1-3 (9th Cir. Feb. 23, 2022).

⁹⁸*Id.* at *1, *3-4; BALANCING WILDLIFE PROTECTION AND RESPONSIBLE PESTICIDE USE, *supra* note 90.

⁹⁹Stip. Partial Settlement Agreement at 1-3, Natural Res. Def. Council, Inc. v. Regan, [No. 17-cv-02034-TSC](#) (D.D.C. Jan. 28, 2021).

published its final BE for imidacloprid in June 2022.¹⁰⁰ In March 2022, the parties [settled](#) the remaining claims, requiring BEs for acetamiprid and dinotefuran by October 2024.¹⁰¹ In addition, EPA published final BEs for [clothianidin and thiamethoxam](#)¹⁰² and published [draft BEs for sulfoxaflor](#)¹⁰³ and [inpyrfluxam](#).¹⁰⁴ After incorporating conservation measures, FWS published a [final Biological Opinion \(BiOp\) for malathion](#), finding no J/AM.¹⁰⁵ NMFS revised its 2017 BiOp for malathion, chlorpyrifos, and diazinon; after EPA and the registrants agreed to mitigation measures, NMFS issued a [final BiOp](#) finding no J/AM.¹⁰⁶

B. Pesticide Registration Improvement Act (PRIA) Developments

The Pesticide Registration Improvement Act of 2022 (PRIA 5) became law as part of the Consolidated Appropriations Act of 2023 (Act).¹⁰⁷ PRIA 5 extends EPA's authority to collect registration service fees under FIFRA § 33 until September 30, 2027 and extends the subsequent phaseout of EPA's authority until September 30, 2029. PRIA 5 also amended FIFRA § 3(f) to establish new bilingual (English-Spanish) labeling requirements for pesticides; extended and modified EPA's authority to collect registration maintenance fees under FIFRA § 4(i); extends the ban on tolerance fees in section 408(m)(3) of the Federal Food, Drug, and Cosmetics Act until September 30, 2027; extensively amended FIFRA § 4(k) establishing and governing the Reregistration and Expedited Processing Fund; and mandated the posting on a single EPA webpage certain aggregated information on pesticide regulation under FIFRA. Separately, the Act itself extended the registration review deadline in FIFRA § 3(g) until October 1, 2026 and required that each IRRD include measures, where applicable, to reduce the effects of the relevant pesticide on species listed or habitats designated under the ESA.

C. Pesticide Registration Review Status Update

[EPA released a status update](#) on the Agency's progress completing registration reviews for the 726 conventional, biopesticide, and antimicrobial pesticide active

¹⁰⁰[Final National Level Listed Species Biological Evaluation for Imidacloprid](#), U.S. ENVTL. PROT. AGENCY (lastvisited Mar. 18, 2023).

¹⁰¹Stip. Settlement Agreement at 1, 4, Natural Res. Def. Council, Inc. v. Regan, [No. 17-cv-02034-TSC](#) (D.D.C. Mar. 7, 2022).

¹⁰²Press Release, U.S. Env'tl. Prot. Agency, [EPA Finalizes Biological Evaluations Assessing Potential Effects of Three Neonicotinoid Pesticides on Endangered Species](#) (June 16, 2022).

¹⁰³[Memorandum](#) from Keith Sappington, Senior Sci. Advisor, Env'tl. Risk Branch 5, U.S. Env'tl. Prot. Agency, to Marianne Lewis, Risk Manager Reviewer, Dkt. No. EPA-HQ-OPP-2010-0889-0604 (July 15, 2022).

¹⁰⁴[Memorandum](#) from Katherine Stebbins, Biologist, Env'tl. Risk Branch III, U.S. Env'tl. Prot. Agency, to Stephanie Suarez, Risk Manager, Dkt. No. EPA-HQ-OPP-2018-0038-0051 (Oct. 24, 2022).

¹⁰⁵U.S. FISH AND WILDLIFE SERV., [BIOLOGICAL AND CONFERENCE OPINION ON THE REGISTRATION OF MALATHION PURSUANT TO THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT](#) (Feb. 28, 2022).

¹⁰⁶NAT'L MARINE FISHERIES SERV., [REVISED CONFERENCE AND BIOLOGICAL OPINION ON THE ENVIRONMENTAL PROTECTION AGENCY'S REGISTRATION REVIEW OF PESTICIDE PRODUCTS CONTAINING CHLORPYRIFOS, MALATHION, AND DIAZINON](#) (June 30, 2022).

¹⁰⁷[H.R. 2617](#), 117th Cong., 2nd Sess. (2022).

ingredients registered before October 1, 2007.¹⁰⁸ [By law](#), EPA was to complete all of these reviews no later than October 1, 2022;¹⁰⁹ however the status update reported that the Agency completed only 151 final registration review decisions (or 21% of the total number of pesticides under registration review). [EPA also reported](#) that it had completed 685 draft risk assessments (or 94% of the total); 633 proposed interim or proposed final registration decisions (or 87% of the total); and issued 431 interim decisions (or 60% of the total).¹¹⁰ Of the 582 interim or final decisions issued at the time of the update, 140 review cases resulted in cancellation of some or all pesticidal uses. In total, there are still 144 pesticides out of the 726 for which EPA has issued neither an interim nor final registration review decision. EPA currently projects registration review activities running through FY 2026.¹¹¹

EPA moved to suspend a registration under FIFRA section [3\(c\)\(2\)\(B\)\(iv\)](#)¹¹² due to the sole registrant's alleged failure "to take appropriate steps to secure the data" required by a 2011 data call-in.¹¹³ The matter was set for hearing,¹¹⁴ but before the hearing, the ALJ granted EPA's motion for accelerated decision on the grounds that there were no genuine issues of material fact. That decision was reversed by EPA's Environmental Appeals Board (EAB), which held that the proper test was not whether the registrant had submitted the required data, but, as required by section 3(c)(2)(B)(iv), whether the registrant had "take[n] the appropriate steps to secure the data required," which could include, for example, consideration of efforts to secure data call-in waivers.¹¹⁵

D. *Antimicrobial Product Policy*

In 2022, EPA activated its 2016 "Emerging Viral Pathogen" guidance ([EVP Guidance](#))¹¹⁶ for two additional viral pathogens: Ebola virus¹¹⁷ and monkeypox virus.¹¹⁸ EPA first activated the EVP guidance in January 2020 at the start of the COVID-19 pandemic.¹¹⁹ The policy reflected in the EVP Guidance allows antimicrobial pesticide manufactures to make specific limited off-label efficacy claims for a limited time against

¹⁰⁸Press Release, U.S. Env'tl. Prot. Agency, Pesticide Registration Review Deadline: Status Update and Plans for Remaining Work (Sept. 26, 2022).

¹⁰⁹7 U.S.C. § 136a(g)(1)(A)(iii).

¹¹⁰Press Release, Pesticide Registration Review Deadline: Status Update and Plans for Remaining Work, *supra* note 108.

¹¹¹[Upcoming Registration Review Actions](#), ENVTL. PROT. AGENCY (last visited Mar. 25, 2023).

¹¹²7 U.S.C. § 136a(c)(2)(B)(iv).

¹¹³Notice of Intent to Suspend Dimethyl Tetrachloroterephthalate (DCPA) Technical Registration, [87 Fed. Reg. 25,262](#) (Apr. 28, 2022).

¹¹⁴Notice of Objections to Notice of Intent to Suspend Dimethyl Tetrachloroterephthalate (DCPA) Technical Registration; Notice of Public Hearing, [87 Fed. Reg. 37,507](#) (June 23, 2022).

¹¹⁵[In Re Amvac Chemical Corp.](#), 18 E.A.D. 769, 770, 787 (2022).

¹¹⁶U.S. ENVTL. PROT. AGENCY, GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING VIRAL PATHOGENS NOT ON EPA-REGISTERED DISINFECTANT LABELS (2016).

¹¹⁷Press Release, U.S. Env'tl. Prot. Agency, [EPA Releases Updated Lists of Disinfectants for Emerging Viral Pathogens Including Ebola](#) (Oct. 19, 2022).

¹¹⁸Press Release, U.S. Env'tl. Prot. Agency, [EPA Releases List of Disinfectants for Emerging Viral Pathogens \(EVPs\) Including Monkeypox](#) (May 26, 2022).

¹¹⁹[Emerging Viral Pathogen Guidance and Status for Antimicrobial Pesticides, U.S. ENVTL. PROT. AGENCY](#) (last visited Mar. 18, 2023).

designated emerging pathogens without organism-specific efficacy data or label amendments.

EPA registered the first antimicrobial pesticide product approved to make claims for use as an air sanitizer against bacteria *and viruses*.¹²⁰ The Agency also revised and finalized efficacy test methods and guidance to support label claims for residual efficacy on hard, non-porous surfaces.¹²¹ The test method anticipates only two types of products – disinfectants with residual efficacy and supplemental residual antimicrobial products (*e.g.*, antimicrobial paints or coatings) that do not support disinfection claims and are intended only as a supplement to standard disinfection practices.

EPA again extended the life of a temporary amendment to Pesticide Registration Notice ([PRN](#)) [98-10](#)¹²² that allows registrants of products approved to make emerging pathogen efficacy claims against SARS-CoV-2 to make minor product formulation changes (active ingredients sourced from commodity chemicals) without first obtaining formal Agency approval.¹²³ The March 15, 2023 termination deadline is intended to give the Agency adequate time to review and approve as permanent those formulation or manufacturing amendments submitted during the period of the temporary amendment.

E. PFAS Actions Under FIFRA

Due to potential hazard concerns, EPA removed twelve PFAS chemicals from the Agency’s list of approved inert ingredients; none were in active use.¹²⁴ EPA is investigating whether any approved active ingredients may be classified as PFAS and advised that it would view any level of PFAS impurities discovered in a pesticide product to be potentially toxicologically significant and reportable¹²⁵ under FIFRA section 6(a)(2).¹²⁶ EPA [released study data](#) from its evaluation of the potential for incidentally produced PFAS to leach into liquid pesticides from fluorinated high-density polyethylene (HDPE) containers used to store and transport pesticide products and reported that PFAS could leach into both solvent and water-based formulations from such containers.¹²⁷

F. Action on Pesticide Regulatory Petitions Submitted to EPA

¹²⁰Press Release, U.S. Env’tl. Prot. Agency, [EPA Registers Air Sanitizer for Residential and Commercial Use Against Influenza and Coronavirus](#) (Oct. 6, 2022).

¹²¹Press Release, U.S. Env’tl. Prot. Agency, [EPA Releases Test Methods and Guidance for Long-Lasting Antimicrobial Efficacy Claims](#) (Oct. 7, 2022); U.S. ENVTL. PROT. AGENCY, [GUIDANCE FOR PRODUCTS ADDING RESIDUAL EFFICACY CLAIMS](#) (2022).

¹²²[PRN 98-10: Notifications, Non-Notifications and Minor Formulation Amendments](#), U.S. ENVTL. PROT. AGENCY (last visited Mar. 18, 2023); *see generally* U.S. ENVTL. PROT. AGENCY, [PRN 98-10: NOTIFICATIONS, NON-NOTIFICATIONS AND MINOR FORMULATION AMENDMENTS](#) (1998).

¹²³U.S. ENVTL. PROT. AGENCY, [EXTENSION OF THE TERMINATION DATE FOR THE TEMPORARY AMENDMENTS TO PESTICIDE REGISTRATION \(PR\) NOTICE 98-10: NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS AND REGISTRANTS OF PESTICIDE PRODUCTS](#) (2022).

¹²⁴Pesticides; Removal of PFAS Chemicals From Approved Inert Ingredient List for Pesticide Products, [87 Fed. Reg. 76,488](#) (Dec. 14, 2022).

¹²⁵[Per- and Polyfluoroalkyl Substances \(PFAS\) in Pesticide and Other Packaging](#), ENVTL. PROT. AGENCY (last visited Mar. 18, 2023) (citing [40 C.F.R. § 159.155\(a\)\(5\) \(1998\)](#)).

¹²⁶[7 U.S.C. § 136d\(a\)\(2\)](#).

¹²⁷Press Release, U.S. Env’tl. Prot. Agency, [EPA Releases Data on Leaching of PFAS in Fluorinated Packaging](#) (Sept. 8, 2022).

EPA denied a 2017 petition to exclude pesticide-treated seeds from the scope of FIFRA's [treated articles exemption](#) as unnecessary because EPA assures proper seed treatment instructions during the registration process of each seed treatment pesticide.¹²⁸ Nonetheless, EPA stated in the denial letter that it would explore, through an advanced notice of proposed rulemaking, whether a rule governing the distribution of unregistered treated seeds is warranted.

The U.S. Court of Appeals for the Ninth Circuit vacated EPA's July 21, 2020 denial of a 2009 petition to cancel all pet uses of tetrachlorvinphos (TCVP) because the denial was not supported by substantial evidence and ordered EPA to issue a new decision within 120 days.¹²⁹ In response to the order, EPA partially granted and partially denied the 2009 petition.¹³⁰ EPA found that there are unacceptable risks from TCVP pet collars for children and stated its intent to draft a proposed Notice of Intent to Cancel TCVP pet collar registrations, subject to reconsideration in light of data expected from registrants from further pending exposure studies.

G. Endocrine Disruptor Screening Program

A coalition of non-profit organizations filed a complaint under section 702 of the Administrative Procedures Act¹³¹ alleging that EPA had failed to develop and implement an endocrine screening program for all pesticide chemicals by 1999 as required by the Food Quality Protection Act and seeking injunctive relief to compel EPA to complete the testing under court supervision.

H. Agricultural Worker Protection Standard

EPA published a notice¹³² confirming that, due to a court-ordered stay of the 2020 amendments to the application exclusion zone (AEZ) requirements of the Agricultural Worker Protection Standard (WPS) (codified at 40 C.F.R. pt. 170), the currently applicable and enforceable AEZ requirements are those that were in effect immediately before the 2020 amendments. These were issued in 2015 and are available in the Federal Register.¹³³ Proposed amendments to the stayed 2020 AEZ regulations were circulated to the Secretary of the USDA in late 2022 ahead of a public proposal.¹³⁴

¹²⁸[Letter](#) from Edward Messina, Esq., Dir., Off. Of Pesticide Programs, U.S. Env'tl. Prot. Agency, to George Kimbrell, Legal Dir., Ctr. for Food Safety, EPA Dkt. No. EPA-HQ-OPP-2018-0805-0104 (Sept. 27, 2012).

¹²⁹[Nat. Res. Def. Council v. EPA](#), 31 F.4th 1203, 1203 (9th Cir. 2022).

¹³⁰EDWARD MESSINA, OFF. OF CHEM. SAFETY AND POLLUTION PREVENTION, U.S. ENVTL. PROT. AGENCY, [AGENCY RESPONSE TO THE NATURAL RES. DEF. COUNCIL'S \(NRDC\) APRIL 2009 TETRACHLORVINPHOS PETITION](#), Dkt. No. EPA-HQ-OPP-2009-0308, (2022) at 5-9.

¹³¹Complaint for Declaratory and Injunctive Relief, [Alianza Nacional de Campesinas v. U.S. Env'tl Prot. Agency](#), No. 22-cv-9030 (N.D. Cal. Dec. 20, 2022); [21 U.S.C. § 346a\(p\)](#).

¹³²Pesticides; Agricultural Worker Protection Standard; Revision of the Application Exclusion Zone Requirements; Court Order; Stay of Effectiveness, [87 Fed. Reg. 29,673](#) (May 16, 2022) (to be codified at 40 C.F.R. pt. 170).

¹³³Pesticides; Agricultural Worker Protection Standard Revisions, [80 Fed. Reg. 67,495](#) (Nov. 2, 2015) (to be codified at 40 C.F.R. pt. 170).

¹³⁴Notification of Submission to the Secretary of Agriculture; Pesticides; Agricultural Worker Protection Standard; Reconsideration of the Application Exclusion Zone Amendments, [87 Fed. Reg. 74,072](#) (Dec. 2, 2022).

I. State Pesticide Law Developments of National Significance

In 2020, the Eastern District of California granted summary judgment for industry plaintiffs alleging that the cancer warning required by California’s Proposition 65 for the herbicide glyphosate violated the First Amendment. The court permanently enjoined the Proposition 65 warning requirement for glyphosate.¹³⁵ The Attorney General of California appealed the decision to the Ninth Circuit.¹³⁶ However, those proceedings have been held in abeyance. At the same time, the California Office of Environmental Health Hazard Assessment (OEHHA) developed a new safe harbor warning for glyphosate that might satisfy the requirements of both Proposition 65 and the First Amendment. OEHHA’s new glyphosate safe harbor warning regulation was promulgated on September 1, 2022.¹³⁷ The Ninth Circuit appeal remains undecided.

In *Carson v. Monsanto Co.*, a glyphosate personal injury case, a panel of the Eleventh Circuit Court of Appeals reversed a district court decision, holding that state duties to warn of alleged pesticide health hazards that are inconsistent with approved FIFRA labeling are preempted by FIFRA.¹³⁸ The Eleventh Circuit granted Monsanto’s petition for rehearing en banc, which vacates the prior opinion and stays the mandate.¹³⁹

The Maine Legislature amended the Maine Pesticide Control Act to prohibit the distribution in Maine of either a pesticide that has been contaminated by PFAS or, beginning January 1, 2030, a pesticide that contains intentionally added PFAS unless the Maine Department of Environmental Protection has determined by rule that the use of PFAS in the product is currently unavoidable.¹⁴⁰

III. EMERGENCY PLANNING AND COMMUNITY RIGHT-TO-KNOW ACT (EPCRA)¹⁴¹

EPA issued several amendments to the Toxics Release Inventory (TRI) reporting requirements, including an amended definition of “parent company,” which now refers to the highest-level U.S. company in a corporate family, a requirement to report the identity of a foreign parent under certain conditions, and provisions to assure uniform naming conventions for parent companies.¹⁴² In a separate proceeding, EPA updated the list of North American Industry Classification system (NAICS) codes subject to reporting under TRI to reflect NAICS revisions by the Office of Management and Budget.¹⁴³

¹³⁵[Nat’l Ass’n of Wheat Growers v. Becerra](#), 468 F. Supp. 3d 1247, 1252-254, 1266 (E.D. Cal. 2020).

¹³⁶[Nat’l Ass’n of Wheat Growers v. Becerra](#), [No. 20-16758](#) (9th Cir. 2020).

¹³⁷[Safe Harbor Warning Regulation for Exposures to Glyphosate from Consumer Products](#), CA. OFF. OF ENVTL. HEALTH HAZARD ASSESSMENT (last visited Mar. 18, 2023); *see also* [CAL. CODE REGS. tit. 27, §§ 25607.48, 25607.49](#) (2022).

¹³⁸[Carson v. Monsanto](#), No. 21-10994 (11th Cir. Jul. 7, 2022).

¹³⁹[Memorandum to Counsel or Parties at 1](#), *Carson v. Monsanto*, No. 21-10994 (11th Cir. Dec. 19, 2022).

¹⁴⁰[H.P. 1501 - L.D. 2019](#), 130th Leg., Reg. Sess. (Me. 2022) (codified in relevant part at [ME. REV. STAT. ANN. tit. 7, § 606\(1\)\(H\)-\(I\)](#) (2022)).

¹⁴¹[42 U.S.C. §§ 11001-11050](#).

¹⁴²Parent Company Definition for Toxics Release Inventory (TRI) Reporting, [87 Fed. Reg. 63,950](#) (Oct. 21, 2022) (to be codified at 40 C.F.R. pt. 372).

¹⁴³Community Right-to-Know; Adopting 2022 North American Industry Classification System (NAICS) Codes for Toxics Release Inventory (TRI) Reporting, [87 Fed. Reg. 72,891](#)

EPA added twelve chemicals to the TRI list of reportable substances following rulemaking initiated in response to a 2014 petition by the Toxics Use Reduction Institute.¹⁴⁴ Prompted by litigation from the proponents,¹⁴⁵ EPA issued a supplemental notice of proposed rulemaking to add the diisononyl phthalate (DINP) category to the TRI reporting list.¹⁴⁶

EPA took two actions under TRI respecting PFAS. By direct final rule, EPA added five additional PFAS substances to the TRI list that were determined to meet the automatic TRI listing criteria in the FY2020 NDAA.¹⁴⁷ EPA also proposed to designate all 180 PFAS added so far to the TRI list by the FY2020 NDAA as ‘Chemicals of Special Concern.’¹⁴⁸ This designation would make inapplicable an exemption for reporting to customers *de minimis* quantities of TRI substances present in products as impurities, and disallow reporting the listed PFAS using the abbreviated TRI reporting format (Form A).

IV. BIOTECHNOLOGY DEVELOPMENTS

EPA registered a quintuple-stack genetically engineered corn insect pest plant-incorporated-protectant product that includes a double-strand RNA mode of action.¹⁴⁹ EPA amended the FIFRA section 5 Experimental Use Permit for trial releases of the genetically engineered OX5034 *Aedes aegypti* mosquito.¹⁵⁰ EPA’s action extends the duration of the OX5034 *Aedes aegypti* Experimental Use Permit to April 30, 2024 and expands authorization for releases to four counties in California.

The U.S. Animal Plant Health Inspection Service (APHIS) issued its first Regulatory Status Review (RSR) determination for a genetically engineered food crop under its 2020 amended 7 C.F.R. Part 340 regulation, which replaced the former petition

(Nov. 28, 2022), *amended by* Community Right-to-Know; Adopting 2022 North American Industry Classification System (NAICS) Codes for Toxic Release Inventory (TRI) Reporting; Correction, [87 Fed. Reg. 74,518](#) (Dec. 6, 2022) (to be codified at 40 C.F.R. pt. 372).

¹⁴⁴Addition of Certain Chemicals; Community Right-to-Know Toxic Chemical Release Reporting, [87 Fed. Reg. 73,475](#) (Nov. 30, 2022) (to be codified at 40 C.F.R. pt. 372).

¹⁴⁵Proposed Consent Decree, Unreasonable Delay Claim Regarding Toxics Release Inventory Listing, [87 Fed. Reg. 20,853](#) (Apr. 8, 2022).

¹⁴⁶Addition of Diisononyl Phthalate Category; Community Right-to-Know Toxic Chemical Release Reporting, Proposed rulemaking; Supplemental notice, [87 Fed. Reg. 48,128](#) (proposed Aug. 8, 2022) (to be codified at 40 C.F.R. pt. 372).

¹⁴⁷Implementing Statutory Addition of Certain Per- and Polyfluoroalkyl Substances (PFAS) to the Toxics Release Inventory Beginning With Reporting Years 2021 and 2022, [87 Fed. Reg. 42,651](#) (July 18, 2022), *as amended by* [87 Fed. Reg. 47,102](#) (Aug. 2, 2022) (to be codified at 40 C.F.R. pt. 372).

¹⁴⁸Changes to Reporting Requirements for Per- and Polyfluoroalkyl Substances and to Supplier Notifications for Chemicals of Special Concern; Community Right-to-Know Toxic Chemical Release Reporting, [87 Fed. Reg. 74,379](#) (proposed Dec. 5, 2022) (to be codified at 40 C.F.R. pt. 372).

¹⁴⁹Notice of Pesticide Registration, [EPA Reg. No. 524-664](#) (Mar. 1, 2022).

¹⁵⁰Amendment to Experimental Use Permit 93167-EUP-2, [EPA Docket No. EPA-HQ-OPP-2019-0274-0470](#) (Mar. 7, 2022); Press Release, U.S. Env’tl. Prot. Agency, [Following Review Available Data and Public Comments EPA Expands and Extends Testing of Genetically Engineered Mosquitoes to Reduce Mosquito Populations](#) (Mar. 7, 2022).

for determination of nonregulated status process.¹⁵¹ The APHIS RSR determination concerned a tomato plant that is genetically engineered to express increased flavonoid content (hence its unique purple color). APHIS released for public comment a draft environmental impact statement (DEIS) and draft plant pest risk assessment (PPRA) for a genetically engineered American chestnut variety that can coexist with the fungus that causes chestnut blight and is intended to restore the functionally extinct American chestnut to its natural range.¹⁵²

In response to a court decision ordering additional Endangered Species Act (ESA) and NEPA analyses,¹⁵³ the U.S. Food and Drug Administration (FDA) prepared and released for public comment a draft amended Environmental Assessment (EA) for the AquaBounty genetically engineered salmon.¹⁵⁴ FDA previously had made a “no effect” determination for producing and rearing the AquaBounty salmon.

In an action intended to have long-term, significant beneficial effects on the development and expansion of biotechnology in the U.S., President Biden signed Executive Order 14081, Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy.¹⁵⁵

V. STATE CHEMICAL CONTROL AND DISCLOSURE REGULATION

In 2022, at least six states enacted new laws that restrict PFAS in products. California passed laws that prohibit distribution or sale of cosmetic products containing intentionally added PFAS beginning January 1, 2025,¹⁵⁶ and restrict the amount of PFAS in “textile articles” beginning in 2025.¹⁵⁷ New Colorado legislation phases in prohibitions on a wide range of PFAS-containing products, starting in January 2024 with carpets and rugs, fabric treatments, food packaging, juvenile products, and oil and gas products.¹⁵⁸ A Hawaii law prohibits food packaging with intentionally added PFAS and restricts use of PFAS-containing Class B firefighting foam starting in 2024.¹⁵⁹ Maryland’s new law prohibits or restricts PFAS-containing firefighting foam, rugs and carpets, and food

¹⁵¹Press Release, Animal and Plant Health Inspection Serv., [APHIS Issues First Regulatory Status Review Response: Norfolk Plant Sciences’ Purple Tomato](#) (Sep. 7, 2022).

¹⁵²State University of New York College of Environmental Science and Forestry; Availability of a Draft Environmental Impact Statement and Draft Plant Pest Risk Assessment for Determination of Nonregulated Status for Blight-Tolerant Darling 58 American Chestnut (*Castanea dentata*) Developed Using Genetic Engineering, [87 Fed. Reg. 67,861](#) (Nov. 10, 2022).

¹⁵³[Inst. For Fisheries Res. v. U. S. Food and Drug Administration](#), 499 F. Supp. 3d 657 (N.D. Cal., 2020).

¹⁵⁴Press Release, Food and Drug Admin., [FDA Releases Draft Amended Environmental Assessment for AquaAdvantage Salmon and Announces Virtual Public Meeting](#) (Nov. 16, 2022).

¹⁵⁵Exec.Order 14,081, Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy, [87 Fed. Reg. 56,849](#) (Sept. 15, 2022).

¹⁵⁶[Assemb. B. 2771, 2022 Leg., Leg. Sess. \(Cal. 2022\)](#) (codified at CAL. HEALTH & SAFETY CODE §§ 108981–108982).

¹⁵⁷[Assemb. B. 1817, 2022 Leg., Leg. Sess. \(Cal. 2022\)](#) (codified at CAL. HEALTH & SAFETY CODE §§ 108970–108971).

¹⁵⁸[H.B. 22-1345](#), 74th Gen. Assemb., Reg. Sess. (Colo. 2022) (largely codified at COLO. REV. STAT. §§ 25-5-1303.5, 25-15-601–25-15-604).

¹⁵⁹[H.B. 1644](#), 31st Leg., Reg. Sess. (Haw. 2022).

packaging.¹⁶⁰ Ohio prohibits use of PFAS-containing Class B firefighting foams for training or testing purposes.¹⁶¹ Rhode Island enacted a law that will prohibit sales of food packages containing intentionally added PFAS beginning on January 1, 2024.¹⁶²

Both Delaware¹⁶³ and New York¹⁶⁴ enacted laws prohibiting the sale of, *inter alia*, upholstered furniture containing specified flame-retardant chemicals. Initial reports of flame-retardant chemicals in enclosures or stands for electronic displays were required in New York by December 31, 2022.¹⁶⁵

¹⁶⁰[S.B. 0273](#), Gen. Assemb., Reg. Sess. (Md. 2022).

¹⁶¹[H.B. 158](#), 135th Gen. Assemb., Reg. Sess. (Ohio 2022).

¹⁶²23 R.I. GEN. LAWS ANN. §§ 23-18.13-1–23-18.13-13 (2022).

¹⁶³[H.B. 77](#), 151st Gen. Assemb. Reg. Sess. (Del. 2022).

¹⁶⁴[S.B. S7737](#), 2022 Senate, Leg. Sess. (N.Y. 2022); [S.B. S4630B](#), 2022 Senate, Leg. Sess. (N.Y. 2022) (codified at N.Y. ENV'T CONSERV. LAW §§ 37-1001–37-1013 (McKinney 2021)).

¹⁶⁵See DEP'T OF ENV'T'L CONSERV., [FLAME RETARDANT CHEMICALS](#) (last visited Mar. 18, 2023).