

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

Environment, Energy, and Resources Law: The Year in Review 2021

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

Copyright 2022 American Bar Association. All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission of the publisher. To request permission, contact the ABA's Department of Licensing and Copyrights via www.americanbar.org/utility/reprint.

The materials contained herein represent the opinions of the authors and editors and do not necessarily express the views or position of the American Bar Association, the Section of Environment, Energy, and Resources, or The University of Tulsa College of Law.

Nothing contained herein is to be considered as the rendering of legal advice for specific cases, and readers are responsible for obtaining such advice from their own legal counsel. These materials and any forms and agreements herein are intended for educational and informational purposes only.

Chapter H: PESTICIDES, CHEMICAL REGULATION, AND RIGHT-TO-KNOW 2021 Annual Report¹

I. TOXIC SUBSTANCES CONTROL ACT (TSCA)

The first year of the Biden Administration was marked largely by a pause in new Environmental Protection Agency (EPA) action, as the new Administration focused much of its efforts on reviewing and working to amend many of the TSCA rules and policies established by the Trump Administration. As a result, EPA proposed none of the several section 6 risk management rules due during the year, and instead focused on rethinking the initial ten risk evaluations completed during the Trump Administration. EPA also significantly slowed its completion of new chemical reviews and issuance of accompanying section 5(e) orders and significant new use rules (SNUR).

A. *New Chemicals Program and Significant New Use Rules (SNUR)*

EPA made [significant changes](#) to its approach to new chemical review and regulation under TSCA section 5.² It announced that it would cease to use the “non-order SNUR” mechanism and would resume issuing section 5(e) orders in every case in which EPA identified potential risks associated with any intended or foreseeable uses of a new chemical. It also announced that it would cease assuming that personal protective equipment (PPE) identified in Safety Data Sheets (SDS) would be used; instead, EPA would issue TSCA section 5(e) orders whenever EPA concluded that PPE is necessary to protect against unreasonable risk.

EPA also [established](#) a new policy that it generally would no longer view per- and polyfluoroalkyl substances (PFAS) as eligible for Low Volume Exemptions (LVE) or Low Release/Low Exposure Exemptions (LoREX).³ EPA also established the [PFAS Low Volume Exemption Stewardship Program](#), and asked PFAS LVE submitters to voluntarily withdraw their LVEs and submit premanufacture notices (PMNs) if they wish to continue to manufacture the substance.⁴ The Agency characterized [the program](#) as a renewal of its 2016 PFAS outreach effort that led to the voluntary withdrawal of “more than half of the 82 long-chain PFAS LVEs” on the market at the time.⁵

More broadly, EPA’s pace of completing new chemical determinations remained slow and indeed slowed considerably in 2021. According to data released by EPA, the Agency made risk determinations on just 70 PMNs in 2021 compared to an inventory of

¹Authors: Margaret Barry, Larry Culleen, and Judah Prero, Arnold & Porter Kaye Scholer LLP; Lynn Bergeson, Christopher Blunck, Richard Engler, Ph.D., Kelly Garson, Edith Nagy, and Todd Stedeford, Bergeson & Campbell, P.C.; Tom Berger and James Votaw, Keller and Heckman LLP; Lauren Baldwin, Amy Berg, and Freedom S.N. Smith, Ice Miller LLP; Sara Beth Watson, Erik Janus, Steptoe & Johnson LLP; and Keith Matthews, Wiley Rein LLP.

²Press Release, Env'tl. Prot. Agency, Important Updates on EPA’s TSCA New Chemicals Program (Mar. 29, 2021).

³Press Release, Env'tl. Prot. Agency, EPA Announces Changes to Prevent Unsafe New PFAS from Entering the Market (Apr. 27, 2021).

⁴Press Release, Env'tl. Prot. Agency, EPA Launches Stewardship Program to Reduce PFAS in the Marketplace (July 14, 2021).

⁵*PFAS Low Volume Exemption Stewardship Program*, ENVTL. PROT. AGENCY (last updated Jan. 18, 2022).

218 new PMN submissions and 136 remaining on hand from prior years.⁶ Indeed, EPA’s pace is slowing with time. EPA only made 12 determinations after September 1st. Therefore, it appears the backlog of pending PMNs will continue to grow. During 2021, EPA proposed 114 SNURs, including both non-order SNURs derivative of determinations made previously and order-based SNURs. This is comparable to the 117 SNURs EPA proposed during 2020. Even so, 70 PMNs that were the subjects of orders have yet to see SNURs proposed. The oldest cases have been waiting between four and five years for conforming SNURs to be proposed.

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

1. Risk Evaluation for Existing Chemicals—EPA Implementing New Policy and Procedures

In 2021, under the Biden administration’s new leadership, EPA reconsidered the Agency’s approach to TSCA section 6(b) risk evaluations. As part of these efforts, Assistant Administrator Michal Freedhoff [announced](#) three changes in policy that will significantly affect how EPA will conduct risk evaluations.⁷ First, EPA will develop and implement “fenceline community” exposure screening.⁸ The initial 10 risk evaluations, performed during the Trump administration, did not assess air, water or disposal releases to the environment or “exposures to the general population because these pathways were already regulated, or could be regulated, under other EPA-administered statutes, such as the Clean Air Act, Safe Drinking Water Act, and Clean Water Act.”⁹ EPA leadership under the Biden Administration determined that this approach was inadequate to assess “potential exposures to potentially exposed or susceptible subpopulations, including fenceline communities.”¹⁰ The proposed fenceline screening methodology was [released](#) for public comment in early 2022.¹¹

EPA changed the assumptions it made about compliance with occupational safety standards when evaluating potential occupational exposures.¹² Instead of assuming workers comply with applicable Occupational Safety and Health Administration (OSHA) exposure control practices, EPA intends to determine risk assuming that there are no applicable occupational safety standards and practices, including use of PPE (the “Baseline Scenario”). The actual effects of PPE and compliance with other OSHA safety standards would be considered only at the risk management stage. The new policy was first applied

⁶See [Status of Pre-Manufacture Notices Reviewed Under Section 5 of the Toxic Substances Control Act \(TSCA\)](#), ENVTL. PROT. AGENCY (last updated Nov. 10, 2021); see also [Premanufacture Notices \(PMNs\) and Significant New Use Notices \(SNUNs\) Table](#), ENVTL. PROT. AGENCY (last visited Mar. 23, 2022).

⁷Press Release, Env’tl. Prot. Agency, EPA Announces Path Forward for TSCA Chemical Risk Evaluations (June 30, 2021) [hereinafter EPA Risk Evaluations PR].

⁸See ENVTL. PROT. AGENCY, DRAFT TSCA SCREENING LEVEL APPROACH FOR ASSESSING AMBIENT AIR AND WATER EXPOSURES TO FENCELINE COMMUNITIES: VERSION 1.0 (Jan. 2022).

⁹EPA Risk Evaluations PR, *supra* note 7.

¹⁰*Id.*

¹¹See Press Release, Env’tl. Prot. Agency, EPA Releases Screening Methodology to Evaluate Chemical Exposures and Risks to Fenceline Communities (Jan. 21, 2022).

¹²EPA Risk Evaluations PR, *supra* note 7.

in the [proposed](#) revised section 6(b) risk evaluation for the Cyclic Aliphatic Bromide Cluster (HBCD).¹³

The last of the significant policy changes was EPA’s decision to make a single risk determination covering all uses of a chemical, in lieu of making the use-by-use risk determinations made for each of the first ten chemicals.¹⁴ Although this would result in all uses of a chemical being declared unreasonable risks, EPA anticipates that it would consider use-by-use risk determinations during the risk management phase. Like the Baseline Scenario, this so-called “Whole Chemical Approach” was first applied in the proposed revised section 6(b) risk evaluation for HBCD.¹⁵ EPA plans to reevaluate each of the first ten risk evaluation chemicals using this approach.

2. Risk Evaluation—Litigation

Asbestos. EPA’s risk evaluation of asbestos has been the subject of litigation, both regarding the completed risk evaluation of chrysotile asbestos¹⁶ (now referred to as “Part 1” of the asbestos risk evaluation) and EPA’s commitment to consider legacy uses of asbestos in a “Part 2” of the risk evaluation.¹⁷ In a proceeding challenging Part 1 of the risk evaluation, EPA and the petitioners reached an agreement, under which EPA agreed to address legacy uses and associated disposals for six asbestos fiber types in Part 2 of the risk evaluation. In a consent decree filed in a federal district court action in California, EPA agreed to complete Part 2 of its risk evaluation of asbestos by December 1, 2024.¹⁸ EPA anticipated issuing a draft scope document for Part 2 by December 31, 2021.

1,4-Dioxane. Five challenges to EPA’s final TSCA risk evaluation for 1,4-dioxane were filed or transferred to the Ninth Circuit.¹⁹ The consolidated cases are all now being held in abeyance after the court granted EPA’s request for a voluntary remand in light of EPA’s commitment to revisit the risk evaluation.

HBCD. Three challenges to EPA’s risk evaluation of HBCD were filed or transferred to the Ninth Circuit.²⁰ Proceedings in these consolidated cases were stayed after the court granted EPA’s request for a voluntary remand in order to reevaluate its prior risk determinations for this substance.

¹³Cyclic Aliphatic Bromide Cluster (HBCD); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment, 86 Fed. Reg. 74,082 (Dec. 29, 2021); *see also* [Press Release](#), Env’tl. Prot. Agency, EPA Releases Draft Revised Risk Determination for HBCD for Public Comment (Dec. 29, 2021).

¹⁴EPA Risk Evaluations PR, *supra* note 7.

¹⁵Cyclic Aliphatic Bromide Cluster (HBCD); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment, 86 Fed. Reg. at 74,086.

¹⁶*See, e.g.*, [Joint Motion for Abeyance](#) at 2, Asbestos Disease Awareness Organization v. Environmental Protection Agency, No. 21-70160 (9th Cir. filed Oct. 13, 2021).

¹⁷*See, e.g.*, [Joint Motion to Enter Consent Decree](#) at 2, Asbestos Disease Awareness Organization v. Regan, No. 4:21-CV-03716 (N.D. Cal. filed Oct. 13, 2021).

¹⁸*Id.*; *see also* Asbestos Part 2: Supplemental Evaluation Including Legacy Uses and Associated Disposals of Asbestos; Draft Scope of the Risk Evaluation to be Conducted Under the Toxic Substances Control Act; Notice of Availability and Request for Comments, [86 Fed. Reg. 74,088](#), 74,089 (Dec. 29, 2021).

¹⁹Environmental Defense Fund v. EPA, Nos. 21-70162, 21-70194, 21-70721, 21-70684, 21-70930 (9th Cir. filed Aug. 10, 2021).

²⁰Alaska Community Action on Toxics v. EPA, Nos. 20-73578, 21-70009, 20-73099 (9th Cir. filed Aug. 10, 2021).

Methylene Chloride. The Second Circuit upheld EPA's 2019 section 6(a) risk management rule for consumer uses of methylene chloride²¹ against challenges based on, *inter alia*, allegations that the rule was not supported by substantial evidence, that EPA failed to adequately assess its costs, and that the rule was defective because it did not address all unreasonable risks associated with use of the chemical.²² Two challenges to EPA's subsequent risk evaluation for methylene chloride conducted under TSCA's section 6(b) procedures added in 2016 were filed in the Ninth Circuit and are being held in abeyance after the court granted EPA's request for voluntary remand to reevaluate its prior risk determinations for this substance.²³

3. Risk Management—Select PBTs

During the last days of the Trump administration, EPA issued final risk management rules for five persistent, bioaccumulative, and toxic (PBT) chemicals on the TSCA Workplan that banned most uses of those chemicals: Decabromodiphenyl ether (DecaBDE) Phenol; isopropylated phosphate (3:1) (PIP (3:1)); 2,4,6-Tris (tert-butyl) phenol (2,4,6-TTBP); Hexachlorobutadiene (HCBD); and Pentachlorothiophenol (PCTP).²⁴ TSCA section 6(h) required EPA to issue risk management rules for certain TSCA Workplan PBTs without first conducting any risk evaluation. Two cases challenging EPA's TSCA section 6(h) risk management rule for DecaBDE were filed in early 2021 and remain pending.²⁵ EPA subsequently determined that it would review those final rules to determine whether it would be practicable for certain categorical and time-limited exclusions to be narrowed or eliminated.²⁶ EPA also deferred the compliance date for the prohibitions on processing and distribution of PIP (3:1) for use in articles, and for articles to which PIP (3:1) has been added. EPA last proposed to defer the compliance date for

²¹See Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a), [84 Fed. Reg. 11,420](#) (Mar. 27, 2019) (to be codified at 40 C.F.R. pt. 751) (direct final rule).

²²[Labor Council for Latin American Advancement v. EPA](#), 12 F.4th 234 (2d Cir. 2021).

²³See, e.g., [Neighbors for Environmental Justice v. EPA](#), No. 20-72091 (9th Cir. filed July 16, 2020).

²⁴2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP): Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h), [86 Fed. Reg. 866](#) (Jan. 6, 2021) (to be codified at 40 C.F.R. pt. 751) (direct final rule); Decabromodiphenyl Ether (DecaBDE): Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h), [86 Fed. Reg. 880](#) (Jan. 6, 2021) (to be codified at 40 C.F.R. pt. 751) (direct final rule); Hexachlorobutadiene (HCBD): Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h), [86 Fed. Reg. 922](#) (Jan. 6, 2021) (to be codified at 40 C.F.R. pt. 751) (direct final rule); Pentachlorothiophenol (PCTP): Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h), [86 Fed. Reg. 911](#) (Jan. 6, 2021) (to be codified at 40 C.F.R. pt. 751) (direct final rule); 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) (to be codified at 40 C.F.R. pt. 751) (direct final rule).

²⁵[Petition for Review](#) at 1, Alaska Community Action on Toxics v. EPA, No. 21-70168 (9th Cir. filed Jan. 27, 2021); [Petition for Review](#) at 1, Yurok Tribe v. EPA, No. 21-70670 (9th Cir. filed Mar. 19, 2021).

²⁶Press Release, Env'tl. Prot. Agency, EPA Announces Plan for New Rulemaking on PBT Chemicals, Extends Existing Compliance Date to Protect Supply Chains (Sept. 3, 2021).

these uses until October 2024;²⁷ however, the compliance date was originally deferred for 180 days through enforcement discretion as reflected in a [“No Action Assurance” letter](#),²⁸ and by a subsequent rule formally extending the compliance date for those PIP (3:1) uses through early March 2022.²⁹ These extensions were provided at the urgent request of a number of potentially affected industries that asserted they had been caught off-guard by the rule and were unprepared to substitute PIP (3:1) from all components in their supply chains by the original deadline.³⁰

C. Other TSCA Developments

1. Section 4(a)(2) Test Orders

On January 15, 2021, EPA issued TSCA section 4(a)(2) test orders for [nine chemicals](#) that are among the “Next 20” chemicals identified by EPA as high-priority substances now undergoing risk evaluation pursuant to TSCA section 6(b).³¹ These orders represent only the second time EPA has used section 4(a)(2) authority (added by the Lautenberg Act amendments in 2016) to support risk evaluation. The information required in these orders will be used by EPA to inform the corresponding risk evaluations. The test orders require specified environmental hazard testing and/or occupational exposure monitoring. The chemical substances are: 1,1,2-trichloroethane; 1,1-dichloroethane; 1,2-dichloropropane; *o*-dichlorobenzene; *p*-dichlorobenzene; 4,4'-(1-methylethylidene)bis[2,6-dibromophenol]; phosphoric acid, triphenyl ester; 1,2-dichloroethane; and trans-1,2-dichloroethylene.

2. Section 4(h) New Approach Methods

EPA updated its [List of Alternative Test Methods and Strategies](#) (or New Approach Methodologies (NAM)) required under TSCA section 4(h), “Reduction of testing on vertebrates.”³² In accordance with TSCA section 4(h)(2)(C), the NAMs on the list must be “scientifically reliable, relevant, and capable of providing information of equivalent or better scientific reliability and quality to that which would be obtained from vertebrate animal testing.”³³ EPA also updated its [formal work plan](#) to continue to reduce vertebrate

²⁷Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Phenol, Isopropylated Phosphate (3:1); Further Compliance Date Extension, [86 Fed. Reg. 59,684](#) (Oct. 28, 2021) (to be codified at 40 C.F.R. pt. 751).

²⁸Memorandum from Lawrence E. Starfield, Acting Assistant Adm’r, Off. of Enf’t & Compliance Assurance, Env’tl. Prot. Agency, to Michal Freedhoff, Acting Assistant Adm’r, Off. of Chem. Safety & Pollution Prevention, Env’tl. Prot. Agency, No Action Assurance Regarding Prohibition of Processing and Distribution of Phenol Isopropylated Phosphate (3:1), PIP (3:1) for Use in Articles, and PIP (3:1)-containing Articles under 40 CFR 751.407(a)(1) (Mar. 8, 2021) [hereinafter Starfield EPA Memo].

²⁹Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h); Phenol, Isopropylated Phosphate (3:1); Compliance Date Extension, [86 Fed. Reg. 51,823](#) (Sept. 17, 2021) (to be codified at 40 C.F.R. pt. 751) (direct final rule).

³⁰Starfield EPA Memo, *supra* note 28, at 2.

³¹*TSCA Section 4 Test Orders*, ENVTL. PROT. AGENCY (last visited Mar. 3, 2022); *see also* [Press Release](#), Env’tl. Prot. Agency, EPA Issues Test Orders for Nine Chemicals Undergoing Risk Evaluation under TSCA (Jan. 15, 2021).

³²OFF. OF CHEM. SAFETY & POLLUTION PREVENTION, ENVTL. PROT. AGENCY, LIST OF ALTERNATIVE TEST METHODS AND STRATEGIES (OR NEW APPROACH METHODOLOGIES[NAMs]) (Feb. 4, 2021).

³³*Id.*

animal testing.³⁴ The updated plan generally follows the [earlier plan](#), but excludes the goal to end all vertebrate testing by 2035.³⁵

3. Section 8(b) Confidential Business Information (CBI) Inventory Review Rule

After notice and an opportunity to consult with EPA, the Agency [determined](#) that it would strip CBI chemical identity claims associated with 377 chemicals listed on the confidential portion of the TSCA Inventory.³⁶ The CBI claims were disallowed after EPA found that one or more manufacturers of each chemical had reported the identity “during the 2012, 2016, and/or 2020 Chemical Data Reporting (CDR)[] periods,” without claiming the chemical identity as CBI. This waived the CBI claim of the submitter and vitiated the CBI claim of any other manufacturer of the chemical. Each of the 377 chemicals will be listed in the non-confidential portion of the TSCA Inventory when next published.

4. Section 8(d) Health & Safety Data Reporting Rule

On June 29, 2021, EPA [published](#) a final rule under TSCA section 8(d) requiring manufacturers and importers of 20 high-priority substances undergoing TSCA risk evaluation and 30 organohalogen flame retardants (OFR) of interest to the Consumer Product Safety Commission (CPSC) to submit lists and copies of unpublished health and safety studies to EPA.³⁷ EPA represents that it intends to use the information obtained on the 20 high-priority substances to inform its risk evaluations under TSCA section 6, and will use both the high-priority chemical data and OFR data to support evaluations of new chemicals under TSCA section 5, including in “analogue data for read across [and] category development.”³⁸

5. Section 8 Tiered Data Reporting Rule

EPA [initiated](#) a public consultation on the development of a reporting rule to help inform EPA’s TSCA section 6 prioritization, risk evaluation, and risk management activities.³⁹ The potential reporting rule would be [tiered to deliver](#) different fit-to-purpose data sets at specific stages of the existing chemicals risk evaluation program, including

³⁴OFF. OF CHEM. SAFETY & POLLUTION PREVENTION, OFF. OF RSCH. & DEV., ENVTL. PROT. AGENCY, NO. EPA 600/X-21/209, NEW APPROACH METHODS WORK PLAN (Dec. 2021).

³⁵*See, e.g.*, OFF. OF CHEM. SAFETY & POLLUTION PREVENTION, OFF. OF RSCH. & DEV., ENVTL. PROT. AGENCY, NO. EPA 615B20001, NEW APPROACH METHODS WORK PLAN (June 2020).

³⁶Press Release, Env’tl. Prot. Agency, Now Available: Updates to Confidential States of Chemicals on the TSCA Inventory (Oct. 13, 2021).

³⁷Health and Safety Data Reporting; Addition of 20 High-Priority Substances and 30 Organohalogen Flame Retardants, 86 Fed. Reg. 34,147 (June 29, 2021) (to be codified at 40 C.F.R. pt. 716) (direct final rule); Health and Safety Data Reporting; Addition of 20 High-Priority Substances and 30 Organohalogen Flame Retardants; Extension of Submission Deadline, [86 Fed. Reg. 54,386](#) (Oct. 1, 2021) (to be codified at 40 C.F.R. pt. 716) (direct final rule).

³⁸*Id.* at 34,150.

³⁹Development of Tiered Data Reporting To Inform TSCA Prioritization, Risk Evaluation, and Risk Management; Notice of Public Meeting and Opportunity To Comment, 86 Fed. Reg. 37,152 (July 14, 2021).

identifying and prioritizing candidates for risk evaluation and assessing substances designated as high priority for section 6 risk evaluation.⁴⁰

6. Section 26 Fees Rule Amendments

EPA [proposed](#) amendments to the TSCA Fees Rule, which, if adopted as proposed, would significantly increase certain fees, expand the kinds of events that triggered fee payments, and create exemptions from EPA-initiated risk evaluation fees for manufacturers and importers of impurities and byproducts.⁴¹ Separately, on November 23, 2021, EPA [announced](#) a statutorily required, triennial amendment to fee amounts based on inflation.⁴²

D. National Program Chemicals (Mercury, Lead, Polychlorinated Biphenyls (PCBs))

EPA [amended](#) the TSCA mercury inventory reporting rules to remove the reporting exemption for pre-assembled products that contain a mercury-added component.⁴³ The amendment implements a 2020 [decision](#) by the U.S. Court of Appeals for the Second Circuit vacating the reporting exemption.⁴⁴ EPA will update the mercury inventory reporting rule [compliance guide and other supporting materials](#) to list these new reporting requirements.⁴⁵

EPA proposed “to withdraw two Frequently Asked Questions (FQs) concerning property management companies (PMCs) and their compliance responsibilities under the . . . Lead Renovation, Repair and Painting (RRP) Rule.”⁴⁶ Going forward, EPA intends to assess compliance by PMCs with the RRP rule, just as it would for any other entity.

EPA proposed to amend the PCB cleanup and disposal rules.⁴⁷ The proposal would, *inter alia*, expand analytical testing options; amend the “performance-based disposal option for PCB remediation waste;” remove “the provision allowing PCB bulk product waste to be disposed as roadbed material;” provide more flexibility for addressing “spills that occur during emergency situations (*e.g.*, hurricanes or floods); [and] harmoniz[e] the general disposal requirements for PCB remediation waste.”⁴⁸

II. PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS)

⁴⁰OFF. OF POLLUTION PREVENTION & TOXICS, ENVTL. PROT. AGENCY, NO. EPA-HQ-OPPT-2021-0436-0003, PUBLIC WEBINAR, DEVELOPMENT OF TIERED DATA REPORTING FOR TSCA PRIORITIZATION, RISK EVALUATION, AND RISK MANAGEMENT (July 27, 2021).

⁴¹Fees for the Administration of the Toxic Substances Control Act (TSCA), 86 Fed. Reg. 1890 (Jan. 11, 2021) (to be codified at 40 C.F.R. pt. 700).

⁴²Press Release, Env'tl. Prot. Agency, EPA Announces First Mandated Adjustment for TSCA Fees (Nov. 23, 2021).

⁴³Response to Vacatur of Certain Provisions of the Mercury Inventory Reporting Rule, 86 Fed. Reg. 61,708 (Nov. 8, 2021) (to be codified at 40 C.F.R. pt. 713) (direct final rule).

⁴⁴Natural Resources Defense Council, Inc. v. EPA, 961 F.3d 160 (2d Cir. 2020).

⁴⁵*See generally Resources for the Mercury Inventory Reporting Rule*, ENVTL. PROT. AGENCY (last visited Mar. 23, 2022).

⁴⁶Withdrawal of Two Answers to Frequent Questions About Property Management Companies and the Toxic Substances Control Act Lead-Based Paint Renovation, Repair, and Painting Rule, [86 Fed. Reg. 60,812](#) (Nov. 4, 2021).

⁴⁷Alternate PCB Extraction Methods and Amendments to PCB Cleanup and Disposal Regulations, [86 Fed. Reg. 58,730](#) (Oct. 22, 2021) (to be codified at 40 C.F.R. pt. 761).

⁴⁸*Id.*

PFAS continued to be the focus of intense regulatory and legislative activity at the Federal and State levels. PFAS contains carbon-fluorine bonds, which impart extreme resistance to degradation and have led to their moniker as “forever chemicals.”⁴⁹ Some PFAS are routinely detected in the environment, wildlife, and even humans. In 2021, public attention and congressional scrutiny of PFAS have led to the placement of these substances at the forefront of the federal and state regulatory agendas.

EPA pressed ahead with its “whole agency” approach to PFAS. EPA assessed the non-cancer effects and potential carcinogenicity of short- and long-chain PFAS. EPA’s Office of Research and Development (ORD) and Office of Water (OW) derived subchronic and chronic non-cancer oral reference doses (RfD) for “GenX” chemicals,⁵⁰ perfluorooctanoic acid (PFOA),⁵¹ perfluorooctane sulfonic acid (PFOS),⁵² and perfluorobutane sulfonic acid (PFBS).⁵³ The final PFBS toxicity values superseded less stringent values published during the Trump Administration⁵⁴ that were alleged to have been compromised by political interference.⁵⁵

EPA proposed a TSCA section 8(a)(7) reporting and recordkeeping rule for PFAS.⁵⁶ Section 8(a)(7) was added to TSCA by the National Defense Authorization Act for Fiscal Year 2020 (FY 2020 NDAA).⁵⁷ The amendment directed EPA to promulgate a rule no later than January 1, 2023, requiring “each person who has manufactured a chemical substance that is a [PFAS] in any year since January 1, 2011 to [submit] information [as] described [under] TSCA section 8(a)(2)(A) through (G).”⁵⁸ The proposed rule omitted reporting exemptions that are commonly found in other TSCA information reporting rules such as, for example, exemptions for impurities, byproducts, R&D substances, and components of imported articles.

⁴⁹[PFAS](#), GREEN SCI. POL’Y INST. (last visited Mar. 24, 2022).

⁵⁰OFF. OF WATER, ENVTL. PROT. AGENCY, NO. 822R-21-010, HUMAN HEALTH TOXICITY VALUES FOR HEXAFLUOROPROPYLENE OXIDE (HFPO) DIMER ACID AND ITS AMMONIUM SALT (CASRN 13252-13-6 AND CASRN 62037-80-3), ALSO KNOWN AS “GENX CHEMICALS,” at 28-30 (Oct. 2021).

⁵¹OFF. OF WATER, ENVTL. PROT. AGENCY, NO. 822D21001, PROPOSED APPROACHES TO THE DERIVATION OF A DRAFT MAXIMUM CONTAMINANT LEVEL GOAL FOR PERFLUOROOCTANOIC ACID (PFOA) (CASRN 335-67-1) IN DRINKING WATER, EXTERNAL PEER REVIEW DRAFT 3-4 (Nov. 2021).

⁵²OFF. OF WATER, ENVTL. PROT. AGENCY, NO. 822D21002, PROPOSED APPROACHES TO THE DERIVATION OF A DRAFT MAXIMUM CONTAMINANT LEVEL GOAL FOR PERFLUOROOCTANE SULFONIC ACID (PFOS) (CASRN 1763-23-1) IN DRINKING WATER, EXTERNAL PEER REVIEW DRAFT 3-4 (Dec. 2021).

⁵³OFF. OF RSCH. & DEV., ENVTL. PROT. AGENCY, NO. EPA/600/R-20/345F, HUMAN HEALTH TOXICITY VALUES FOR PERFLUOROBUTANE SULFONIC ACID (CASRN 375-73-5) AND RELATED COMPOUND POTASSIUM PERFLUOROBUTANE SULFONATE (CASRN 29420-49-3), at 1-4 (Apr. 2021).

⁵⁴Press Release, Env’tl. Prot. Agency, EPA Delivers Results on PFAS Action Plan (Jan. 19, 2021).

⁵⁵Press Release, Env’tl. Prot. Agency, EPA Takes Action to Protect Scientific Integrity (Feb. 9, 2021).

⁵⁶TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 86 Fed. Reg. 33,926 (June 28, 2021) (to be codified at 40 C.F.R. pt. 705).

⁵⁷National Defense Authorization Act for Fiscal Year 2020 (FY2020 NDAA), [Pub. L. No. 116-92](#), § 7351, 133 Stat. 1198, 2289 (2019) (PFAS Data Call, Subtitle E - Toxic Substances Control Act).

⁵⁸TSCA § 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 86 Fed. Reg. at 33,927 (internal quotations omitted).

EPA released its [National PFAS Testing Strategy](#), that includes the approaches EPA used to categorize thousands of PFAS and to identify 24 PFAS candidate substances for testing.⁵⁹ EPA stated that it intends to use “its TSCA section 4 order authority to require PFAS manufacturers to conduct” testing on the candidate substances to inform data gaps EPA identifies in its PFAS tiered-testing scheme.⁶⁰ EPA anticipates issuing additional orders as it identifies manufactures of other PFAS in the future.⁶¹

On reconsideration, EPA granted in part a [TSCA section 21 petition](#)⁶² seeking EPA to compel manufacturers to perform health and environmental effects testing on 54 PFAS found in the Cape Fear River.⁶³ The petition was initially denied by EPA during the Trump Administration.⁶⁴

III. EMERGENCY PLANNING AND COMMUNITY RIGHT-TO-KNOW ACT (EPCRA)⁶⁵

Three PFAS were added to the list of chemicals subject to annual Toxics Release Inventory (TRI) reporting⁶⁶ pursuant to the automatic listing provisions of the FY 2020 NDAA.⁶⁷ Any PFAS added to the scope of an existing TSCA SNUR is also added to the TRI reporting list.⁶⁸ On July 20, 2020, EPA modified an existing SNUR to include the three PFAS; thereby, triggering the FY 2020 NDAA mechanism for listing under EPCRA section 313.⁶⁹ The three PFAS are: silver(I) perfluorooctanoate (335-93-3), perfluorooctyl iodide (507-63-1), and potassium perfluorooctanoate (2395-00-8). Reporting forms for these chemicals are due July 1, 2022 for 2021 data if TRI reporting thresholds are met.

In response to an interest group’s [2014 petition](#),⁷⁰ EPA proposed to add 12 additional chemicals to the TRI reporting list.⁷¹ The chemicals proposed for addition include: Dibutyltin dichloride (683-18-1), 1,3-Dichloro-2-propanol (96-23-1), Formamide (75-12-7), 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran (1222-05-5), N-Hydroxyethylethylenediamine (111-41-1), Nitritotriacetic acid trisodium

⁵⁹ENVTL. PROT. AGENCY, NATIONAL PFAS TESTING STRATEGY: IDENTIFICATION OF CANDIDATE PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS) FOR TESTING (Oct. 2021).

⁶⁰*Id.* at 3.

⁶¹*Id.* at 11.

⁶²CTR. FOR ENVTL. HEALTH ET AL., PETITION TO REQUIRE HEALTH AND ENVIRONMENTAL TESTING UNDER THE TOXIC SUBSTANCES CONTROL ACT ON CERTAIN PFAS MANUFACTURED BY CHEMOURS IN FAYETTEVILLE, NORTH CAROLINA 1-2 (Oct. 13, 2020).

⁶³[Press Release](#), Env’tl. Prot. Agency, EPA Grants Petition to Order Testing on Human Health Hazards of PFAS (Dec. 28, 2021).

⁶⁴*See* TSCA Section 21 Petition for Rulemaking; Reasons for Agency Response; Denial of Requested Rulemaking, [86 Fed. Reg. 6602](#) (Jan. 22, 2021) (to be codified at 40 C.F.R. ch. undefined).

⁶⁵42 U.S.C. §§ 11001-11050 (2019).

⁶⁶Implementing Statutory Addition of Certain Per- and Polyfluoroalkyl Substances (PFAS) to the Toxics Release Inventory Beginning With Reporting Year 2021, [86 Fed. Reg. 29,698](#) (June 3, 2021) (to be codified at 40 C.F.R. pt. 372) (direct final rule).

⁶⁷National Defense Authorization Act for Fiscal Year 2020 (FY2020 NDAA), § 7351.

⁶⁸*Id.* at § 7321(c)(1)(A)(iii).

⁶⁹Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule, [85 Fed. Reg. 45,109](#), 45,112 (July 27, 2020) (to be codified at 40 C.F.R. pt. 721) (direct final rule).

⁷⁰*See* Letter from Mike Ellenbecker, Dir., and Liz Harriman, Deputy Dir., Mass. Toxics Use Reduction Inst., to Gina McCarthy, Adm’r, Off. of the Adm’r, Env’tl. Prot. Agency, Proposed Additions to the TRI Chemical List (May 6, 2014).

⁷¹Addition of Certain Chemicals; Community Right-to-Know Toxic Chemical Release Reporting, [86 Fed. Reg. 57,614](#) (Oct. 18, 2021) (to be codified at 40 C.F.R. pt. 372).

salt (5064-31-3), p-(1,1,3,3-Tetramethylbutyl)phenol (140-66-9), 1,2,3-Trichlorobenzene (87-61-6), Triglycidyl isocyanurate (2451-62-9), Tris(2-chloroethyl) phosphate (115-96-8), Tris(1,3-dichloro-2-propyl) phosphate (13674-87-8), and Tris(dimethylphenol) phosphate (25155-23-1).

On April 29, 2021, EPA [announced](#) that it would expand TRI reporting requirements to include additional chemicals and facilities, “to advance Environmental Justice, improve transparency, and increase access to environmental information.”⁷² For example, in addition to the three PFAS added to the TRI list for the 2021 reporting year, EPA anticipates more PFAS additions to the TRI, including PFBS. Additionally, EPA plans to propose adding the chemicals in the [TSCA Work Plan for Chemical Assessments](#)⁷³ and other TSCA high-priority substances to the TRI.⁷⁴ The agency also “plans to finalize a rule to add natural gas processing facilities to the list of industry sectors covered under the” TRI reporting requirements.⁷⁵ Likewise, EPA plans to [broaden](#) TRI reporting requirements for ethylene oxide (EtO) to include certain contract sterilization facilities that use EtO to sterilize medical equipment but are not currently required to report this information.⁷⁶ EPA sent letters to 31 contract sterilization “facilities providing notice that it is considering requiring [these] facilities to report EtO releases to the TRI” pursuant to its discretionary authority under EPCRA.⁷⁷ Some of these facilities also are being considered for ethylene glycol reporting.

EPA made key TRI resources available in Spanish for the first time by publishing a [Spanish version](#) of the TRI website.⁷⁸

IV. BIOTECHNOLOGY DEVELOPMENTS

2021 saw a number of significant Federal regulatory actions related to non-pharmaceutical biotechnology. In April, Oxitec Ltd. began initial [releases](#) of the OX5034 genetically engineered *Aedes aegypti* mosquito in the Florida Keys under experimental use regulatory approvals granted by the EPA and the Florida Department of Agriculture and Consumer Services (FDACS).⁷⁹ EPA published its [response to comments](#) on its September 9, 2020 draft framework for addressing lepidopteran pests resistance to corn and cotton crops genetically engineered to express *Bacillus thuringiensis* (B.t.) Cry proteins.⁸⁰

⁷²[Press Release](#), Env'tl. Prot. Agency, EPA Announces Plan to Update Toxics Release Inventory to Advance Environmental Justice (Apr. 29, 2021).

⁷³OFF. OF POLLUTION PREVENTION & TOXICS, ENVTL. PROT. AGENCY, TSCA WORK PLAN FOR CHEMICAL ASSESSMENTS: 2014 UPDATE (Oct. 2014).

⁷⁴*Id.*

⁷⁵*Id.*

⁷⁶Press Release, Env'tl. Prot. Agency, EPA Takes Next Step to Broaden TRI Reporting Requirements for Ethylene Oxide (Oct. 13, 2021).

⁷⁷*Id.*

⁷⁸[Press Release](#), Env'tl. Prot. Agency, Toxics Release Inventory Website Now Available in Spanish (Feb. 11, 2021).

⁷⁹[Press Release](#), Oxitec, Landmark Project to Control Disease Carrying Mosquitoes Kicks Off in the Florida Keys (Apr. 29, 2021).

⁸⁰Memorandum from Kara Welch, Entomologist, Emerging Tech. Branch, Biopesticides & Pollution Prevention Div., Env'tl. Prot. Agency, to Michael Mendelsohn, Branch Chief, Emerging Tech. Branch, Biopesticides & Pollution Prevention Div., Env'tl. Prot. Agency, EPA's Response to Comments Received on the September 9, 2020 Draft Proposal to Address Resistance Risks to Lepidopteran Pests of Corn and Cotton Containing the *Bacillus thuringiensis* (Bt) Plant-Incorporated Protectant (PIP) and Revised Framework for Industry Negotiations (Nov. 23, 2021) (referencing EPA Dkt. No. EPA-HQ-OPP-2019-0682-0052).

On December 28, 2020, the U.S. Department of Agriculture (USDA) [published](#) an advanced notice of proposed rulemaking seeking comment on a potential future rulemaking to transition regulatory jurisdiction over the safety reviews of certain agricultural animals produced by genetic engineering from the Food and Drug Administration (FDA) to USDA.⁸¹ The potential future rulemaking would transition to USDA regulatory jurisdiction over certain agricultural animals (*e.g.*, catfish, cattle, equines (including horses and mules), goats, hogs and pigs, poultry, and sheep) that are developed using genetic engineering.

V. CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD (CSB)

The CSB issued an accidental release [reporting form](#) and [reporting guidance](#) to implement its 2020 accidental release reporting rule for chemical manufacturers, which was required by section 112(r) of the Clean Air Act.⁸² Due to the expiration of the terms of all other Board members, CSB Chairman, Katherine Lemos, was the sole member of the Board in 2021. Late in the year, new CSB members, Sylvia Johnson and Steve Owens, were confirmed by the Senate to serve five-year terms. There was no vote on a third candidate, Jennifer Sass, and her nomination was [returned](#) to President Biden at the end of the session.⁸³

VI. STATE DEVELOPMENTS OF NOTE

At least six states—California, Connecticut, Maine, Maryland, New York, and Vermont—enacted new laws restricting or requiring disclosure of chemicals in consumer, commercial, or industrial products. A majority of these laws focused on PFAS.

California enacted laws that prohibit the sale and distribution of “juvenile products” and food packaging containing “regulated PFAS.”⁸⁴ The prohibition on PFAS-containing juvenile products takes effect on July 1, 2023; the ban on PFAS-containing food packaging takes effect on January 1, 2023. The same legislation that banned PFAS-containing food packaging also established product labeling and disclosure requirements for cookware that contains chemicals listed as Candidate Chemicals in the California Department of Toxic Substances Control (DTSC) Safer Consumer Products program. The new law also bars manufacturers from making claims that their cookware is free of a specific chemical unless no individual chemical from the chemical group or class, to which that specific chemical belongs, is intentionally added to the cookware. In July, DTSC listed carpets and rugs containing PFAS as a “Priority Product” in the Safer Consumer Products program.⁸⁵

In Connecticut, a law enacted in July 2021 imposes restrictions on the use of firefighting foam containing intentionally added PFAS.⁸⁶ Effective on December 31, 2023, the law also bars manufacturers and distributors from offering for sale or for promotion purposes food packages, to which PFAS has been intentionally introduced.

⁸¹Regulation of the Movement of Animals Modified or Developed by Genetic Engineering, 85 Fed. Reg. 84,269 (Dec. 28, 2020) (to be codified at 9 C.F.R. ch. undefined), *comment period reopened*, [86 Fed. Reg. 13,221](#) (Mar. 8, 2021) (to be codified at 9 C.F.R. ch. undefined).

⁸²Accidental Release Reporting, [85 Fed. Reg. 10,074](#) (Feb. 21, 2020) (to be codified at 40 C.F.R. pt. 1604) (direct final rule).

⁸³Jennifer Beth Sass—Chemical Safety and Hazard Investigation Board, P.N. 541, 117th Cong. (1st Sess. 2021).

⁸⁴[A.B. 652](#), 117th Leg., Reg. Sess. (Cal. 2021) (codified at CAL. HEALTH & SAFETY CODE §§ 108945-108947); [A.B. 1200](#), 117th Leg., Reg. Sess. (Cal. 2021) (codified at CAL. HEALTH & SAFETY CODE §§ 109000-109014).

⁸⁵*See* CAL. CODE REGS. tit. 22, §§ 69511(b)(4), 69511.4 (2021).

⁸⁶[S.B. 837](#), 2021 Gen. Assemb., Reg. Sess. (Conn. 2021) (codified at Conn. P.A. 21-191).

Maine legislative action included provisions that will ban, as of January 1, 2030, all products containing intentionally added PFAS, except for any product or product category for which the Maine Department of Environmental Protection (Maine DEP) determines the use of PFAS is “currently [an] unavoidable use.”⁸⁷ Beginning on January 1, 2023, the law requires manufacturer notifications regarding products that contain intentionally added PFAS. It also prohibits the sale of carpets, rugs, and fabric treatments containing intentionally added PFAS, effective January 1, 2023, and authorizes the Maine DEP to prohibit other categories or uses of products containing intentionally added PFAS in advance of the 2030 ban. Maine enacted a separate law restricting use of firefighting or fire-suppressing foams to which PFAS have been intentionally added.⁸⁸

In Maryland, the manufacture, sale, delivery, holding, or offering for sale of cosmetic products containing one or more of 24 chemicals—13 PFAS and 11 other substances—will be banned beginning on January 1, 2025.⁸⁹

In December 2020, New York enacted two chemical regulatory laws. One law, beginning on December 1, 2022, will prohibit use of trichloroethylene as a vapor degreaser, intermediate chemical, refrigerant, or extraction solvent, or in other manufacturing or industrial cleaning processes or uses.⁹⁰ The other law will prohibit distribution and sale of food packaging containing intentionally added PFAS, effective on December 31, 2022.⁹¹

Legislation signed by the Vermont governor in May 2021 will restrict use of class B firefighting foam containing intentionally added PFAS and require notice to purchasers regarding the presence of PFAS in personal protective equipment.⁹² The law also imposes bans, as of July 1, 2023, on residential rugs, carpets, and aftermarket stain and water-resistant treatments for rugs or carpets, to which PFAS have been intentionally added. Bans also will apply to ski wax and related tuning products and food packaging, to which PFAS have been intentionally added. The Vermont law also prohibits manufacture, sale, and distribution of food packages, to which ortho-phthalates have been intentionally added. In addition, the Vermont Department of Health is authorized to prohibit food packages containing intentionally added bisphenols. By adding three PFAS (perfluorohexane sulfonic acid (PFHxS), perfluoroheptanoic acid (PFHpA), and perfluorononanoic acid (PFNA)) to the list of chemicals of high concern to children in Vermont’s Chemicals in Children’s Products program, the law also imposes reporting obligations on manufacturers of children’s products containing these substances.

In Washington, the Department of Ecology (Ecology) issued draft regulatory determinations in November 2021 for each priority consumer product that Ecology previously identified in the Safer Products for Washington program.⁹³ The priority consumer products are product-chemical combinations that meet statutory criteria, including electric and electronic enclosures containing OFRs, personal care and beauty

⁸⁷[H.P. 1113 - L.D. 1503](#), 130th Leg., Reg. Sess. (Me. 2021) (ch. 477 Pub. L., codified at ME. REV. STAT. ANN. tit. 38, § 1612).

⁸⁸[H.P. 1113 - L.D. 1505](#), 130th Leg., Reg. Sess. (Me. 2021) (ch. 449 Pub. L., codified at ME. REV. STAT. ANN. tit. 38, § 424-C).

⁸⁹[H.B. 643](#), 2021 Leg., 442d Sess. (Md. 2021) (codified at MD. CODE ANN. HEALTH-GEN. § 21-259.2).

⁹⁰[S.B. S6829B](#), 203d Leg., 2019 Sess. (N.Y. 2019) (codified as amended at N.Y. ENV’T CONSERV. LAW § 37-0119).

⁹¹[S.B. S8817](#), 203d Leg., 2020 Sess. (N.Y. 2020) (codified as amended at N.Y. ENV’T CONSERV. LAW § 37-0209).

⁹²[S. 20](#), No. 36, 2021 Gen. Assemb., Reg. Sess. (Vt. 2021) (codified at VT. STAT. ANN. tit. 18, §§ 1661-1667, 1671-1675, 1681-1686, 1691-1695, 1773).

⁹³WASH. STATE DEP’T OF ECOL., No. 21-04-047, [DRAFT REGULATORY DETERMINATIONS REPORT TO THE LEGISLATURE: SAFER PRODUCTS FOR WASHINGTON IMPLEMENTATION PHASE 3](#) (Nov. 2021).

products (fragrances), and vinyl flooring containing phthalates. For almost all of the priority consumer products, Ecology made draft regulatory determinations to impose restrictions on uses.

VII. FEDERAL INSECTICIDE FUNGICIDE AND RODENTICIDE ACT (FIFRA)

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

In 2021, EPA and the other members of the Interagency Working Group—Department of the Interior, Department of Commerce, Department of Agriculture, and the Council on Environmental Quality—continued to work on improvements to the consultation process and, in January 2022, EPA [announced](#) a new ESA Protection Policy for New Pesticides.⁹⁴ Under the policy, which became effective on January 11, 2022, EPA will evaluate the potential effects of any new conventional active ingredient (AI) “on federally threatened or endangered (listed) species,[] their designated critical habitats, and initiate ESA consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (the Services), as appropriate.”⁹⁵ EPA will apply the policy to all new conventional active ingredients, including where applications have been submitted to EPA, and EPA has not completed the review.⁹⁶ In addition, for new use applications where there exist significant environmental concerns, including for listed species, EPA may wait to consider whether to approve a new use until the requisite ESA analysis can be completed based on available resources. EPA stated that it is prioritizing conventional pesticides because the Agency believes, in general, that antimicrobials have a limited likelihood of contact with listed species and that biopesticides, due to their mode of action, are less likely to impact listed species. Nevertheless, EPA will “explore applying these new ESA approaches to new biopesticide [active ingredients] and new antimicrobial [active ingredients].”⁹⁷

The Interagency Working Group submitted its third [Report to Congress](#)⁹⁸ outlining its work, including consultation with various stakeholders. EPA and the National Marine Fisheries Service (NMFS) issued for comment two NMFS draft biological opinions on four pesticides: metolachlor, 1,3-D, bromoxynil, and prometryn, which evaluated the impacts on federally listed endangered and threatened species of Pacific salmon and steelhead in Washington, Oregon, and California.⁹⁹ The four active ingredients were the last covered by a 2008 settlement agreement between NMFS and Northwest Center for Alternatives to Pesticides. NMFS finalized the biological opinions in 2021 and EPA required registrants to implement risk reduction measures, including label changes and the Agency’s

⁹⁴Press Release, Env’tl. Prot. Agency, EPA Announces Endangered Species Act Protection Policy for New Pesticides (Jan. 11, 2022) [hereinafter ESA New Pesticides Pol’y].

⁹⁵*Id.*

⁹⁶[Endangered Species Act Policy for New Active Ingredients: Q&A](#), ENVTL. PROT. AGENCY (last visited Mar. 1, 2022).

⁹⁷ESA New Pesticides Pol’y, *supra* note 94.

⁹⁸ENVTL. PROT. AGENCY, DEP’T OF THE INTERIOR, DEP’T OF COMMERCE, DEP’T OF AGRIC., COUNCIL ON ENVTL. QUALITY, [REPORT TO CONGRESS ON IMPLEMENTING IWG RECOMMENDATIONS ON IMPROVING THE CONSULTATION PROCESS REQUIRED UNDER SECTION 7 OF THE ENDANGERED SPECIES ACT FOR PESTICIDE REGISTRATION AND REGISTRATION REVIEW](#) (June 2021).

⁹⁹NAT’L MARINE FISHERIES SERV., [BIOLOGICAL OPINION ON THE ENVIRONMENTAL PROTECTION AGENCY’S REGISTRATION REVIEW OF PESTICIDE PRODUCTS CONTAINING METOLACHLOR AND 1,3 DICHLOROPROPENE](#) (July 2021); NAT’L MARINE FISHERIES SERV., [BIOLOGICAL OPINION ON THE ENVIRONMENTAL PROTECTION AGENCY’S REGISTRATION REVIEW OF PESTICIDE PRODUCTS CONTAINING BROMOXYNIL AND PROMETRYN](#) (July 2021).

[Endangered Species Protection Bulletins](#).¹⁰⁰ EPA also opened a 60-day comment period on the U.S. Fish and Wildlife Service’s (FWS) [draft biological opinion on malathion](#).¹⁰¹ EPA finalized a nationwide biological evaluation for methomyl and carbaryl, which were the first to be conducted using the revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides.¹⁰²

The D.C. Circuit Court of Appeals vacated a registration amendment to add uses in [Farmworkers Association of Florida v. EPA](#).¹⁰³ In January 2021, EPA [issued](#) conditional registrations restricted to oranges and grapefruit in Florida for a limited time with the latest expiration date of April 30, 2023.¹⁰⁴ The conditional registrations also included rate and other restrictions. In its order granting the petitioner’s motion for summary vacatur, and denying the government’s motion for remand without vacatur, the court stated that EPA acknowledged it did not make an ESA determination prior to approving the additional use in Florida. The court added that EPA had “been explicit that it will not provide any reconsideration on remand before 2024 at the earliest – long after the registration at issue has expired.”¹⁰⁵ The order also stated that vacatur would not result in material disruption as the active ingredient had not been registered for use on oranges and grapefruits in Florida for almost 10 years and the State had denied the state registration.

B. Endocrine Disruptor Screening Program

While EPA has conducted some reviews of endocrine disruption under TSCA, the main focus of the U.S. endocrine disruptor policy (*i.e.*, implementation of the Endocrine Disruptor Screening Program or EDSP)¹⁰⁶ is under FIFRA, as modified by the Food Quality Protection Act (FQPA) in 1996.¹⁰⁷ Throughout 2020 and 2021, EPA continued to work towards what the Agency refers to as “the pivot”¹⁰⁸—the inflection point where future

¹⁰⁰[Endangered Species Protection Bulletins](#), ENVTL. PROT. AGENCY (last updated Feb. 17, 2022); *see also* [Press Release](#), Env’tl. Prot. Agency, EPA Takes Steps to Protect Endangered Fish from Pesticide Exposure (July 9, 2021).

¹⁰¹[Biological Opinions Available for Public Comment](#), ENVTL. PROT. AGENCY (last updated July 9, 2021); *see also* [Memorandum](#) from Tracy Perry, Senior Regul. Advisor, Risk Mgmt. & Implementation Branch III, Pesticide Re-evaluation Div., Off. Chem. Safety & Pollution Prevention, Env’tl. Prot. Agency, Opening of 60-day Public Comment Period on U.S. Fish and Wildlife Service (FWS) Draft Biological Opinion on Malathion (Apr. 15, 2021).

¹⁰²*See* [Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides](#), ENVTL. PROT. AGENCY (last updated Aug. 6, 2021).

¹⁰³No. 21-1079 (D.C. Cir. June 7, 2021).

¹⁰⁴OFF. OF PESTICIDE PROGRAMS, ENVTL. PROT. AGENCY, REGISTRATION DECISION FOR THE USES ON ORANGES AND GRAPEFRUIT IN FLORIDA, ALDICARB 4 (Jan. 12, 2021).

¹⁰⁵*Farmworker Ass’n of Fla.*, No. 21-1079, at 1.

¹⁰⁶*See generally* [Endocrine Disruptor Screening Program \(EDSP\) Overview](#), ENVTL. PROT. AGENCY (last updated Dec. 9, 2021).

¹⁰⁷*See* Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (1996).

¹⁰⁸The “pivot” was initially described to the Pesticide Program Dialog Committee in 2015 by Dr. David Dix, *see* PESTICIDE PROGRAM DIALOGUE COMM., ENVTL. PROT. AGENCY, [UPDATE: ENDOCRINE DISRUPTER SCREENING PROGRAM \(EDSP\)](#) (Oct. 2015). Development of test batteries not using animals, incorporation of adverse outcome pathways (AOPs) and Integrated Approaches to Testing and Assessment (IATA) principles, development and utilization of ToxCast, introduction of high-throughput testing to prioritize future testing are all examples of changes made to the program by EPA in the spirit of reducing cost and animal burden for Tier 1, which has been estimated to cost from 0.7 – 1 million dollars per

testing under the EDSP¹⁰⁹ will be conducted mainly by non-animal approaches (colloquially known as NAMs or new alternative methods). More specifically in this context, the pivot refers to the use of high-throughput assays (*in vitro*, *in chemico* methods) and computational models (*in silico* methods) to rapidly screen the approximately 10,000 chemicals found in the EDSP “universe.”¹¹⁰

Towards this end, EPA is establishing NAM test batteries for each major endocrine axis of concern (*i.e.*, estrogen, androgen, steroidogenesis, and thyroid). These test batteries seek to replace existing animal-based approaches for satisfying Tier 1 of the EDSP and are becoming more automated with time. EPA has established such a [battery](#) for the estrogen pathway and has successfully screened approximately 1,800 pesticides using this new approach.¹¹¹ Currently, the Agency is working on androgen, steroidogenesis, and thyroid batteries for use with Tier 1.¹¹²

The EPA Office of the Inspector General (OIG) is continuing its investigation into the progress EDSP has made to date. The findings of the most recent investigation were [released](#) in July 2021.¹¹³ OIG performed this most recent evaluation to determine progress of implementation of Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(p)(3)(a), as well as compliance with section 408(p)(6). The former requires EPA to test all pesticide chemicals for endocrine disruptor potential in man, while the latter requires EPA to take action should it find that a substance interferes with the endocrine system. The OIG found that progress of the EDSP continues to be hampered by lack of implementation controls (such as guidance documents or performance tracking), lack of internal program audits, lack of communication with stakeholders, lack of appropriate resource levels, and lack of consistent follow-through with previous OIG recommendations.

C. *Agricultural Worker Protection Standard*

EPA [finalized revisions](#) “to the Agricultural Worker Protection Standard (WPS) to clarify and simplify the application exclusion zone (AEZ) requirements.”¹¹⁴ The final rule was to be effective on December 29, 2020, but was stayed following multiple lawsuits challenging the rule, which are now consolidated in the Southern District of New York.¹¹⁵

chemical. *See* Use of High Throughput Assays and Computational Tools; Endocrine Disruptor Screening Program; Notice of Availability and Opportunity for Comment, [80 Fed. Reg. 35,350](#) (June 19, 2015).

¹⁰⁹EDSP is a two-tiered testing framework whereby Tier 1 is a test battery composed of 11 *in vitro* and *in vivo* assays intended to determine the potential of chemical interaction with the endocrine system and Tier 2 is a bespoke battery intended to determine quantitative dose-response relationships for adverse endocrine effects discovered during Tier 1. *Id.* at 35,351.

¹¹⁰*See* [Endocrine Disruptor Screening Program \(EDSP\) Universe of Chemicals](#), ENVTL. PROT. AGENCY (last updated June 9, 2021).

¹¹¹*See* [Endocrine Disruptor Screening Program \(EDSP\) Estrogen Receptor Bioactivity](#), ENVTL. PROT. AGENCY (last updated Jan. 27, 2021).

¹¹²[Use of High Throughput Assays and Computational Tools in the Endocrine Disruptor Screening Program](#), ENVTL. PROT. AGENCY (last updated Jan. 27, 2021).

¹¹³OFF. OF THE INSPECTOR GEN., ENVTL. PROT. AGENCY, REP. NO. 21-E-0186, EPA’S ENDOCRINE DISRUPTOR SCREENING PROGRAM HAS MADE LIMITED PROGRESS IN ASSESSING PESTICIDES (July 28, 2021).

¹¹⁴Pesticides; Agricultural Worker Protection Standard; Revision of the Application Exclusion Zone Requirements, 85 Fed. Reg. 68,760 (Oct. 30, 2020) (to be codified at 40 C.F.R. pt. 170) (direct final rule).

¹¹⁵*See* [New York v. EPA](#), Nos. 20-cv-10642, 20-cv-10645 (S.D.N.Y. Jan. 7, 2021).

The court has extended the stay and injunction until December 20, 2021.¹¹⁶ Effective August 19, 2021, EPA terminated¹¹⁷ a 2020 temporary guidance¹¹⁸ regarding respirator protection for agricultural employers and handlers using pesticide products in light of COVID-related equipment shortages. EPA also issued guidance concerning compliance with WPS pesticide safety training requirements during the COVID-19 emergency.¹¹⁹

D. Other Regulatory Developments

Effective on October 1, 2021, pesticide registration service fees for covered applications under the Pesticide Registration Improvement Extension Act of 2018 (PRIA 4) increased five percent.¹²⁰ PRIA 4 expires on September 30, 2023.¹²¹

EPA issued several updated guidance documents for testing in support of pesticide registration applications. EPA announced the availability of a [final guidance](#) for pesticide registrants that “expands the potential for data waivers for acute dermal studies to single technical active ingredients[] used to formulate end-use products,” supporting EPA’s efforts to reduce unnecessary animal testing.¹²² EPA issued updated guidance as to what pesticide manufacturers seeking to register antimicrobial pesticides with claims against an emerging, multidrug-resistant fungal pathogen, *Candida auris* (*C. auris*), should use to evaluate the efficacy of the products.¹²³ EPA also announced the [availability](#) of two test

¹¹⁶Fifth Stipulation & Consent Order, [New York](#), No. 20-cv-10642 (S.D.N.Y. Oct. 12, 2021).

¹¹⁷[Memorandum](#) from Michael Freedhoff, Ph.D., Assistant Adm’r, Off. of Chem. Safety & Pollution Prevention, Env’tl. Prot. Agency, and Lawrence E. Starfield, Acting Assistant Adm’r, Off. of Enf’t and Compliance Assurance, Env’tl. Prot. Agency, to Pesticide Lead Regul. Agencies, Termination of the June 1, 2020 Statement/May 6, 2021 Amendment Regarding Respiratory Protection Shortages and Reduced Availability of Respirator Fit Testing Related to Pesticide Uses Covered by the Agricultural Worker Protection Standard During the COVID-19 Public Health Emergency (Aug. 10, 2021).

¹¹⁸[Memorandum](#) from Alexandra Dapolito Dunn, Assistant Adm’r, Off. of Chem. Safety & Pollution Prevention, Env’tl. Prot. Agency, and Susan Parker Bodine, Assistant Adm’r, Off. of Enf’t & Compliance Assurance, Env’tl. Prot. Agency, to Pesticide Lead Regul. Agencies, Statement Regarding Respiratory Protection Shortages and Reduced Availability of Respirator Fit Testing Regulated to Pesticide Uses Covered by the Agricultural Worker Protection Standard during the COVID-19 Public Health Emergency (June 1, 2020).

¹¹⁹[Memorandum](#) from Richard Keigwin, Dir., Off. of Pesticide Programs, Env’tl. Prot. Agency, to Agric. Emp’rs, Guidance on Satisfying the Annual Pesticide Safety Training Requirement Under the Agricultural Worker Protection Standard During the COVID-19 Emergency (June 18, 2020).

¹²⁰[Pesticide Registration Improvement Extension Act of 2018 \(PRIA 4\)](#), ENVTL. PROT. AGENCY (last updated Oct. 1, 2021).

¹²¹Pesticide Registration Improvement Extension Act of 2018, [Pub. L. No. 116-8](#), § 2, 133 Stat. 484 (2019).

¹²²OFF. OF PESTICIDE PROGRAMS, OFF. OF CHEM. SAFETY & POLLUTION PREVENTION, ENVTL. PROT. AGENCY, No. EPA-705-G-2020-3722, GUIDANCE FOR WAIVING ACUTE DERMAL TOXICITY TESTS FOR PESTICIDE TECHNICAL CHEMICALS & SUPPORTING RETROSPECTIVE ANALYSIS 2 (Dec. 31, 2020); *see also* Pesticides; Final Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Technical Chemicals and Supporting Retrospective Analysis; Notice of Availability, [86 Fed. Reg. 14,625](#) (Mar. 17, 2021).

¹²³[Press Release](#), Env’tl. Prot. Agency, EPA Revises Guidance to Ensure Effectiveness of Antimicrobial Pesticides Against *Candida auris* (Oct. 15, 2021); [Guidance for the Efficacy](#)

guidelines, under the Office of Chemical Safety and Pollution Prevention's (OSCPP) Series 810 - Product Performance Test Guidelines, for imported fire ant treatments and pesticides applied to pets against invertebrate pests, such as fleas, ticks, and mosquitoes, that provide recommendations for the design and execution of studies to evaluate product performance in connection with pesticide registration.¹²⁴

EPA's 2021 information gathering efforts on potential regulatory changes included issuance of an [advanced notice of proposed rulemaking](#) (ANPRM) to solicit public comments on regulatory and policy changes that are necessary to improve the minimum risk pesticide process and other exemptions.¹²⁵ Though EPA has not yet proposed specific changes to these exemption provisions, EPA sought public input to help determine whether changes may ease state implementation of the minimum risk program and whether there is a need to add to or modify classes of pesticidal substances exempt from regulation under FIFRA. EPA also requested public comment on a regulatory model used in EPA's Pesticide in Water Calculator, specifically the Pesticide Root Zone Model Groundwater (PRZM-GW), to determine whether EPA should revise the conceptual model based on EPA's [Analysis of Subsurface Metabolism in Groundwater Modeling](#).¹²⁶ The PRZM-GW estimates pesticide concentrations in vulnerable groundwater sources and is used in human dietary risk assessments.

In expanding access to electronic options to meet requirements under FIFRA, EPA launched an electronic Confidential Statement of Formula Application (eCSF builder) to support pesticide registration applications, and now allows pesticide exporters to submit official Foreign Purchaser Acknowledgement Statements (FPAS) and FPAS annual summaries through the Central Data Exchange Pesticide Submission Portal (CDX PSP).¹²⁷

E. Response to COVID-19

Pesticide products have played an important role in the response to the novel corona virus (2019-nCoV), and EPA took further measures in 2021 to increase the availability and public awareness of pesticides expected to be effective against the virus. In January 2021, EPA issued emergency exemptions to Georgia and Tennessee to use an antiviral air

[Evaluation of Products for Claims against Drug-Resistant *Candida auris*](#), ENVTL. PROT. AGENCY (last updated Nov. 16, 2021).

¹²⁴Final Test Guidelines; OCSPP Series 810—Product Performance Test Guidelines; Notice of Availability, 86 Fed. Reg. 14,750 (Mar. 18, 2021); *see also* OFF. OF CHEM. SAFETY & POLLUTION PREVENTION, ENVTL. PROT. AGENCY, NO. EPA-712-C-21-001, [PRODUCT PERFORMANCE TEST GUIDELINES OCSPP 810.3100: TREATMENTS FOR IMPORTED FIRE ANTS](#) 3 (Jan. 5, 2021); OFF. OF CHEM. SAFETY & POLLUTION PREVENTION, ENVTL. PROT. AGENCY, NO. EPA-712-C21002, [PRODUCT PERFORMANCE TEST GUIDELINES OCSPP 810.3300: THE EFFICACY OF TOPICALLY APPLIED PET PRODUCTS AGAINST CERTAIN INVERTEBRATE PESTS](#) 3 (Jan. 5, 2021).

¹²⁵Pesticides; Modification to the Minimum Risk Pesticide Listing Program and Other Exemptions Under FIFRA Section 25(b), 86 Fed. Reg. 18,232 (Apr. 8, 2021) (to be codified at 40 C.F.R. pt. 152).

¹²⁶OFF. OF CHEM. SAFETY & POLLUTION PREVENTION, OFF. OF RSCH. & DEV., ENVTL. PROT. AGENCY, ANALYSIS OF SUBSURFACE METABOLISM IN GROUNDWATER MODELING 5 (Feb. 16, 2021); *see also* [Press Release](#), Env'tl. Prot. Agency, EPA Releases Analysis of Groundwater Model for Public Comment (Apr. 15, 2021).

¹²⁷[Press Release](#), Env'tl. Prot. Agency, EPA Announces Electronic Process for Submitting Foreign Purchaser Acknowledgement Statements (Aug. 17, 2021); *see also* Electronic Option for Submitting Foreign Purchaser Acknowledgement Statement of Unregistered Pesticides Under the Federal Insecticide, Fungicide and Rodenticide Act; Notice of Availability, [86 Fed. Reg. 46,246](#) (Aug. 18, 2021).

treatment in certain indoor spaces, including health care facilities and food processing facilities.¹²⁸ In July 2021, EPA issued emergency exemptions for the same product to Maryland, Nevada, Pennsylvania, and Texas and revised the terms of all exemptions based on a review of new efficacy data.¹²⁹ In April 2021, EPA granted emergency exemptions to Georgia, Minnesota, and Utah allowing use of an antiviral adhesive film in specified aircraft and airline facilities.¹³⁰ However, EPA revoked emergency exemptions for a product previously authorized for an emergency use as a residual antimicrobial surface coating in Texas and Arkansas.¹³¹ In February 2021, EPA granted an amended registration for an emerging viral pathogen claim to certain copper alloys that allow specific articles such as bedrails and handrails containing these copper alloys to be distributed with claims that they kill certain viruses that come into contact with the articles.¹³²

EPA continued to take enforcement action against companies selling unregistered pesticides or selling products with misleading claims, including claims regarding virus protection.¹³³ EPA also acted against companies for making inaccurate claims that a product was effective against the coronavirus when the product's registration did not encompass these claims.¹³⁴

¹²⁸[EPA Decision Documents for Emergency Exemption Requests for Use of Grignard Pure](#), ENVTL. PROT. AGENCY (last updated Sept. 8, 2021).

¹²⁹*Id.*

¹³⁰[Disinfectant Use and Coronavirus \(COVID-19\)](#), ENVTL. PROT. AGENCY (last updated Sept. 15, 2021).

¹³¹*Id.*

¹³²[Press Release](#), Env'tl. Prot. Agency, EPA Registers Copper Surfaces for Residual Use Against Coronavirus (Feb. 10, 2021); *see also* [Letter](#) from Eric Miederhoff, Off. of Pesticide Programs, Env'tl. Prot. Agency, to Joseph J. Green, Counsel, Copper Dev. Ass'n, PRIA Label Amendment – Add Viral and EVP Claims to Label Product Name: Antimicrobial Copper Alloys-Group 1 (Feb. 10, 2021).

¹³³*See, e.g.*, [Press Release](#), Env'tl. Prot. Agency, U.S. EPA Orders Nevada and California Companies to Stop Selling Illegal Disinfectants (Apr. 1, 2021); [Press Release](#), Env'tl. Prot. Agency, EPA Orders Amazon to Halt Illegal Pesticides Sales (Feb. 9, 2021).

¹³⁴*See, e.g.*, [Press Release](#), Env'tl. Prot. Agency, EPA Orders Philadelphia Company to Stop Making Inaccurate Health Claims About Pesticide (Mar. 31, 2021).