

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

# *Environment, Energy, and Resources Law: The Year in Review 2023*

## **Chapter P · Pesticides and Chemicals**

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## Chapter P: PESTICIDES AND CHEMICALS 2023 Annual Report<sup>1</sup>

In 2023, the Environmental Protection Agency (EPA) made significant progress implementing the Toxic Substances Control (TSCA) section 6 risk evaluation program, completing its rework of risk evaluations conducted under the prior Administration and proposing its first comprehensive risk management rules. It also moved to codify in rules important changes to the risk evaluation process the Biden Administration initially had adopted as policy. The new chemical program generated a number of firsts, including the first 5(f) order in more than 30 years and the first judicial challenge to a 5(e) order. Significant litigation on each of these initiatives was filed and argued in 2023, setting the stage for future clarity on the extent of EPA authority. EPA made significant progress toward addressing difficult and long-standing issues implementing the 1998 endocrine screening program and addressing systemic and practical challenges to meeting Endangered Species Act assessment and mitigation requirements for pesticides, including settlement of the so-called “Mega” litigation.

### I. TOXIC SUBSTANCES CONTROL ACT (TSCA)

#### A. *New Chemicals Program, Significant New Use Rules, and Litigation*

##### 1. New Chemical Review

The U.S. EPA’s pace of completing new chemical determinations remains slow. EPA reported a total of only 153 new PMN, MCAN, and SNUN submissions in calendar year 2023,<sup>2</sup> which is a very significant decrease from earlier periods. By comparison, there were 493 total such notices in fiscal year 2016, the year the TSCA amendments were adopted.<sup>3</sup>

EPA’s Office of Inspector General (OIG) released a report on the results of its audit of the New Chemicals Program after receiving complaints about EPA’s new chemical review process.<sup>4</sup> EPA agreed with OIG’s recommendations, and proposed corrective actions, including the development of a schedule for periodic workforce and workload analysis.

EPA proposed amendments to the new chemicals procedural regulations that, according to EPA, would aid in more timely completion of new chemical reviews by

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<sup>1</sup>L. Margaret Barry, Lawrence Culleen, Arnold & Porter Kaye Scholer LLP; Lynn Bergeson, Lisa R. Burchi, Heather F. Collins, Richard Engler, Ph.D., Carla Hutton, and Edith Nagy, Bergeson & Campbell, P.C.; Javaneh Tarter and Julia Casciotti, Hunton Andrews Kurth LLP; Greg Clark and James Votaw, Keller and Heckman LLP; Julia Hatcher, Allison In, Ashley Maiolatesi and De Vann Sago, Latham & Watkins LLP; Keith Matthews, Hume Ross, Sarah Simonetti and Sara Beth Watson, Wiley Rein LLP.

<sup>2</sup>See [Premanufacture Notices \(PMNs\) and Significant New Use Notices \(SNUNs\) Table](#), U.S. ENVTL. PROT. AGENCY (last updated Feb. 1, 2024).

<sup>3</sup>[Statistics for the New Chemicals Review Program under TSCA](#) (Valid Submissions Received by Fiscal Year), U.S. ENVTL. PROT. AGENCY (last updated Feb. 2, 2024).

<sup>4</sup>OFF. OF INSPECTOR GEN., U.S. ENVTL. PROT. AGENCY, [THE EPA LACKS COMPLETE GUIDANCE FOR THE NEW CHEMICALS PROGRAM TO ENSURE CONSISTENCY AND TRANSPARENCY IN DECISIONS](#) (Aug. 2023).

improving the quality of new chemical notices.<sup>5</sup> The proposed rule also would amend the regulations for low volume exemptions (LVE) and low release and exposure exemptions (LoREX) to require EPA approval of an exemption notice prior to commencement of manufacture, make per- and polyfluoroalkyl substances (PFAS) categorically ineligible for these exemptions, and provide that certain persistent, bioaccumulative, and toxic (PBT) chemical substances are ineligible for these exemptions.

EPA also continued outreach efforts intended to improve the efficiency of new chemical reviews. EPA held the third and final webinar in its series on the Agency's process for new chemical reviews, covering commonly missed information in TSCA section 5 submissions and how EPA evaluates environmental release information for operations that occur at non-submitter sites.<sup>6</sup> For mixed metal oxides (MMO), EPA held the second of two webinars on the standardized process announced in 2022 to assess risk and apply mitigation measures, as appropriate, for MMOs, including new and modified cathode active materials (CAM).<sup>7</sup>

EPA released a new [framework](#) for reviewing new PFAS and new uses of existing PFAS that are also persistent, bioaccumulative and toxic (PBT) chemicals.<sup>8</sup> The framework describes the kinds and timing for data the Agency will require for new chemicals and new uses, keyed to the extent of expected release and exposure.<sup>9</sup>

## 2. Significant New Use Rules

In 2023, EPA proposed significant new use rules (SNUR) for only one batch of controversial new chemicals. EPA proposed SNURs for 18 substances that were fuels made from plastic waste-derived feedstocks.<sup>10</sup> The SNUR focused on the character of the feedstocks rather than the end products and proposed to designate as a significant new use manufacture of any of the fuels with feedstocks containing any quantity of a list of common plastic additives and impurities. As reported below, the underlying 5(e) consent order associated with the SNUR substances was challenged in the U.S. Court of Appeals for the D.C. Circuit.<sup>11</sup>

To advance its [PFAS Strategic Roadmap](#), EPA proposed a SNUR for those PFAS that are currently listed on the TSCA Inventory as “inactive” as a consequence of the

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<sup>5</sup>Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA), [88 Fed. Reg. 34,100](#) (proposed May 26, 2023) (to be codified at 40 C.F.R. pts. 720, 721, 723, 725).

<sup>6</sup>U.S. ENVTL. PROT. AGENCY, [TSCA NEW CHEMICAL ENGINEERING OUTREACH INITIATIVE TO INCREASE TRANSPARENCY AND REDUCE REWORK -- WEBINAR SERIES: PART 3, COMMONLY MISSED INFORMATION](#) (Feb. 28, 2023).

<sup>7</sup>U.S. ENVTL. PROT. AGENCY, [EPA'S NEW CHEMICALS PROGRAM UNDER TSCA, STANDARDIZED APPROACH FOR MIXED METAL OXIDES \(MMOS\) IN CATHODE ACTIVE MATERIALS \(CAMs\) AND MODIFIED CAMs: WEBINAR SERIES: PART 2](#) (Mar. 30, 2023).

<sup>8</sup>[Press Release](#), U.S. Env'tl. Prot. Agency, EPA Announces New Framework to Prevent Unsafe New PFAS from Entering the Market (June 29, 2023).

<sup>9</sup>U.S. ENVTL. PROT. AGENCY, [FRAMEWORK FOR TSCA NEW CHEMICALS REVIEW OF PFAS PREMANUFACTURE NOTICES \(PMNs\) AND SIGNIFICANT NEW USE NOTICES \(SNUNs\)](#) (Jun. 28, 2023).

<sup>10</sup>Significant New Use Rules on Certain Chemical Substances (23-2.5e), [88 Fed. Reg. 39,804](#) (proposed June 20, 2023) (to be codified at 40 C.F.R. pt. 721).

<sup>11</sup>*See infra* note 16 (discussion of the *Cherokee Concerned Citizens* suit) and accompanying text.

Inventory “Reset” Rule.<sup>12</sup> The final SNUR would require submission of a significant new use notice (SNUN) and EPA review before non-exempt manufacture or processing of these PFAS.

EPA published proposed existing chemical SNURs for three flame retardants that are undergoing risk evaluations under TSCA section 6: tris(2-chloroethyl) phosphate (TCEP); tetrabromobisphenol A (TBBPA); and triphenyl phosphate (TPP).<sup>13</sup> EPA stated that the rule is intended to foreclose uses of these chemicals not included within the formal scope of their respective risk evaluations without prior submittal of a SNUN.

EPA issued its first TSCA section 5(f) order since the 1980s. Arising from EPA’s review of Significant New Use Notices, the order barred Inhance Technologies from manufacturing certain PFAS as incidental byproducts from fluorinating high-density polyethylene (HDPE) plastic containers. The Agency found that the PFAS byproducts presented an unreasonable risk of injury to health or the environment.<sup>14</sup> The Agency simultaneously issued a unilateral 5(e) order for certain other PFAS byproducts, barring manufacture pending extensive testing.<sup>15</sup> Inhance promptly challenged these orders, as reported in the next section.

### 3. TSCA Section 5 Litigation

In another first, EPA garnered its first-ever challenge to a section 5(e) consent order. In *Cherokee Concerned Citizens v. EPA*,<sup>16</sup> non-governmental organization (NGO) petitioners challenged the sufficiency of a TSCA section 5(e) order authorizing Chevron U.S.A. Inc. to commence manufacturing certain fuels made from alternative feedstocks, which recognized the existing comprehensive regulation of fuels and fuel handling under the Clean Air Act and other legislation. Petitioners assert the order is insufficiently protective under the statute against unreasonable risk.<sup>17</sup> EPA has moved to dismiss the 2023 challenge to the 2022 order as untimely under the TSCA 60-day statute of limitations for such challenges.<sup>18</sup>

The U.S. District Court for the Eastern District of Pennsylvania heard oral argument in EPA’s suit against Inhance Technologies, in which EPA claims that Inhance is generating PFAS when fluorinating plastic containers in violation of a 2020 SNUR on

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<sup>12</sup>Per- and Poly-Fluoroalkyl Chemical Substances Designated as Inactive on the TSCA Inventory; Significant New Use Rule, [88 Fed. Reg. 4937](#) (proposed Jan. 26, 2023) (to be codified at 40 C.F.R. pt. 721).

<sup>13</sup>Flame Retardants; Significant New Uses Rules for Certain Non-Ongoing Uses, [88 Fed. Reg. 40,728](#) (proposed June 22, 2023) (to be codified at 40 C.F.R. pt. 721).

<sup>14</sup>OFF. OF POLLUTION PREVENTION & TOXICS, U.S. ENVTL. PROT. AGENCY, [TSCA Section 5 Order for a Significant New Use of Certain Chemical Substances, Significant New Use Notice Numbers SN-23-0002, SN-23-0004, & SN-23-005](#) (2023); *see also* [Press Release](#), U.S. Env’tl. Prot. Agency, EPA Takes Action to Protect People from PFAS that Leach from Plastic Containers into Pesticides and Other Products (Dec. 1, 2023).

<sup>15</sup>OFF. OF POLLUTION PREVENTION & TOXINS, U.S. ENVTL. PROT. AGENCY [TSCA SECTION 5 ORDER FOR A SIGNIFICANT NEW USE OF CERTAIN CHEMICAL SUBSTANCES, SIGNIFICANT NEW USE NOTICE NUMBERS SN-23-0003/0006 AND 0008-0011](#) (Dec. 1, 2023).

<sup>16</sup>No. 23-1096 (D.C. Cir. filed Apr. 7, 2023).

<sup>17</sup>[Petitioner’s Non-Binding Statement of Issues](#), *Cherokee Concerned Citizens v. EPA*, No. 23-1096 (D.C. Cir. May 11, 2023).

<sup>18</sup>Respondents’ Motion to Dismiss, *Cherokee Concerned Citizens v. EPA*, No. 23-1096 (D.C. Cir. Nov. 8, 2023).

certain PFAS.<sup>19</sup> After the U.S. District Court for the District of Columbia dismissed a citizen suit brought by the Center for Environmental Health (CEH) and Public Employees for Environmental Responsibility (PEER),<sup>20</sup> CEH and PEER intervened in the EPA case. EPA claims that the burden was on Inhance to notify EPA during the SNUR rulemaking process that it was engaged in an ongoing use of the SNUR substances. Inhance maintains that it had no knowledge at that time that its fluorination process generated PFAS and that any PFAS generated are subject to exemptions for impurities and articles. Both EPA and Inhance have filed motions for summary judgment. Separately, Inhance filed suit in the U.S. Court of Appeals for the Fifth Circuit to challenge EPA's TSCA section 5(f) and (e) orders that would prohibit Inhance from continuing its container fluorination process.<sup>21</sup> The court granted Inhance's motions for expedited briefing and argument and a stay of the Orders pending appeal.

A suit brought by a coalition of NGOs against EPA for failure to disclose non-confidential information from TSCA section 5 new chemical notices remains ongoing. Although EPA has asserted that it now has made available to the public all PMN forms and supplementary correspondence to the extent required to be disclosed, plaintiffs contend EPA has incorrectly deferred to CBI claims by submitters as the basis for withholding documents.<sup>22</sup> EPA's motion for judgment on the pleadings based solely on justiciability and jurisdiction remains pending.

#### *B. Test Order Activity and Litigation*

In 2023, EPA issued two new test orders under its [National PFAS Testing Strategy](#). The first requires testing on trifluoro(trifluoromethyl)oxirane (HFPO), a substance used in making plastics.<sup>23</sup> The second test order requires testing on 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoyl fluoride (HFPO-DAF), a reactant used in organic chemical manufacturing.<sup>24</sup> EPA also acted on a TSCA section 21 petition seeking a test order. An NGO coalition withdrew and resubmitted a petition requesting a TSCA section 4 order to perform human and environmental health and safety testing for polyvinyl alcohol (PVA/PVOH) as it is used in product categories (e.g., laundry and dishwasher detergent pods) relevant to the EPA Safer Choice program.<sup>25</sup> The coalition also petitioned under the Administrative Procedure Act to change the status of PVA/PVOH on EPA's Safer Chemical Ingredients List (SCIL). EPA denied both petitions because petitioners did not

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<sup>19</sup>[United States v. Inhance Technologies](#), No. 5:22-cv-05055-JFM (E.D. Pa. filed Dec. 19, 2022).

<sup>20</sup>[Ctr. for Env'tl. Health v. Inhance](#), No. 1:22-cv-03819-JEB, slip op. (D.D.C. Apr. 26, 2023).

<sup>21</sup>[Inhance Technologies LLC v. EPA](#), No. 23-60620 (5th Cir. filed Dec. 8, 2023).

<sup>22</sup>Notice at 2-3, [Env'tl. Def. Fund v. Regan](#), No. 1:20-cv-00762-LLA (D.D.C. Jan. 18, 2023).

<sup>23</sup>[Press Release](#), U.S. Env'tl. Prot. Agency, EPA Issues Next Test Order Under National Testing Strategy for PFAS Used in Plastics, Chemical Manufacturing (Jan. 4, 2023).

<sup>24</sup>[Press Release](#), U.S. Env'tl. Prot. Agency, EPA Issues Next Test Order Under National Testing Strategy for PFAS Used in Chemical Manufacturing (Aug. 15, 2023).

<sup>25</sup>BLUELAND, ET AL., [PETITION TO REQUEST HEALTH AND ENVIRONMENTAL TESTING AND REGULATION ON POLYVINYL ALCOHOL UNDER THE TOXIC SUBSTANCES CONTROL ACT AND AN UPDATE TO THE CHEMICAL SAFETY STATUS OF POLYVINYL ALCOHOL ON THE EPA'S SAFER CHEMICAL INGREDIENTS LIST](#) (Jan. 26, 2023).

establish the need for testing under section 4 or demonstrate that PVA/PVOH does not meet the SCIL criteria.<sup>26</sup>

The U.S. Court of Appeals for the District of Columbia Circuit held oral argument in the Vinyl Institute, Inc.’s suit against EPA seeking review of EPA’s 2022 TSCA section 4(a)(2) test order for 1,1,2-trichloroethane, particularly the requirement for an Avian Reproduction Test.<sup>27</sup>

National Foam, Inc. filed suit in the U.S. Court of Appeals for the District of Columbia Circuit, seeking review of a 2022 TSCA section 4(a)(2) test order for PFAS 6:2 fluorotelomer sulfonamide betaine on the grounds that National Foam is not a “processor” subject to order.<sup>28</sup> Following mediation, EPA granted National Foam an exemption from testing, subject to the cost reimbursement provisions of the order, and the parties asked the court to hold the case in abeyance completion of testing by other order recipients.<sup>29</sup>

DuPont de Nemours filed a petition in the U.S. Court of Appeals for the Third Circuit challenging EPA’s issuance of the 2023 test order for HFPO to DuPont.<sup>30</sup> EPA subsequently determined that DuPont de Nemours was not a HFPO manufacturer, and the court granted the parties’ motion to dismiss the case on May 22, 2023.

The U.S. District Court for the Eastern District of North Carolina granted an EPA motion to dismiss in litigation challenging EPA’s response to a 2020 TSCA section 21 petition seeking a section 4 test rule for 54 PFAS, finding that EPA granted the petition and that the court lacks jurisdiction to review such a grant.<sup>31</sup> Petitioners filed an appeal in the U.S. Court of Appeals for the Fourth Circuit.<sup>32</sup>

### *C. Regulation of Existing Chemicals*

#### *1. Prioritization, Risk Evaluation, and Risk Management*

During 2023, EPA’s ongoing effort to revisit its risk evaluations and belatedly comply with statutory deadlines resulted in a flurry of activity. The Agency issued a revised final risk determination for trichloroethane (TCE); this time, as a whole chemical substance determining, that 52 out of 54 conditions of use contribute to finding that TCE presents an unreasonable risk of injury to human health.<sup>33</sup> This revision did not reflect the previous assumption that workers always and appropriately use PPE, which the Agency moved away from in revising the risk evaluation process rule, discussed below. Following this determination, EPA proposed a section 6 risk management rule for TCE to ban all commercial and industrial uses of TCE, with longer compliance timeframes and workplace

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<sup>26</sup>Polyvinyl Alcohol (PVA); Toxic Substances Control Act (TSCA) Section 21 Petition for Rulemaking; Reasons for Agency Response; Denial of Requested Rulemaking, [88 Fed. Reg. 25,590](#) (proposed Apr. 27, 2023).

<sup>27</sup>Petition for Review, Vinyl Institute v. EPA, No. 22-1089 (D.C. Cir filed May 23, 2022).

<sup>28</sup>Nat’l Foam v. EPA, No. 22-1208 (D.C. Cir. filed Aug. 15, 2022).

<sup>29</sup>Joint Motion to Hold Case in Abeyance, Nat’l Foam v. EPA, No. 22-1208 (D.C. Cir. May 8, 2023).

<sup>30</sup>DuPont de Nemours Inc v. EPA, No. 23-1444 (3d Cir. filed Mar. 9, 2023).

<sup>31</sup>Order Granting Defendant’s Motion to Dismiss, Ctr. for Env’tl. Health v. Regan, No. 7:22-CV-00073-M (E.D.N.C. Mar. 30, 2023).

<sup>32</sup>[Ctr. for Env’tl. Health v. Regan](#), No. 23-1476 (4th Cir. filed May 1, 2023).

<sup>33</sup>Trichloroethylene (TCE); Revision to the Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability, [88 Fed. Reg. 1222](#) (Jan. 9, 2023).

controls allowed for certain activities and uses.<sup>34</sup> The proposal includes banning disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works, except for cleanup projects temporarily exempted under the TSCA section 6(g) critical use provision.

Similarly, EPA proposed a section 6 risk management rule for methylene chloride that would ban all consumer uses and most industrial uses, providing time-limited exemptions for certain military, critical infrastructure, or emergency-related uses with conditions to comply with a workplace chemical protection program (“WCCP”).<sup>35</sup>

EPA revised its prior risk evaluation for 1,4-dioxane,<sup>36</sup> and proposed risk management rules for perchloroethylene (PCE) and carbon tetrachloride (CTC). The revised risk determination finding that 1,4-dioxane presents an unreasonable risk of injury to human health under its conditions of use supplemented the 2020 risk evaluation, which did not consider various air and water exposure pathways.<sup>37</sup> For PCE, EPA proposed to ban most uses (including all consumer uses) and, as it did with TCE and methylene chloride, EPA proposed a WCCP for uses not prohibited to address the unreasonable risk to human health.<sup>38</sup> For CTC, the Agency proposed to establish a WCCP for uses not prohibited, in addition to banning uses that have been phased out.<sup>39</sup> Both proposed rules establish recordkeeping and downstream notification requirements.

Two suits were filed against EPA over its failure to meet statutory deadlines to complete section 6 risk evaluations.<sup>40</sup> The cases concern the twenty high priority substance risk evaluations (filed by a group of NGOs) and two manufacturer-requested risk evaluations (filed by the American Chemical Council).

Concerning the latter, EPA announced that it will perform a cumulative risk assessment of one of the manufacturer-requested substances, DINP, with five other phthalates separately designated as “high priority” by EPA.<sup>41</sup> EPA also released a draft proposed principles document for cumulative risk assessment, to take into account combined human health exposure to multiple chemical substances with similar effects.<sup>42</sup>

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<sup>34</sup>Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA), [88 Fed. Reg. 74,712](#) (proposed Oct. 31, 2023) (to be codified at 40 C.F.R. pt. 751).

<sup>35</sup>Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA), [88 Fed. Reg. 28,284](#) (proposed May 3, 2023) (to be codified at 40 C.F.R. pt. 751).

<sup>36</sup>1,4-Dioxane; Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment, [88 Fed. Reg. 48,249](#) (July 26, 2023).

<sup>37</sup>1,4-Dioxane; Draft Supplement to the TSCA Risk Evaluation; Science Advisory Committee on Chemicals (SACC) Meeting; Notice of Meeting and Request for Comment, [88 Fed. Reg. 43,562](#) (July 10, 2023).

<sup>38</sup>Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA), [88 Fed. Reg. 39652](#) (proposed June 16, 2023) (to be codified at 40 C.F.R. pt. 751).

<sup>39</sup>Carbon Tetrachloride (CTC); Regulation Under the Toxic Substances Control Act (TSCA), [88 Fed. Reg. 49,180](#) (proposed July 28, 2023) (to be codified at 40 C.F.R. pt. 751).

<sup>40</sup>Cnty. In-Power and Dev. Ass’n. v. EPA, 304 F. Supp. 3d 212 (D.D.C. filed Sept. 18, 2023); Complaint for Declaratory and Injunctive Relief, Am. Chemistry Council v. EPA, No. 1:23-cv-03726-DLF (D.D.C. filed Dec. 13, 2023).

<sup>41</sup>U.S. ENVTL. PROT. AGENCY, [DRAFT PROPOSED APPROACH FOR CUMULATIVE RISK ASSESSMENT OF HIGH-PRIORITY PHTHALATES AND A MANUFACTURER-REQUESTED PHTHALATE UNDER THE TOXIC SUBSTANCES CONTROL ACT](#) (Feb. 2023).

<sup>42</sup>U.S. ENVTL. PROT. AGENCY, [DRAFT PROPOSED PRINCIPLES OF CUMULATIVE RISK ASSESSMENT UNDER THE TOXIC SUBSTANCES CONTROL ACT](#) (Feb. 2023).

Both of these documents were released for public comment and were reviewed by the Science Advisory Committee on Chemicals (SACC).

EPA proposed to modify the rules governing procedures for chemical substance risk evaluations established in 2017, to codify changes to the implementation approach adopted by the EPA during the Biden Administration.<sup>43</sup> Proposed procedural changes include EPA assessment of all exposure pathways regulated under other environmental statutes; excluding consideration of the exposure reduction effects of worker PPE at the risk evaluation stage; and making determinations of unreasonable risk for a chemical as a whole, and not separately for each condition of use. EPA also proposed deleting the current regulatory definitions of “best available science” and “weight of scientific evidence” to provide EPA with additional flexibility.

In December 2023, EPA designated five chemicals as candidates for risk evaluation: acetaldehyde, acrylonitrile, benzenamine; 4,4'-Methylene bis(2-chloroaniline) (MBOCA), and vinyl chloride, and identified the next ten substances it anticipates designating for prioritization in December 2025 and 2026.<sup>44</sup> EPA must finalize the prioritization of the five substances by December 2024. These designations reflect the Agency’s determination that it will complete in the next year only five of the 20 pending risk evaluations, which were already overdue by at least six months in December 2023.

## 2. Petitions for Section 6 Risk Management Rules

EPA granted a citizen petition filed on behalf of three federally recognized Tribes requesting EPA to initiate rulemaking to prohibit the manufacturing, processing, use, and distribution of N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD), a chemical which is used as an anti-degradant in tires. In granting this petition, EPA indicated that it planned to issue an advanced notice of proposed rulemaking under TSCA section 6(a) to consider the possibility of bans or restrictions as well as whether technically and economically feasible alternatives exist for the use of 6PPD in tires; and to undertake additional data gathering activities, initially through TSCA section 8(d), which may be followed by testing requirements under TSCA section 4.<sup>45</sup>

The long-running challenge TSCA section 21 litigation, *Food & Water Watch v. EPA*, was set for a second trial in 2024. The case concerns EPA’s denial of a 2016 petition under TSCA section 21 to ban fluoridation of drinking water due to claimed neurotoxic effects.<sup>46</sup> After conducting a bench trial in 2020, the court put the case in abeyance in part to allow the EPA to consider new studies not available at the time of the original petition, and an anticipated new study by the National Toxicology program.<sup>47</sup> In the new trial, EPA is expected to present the Agency’s perspective on the minimum legal requirements for a

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<sup>43</sup>Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), [88 Fed. Reg. 74,292](#) (proposed Oct. 30, 2023) (to be codified at 40 C.F.R. pt. 702).

<sup>44</sup>Initiation of Prioritization Under the Toxic Substances Control Act (TSCA); Request for Comment, [88 Fed. Reg. 87,423](#) (Dec. 18, 2023).

<sup>45</sup>[Letter from Michal Freedhoff](#), Assistant Administrator for Chem. Safety and Pollution Prevention, U.S. Env’tl. Prot. Agency, to Elizabeth Forsyth, Earthjustice Biodiversity Def. Program, and Katherine O’Brien, Earthjustice Toxic Exposure & Health Program (Nov. 2, 2023).

<sup>46</sup>[Food & Water Watch, Inc. v. United States Env’t Prot. Agency](#), 291 F. Supp. 3d 1033, 1037–38 (N.D. Cal. 2017).

<sup>47</sup>Plaintiff’s Motion to Lift Stay and Take Case Out of Abeyance, *Food & Water Watch v. EPA*, No 3:17-cv-02162-EMC (N.D. Cal. Sep. 12, 2022).



section 6 risk determination in relation to specific fact patterns,<sup>48</sup> which in turn play an important role in future challenges to risk determinations and risk management rules for other chemicals.

### 3. Persistent, Bioaccumulative, and Toxic (PBT) Chemicals

As previously announced,<sup>49</sup> EPA reevaluated the exemptions previously granted for certain uses of five otherwise banned persistent, bioaccumulative, and toxic chemicals (PBTs) and proposed rule changes to further narrow the exemptions applicable decabromodiphenyl ether (decaBDE) and phenol, isopropylated phosphate (PIP (3:1)), and confirmed the October 2024 compliance date for PIP (3:1) in articles.<sup>50</sup> EPA also issued temporary, emergency enforcement relief concerning decaBDE-containing wire and cable insulation for nuclear power generation facilities.<sup>51</sup>

#### D. TSCA Section 8 Reporting and Information Collection Rules

EPA issued a TSCA section 8(a) rule establishing a one-time reporting requirement applicable to those who have manufactured or processed asbestos and asbestos-containing articles, including as an impurity, between 2019 and 2022 with annual sales above \$500,000 in any of those years.<sup>52</sup> The rule created a reporting deadline of May 24, 2024. The term “asbestos” includes several types of asbestos, including chrysotile, crocidolite, amosite, anthophyllite, tremolite, actinolite, and libby amphibole asbestos.

EPA finalized a one-time TSCA section 8(a)(7) reporting, and associated recordkeeping, requirement for PFAS manufactured (including imported) between 2011 and 2022.<sup>53</sup> The final rule uses the same structure-based PFAS definition that EPA has used in other contexts,<sup>54</sup> which is narrower than the definition used by the Organization for

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<sup>48</sup>See Defendants’ Trial Brief for Second Phase of Trial at 7, Food & Water Watch, Inc. v. EPA, No 3:17-cv-02162-EMC (N.D. Cal. Dec. 22, 2023).

<sup>49</sup>See, e.g., Regulation 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).

<sup>50</sup>Decabromodiphenyl Ether and Phenol, Isopropylated Phosphate (3:1); Revision to the Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under the Toxic Substances Control Act (TSCA), [88 Fed. Reg. 82,287](#) (proposed Nov. 24, 2023) (to be codified at 40 C.F.R. pt. 751).

<sup>51</sup>[Memorandum](#) from Lawrence Starfield, Acting Asst. Admin, Off. of Enforcement and Compliance Assurance, to Michal Freedhoff, Asst. Admin., Off. of Chem. Safety and Pollution Prevention, Enforcement Statement Regarding the Prohibition of Processing and Distribution in Commerce of Decabromodiphenyl Ether (DecaBDE)-Containing Wire and Cable Insulation in Nuclear Power Generation Facilities under 40 C.F.R. § 751.405(a)(2)(ii) (May 2, 2023).

<sup>52</sup>Asbestos; Reporting and Recordkeeping Requirements Under the Toxic Substances Control Act (TSCA), [88 Fed. Reg. 47,782](#) (July 25, 2023) (to be codified at 40 C.F.R. pt. 704).

<sup>53</sup>Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, [88 Fed. Reg. 70,516](#) (Oct. 11, 2023) (to be codified at 40 C.F.R. pt. 705).

<sup>54</sup>40 C.F.R. § 705.3 (2023) (defining “PFAS”). This is the same definition EPA used, for example, under the TSCA new chemicals program. *see* U.S. ENVTL. PROT. AGENCY,

Economic Co-operation and Development (OECD) and United Nations Environment Programme (UNEP), which has been relied on by some countries.<sup>55</sup> The final rule applies to any person who manufactured or imported any chemical substance, or mixture containing any chemical substance, that satisfies the Rule’s PFAS definition.<sup>56</sup> There are none of the typical TSCA reporting exemptions for small businesses, research and development substances, intermediates, impurities, byproducts, articles or de minimis quantities. The subject persons must submit information concerning chemical identity, disposal, environmental and health effects, uses, volumes made and produced, and worker exposure, among others. Although there is no exemption, there are streamlined reporting options for small quantities of R&D substances and articles containing PFAS. The reporting period begins on November 12, 2024, and runs through May 8, 2025, or through November 10, 2025, for small businesses that import PFAS only in articles.<sup>57</sup>

#### *E. Confidential Business Information*

EPA finalized a rule concerning requirements for the assertion and treatment of Confidential Business Information (CBI) claims under TSCA.<sup>58</sup> This rule is the outcome of EPA codifying and consolidating all TSCA CBI claim procedures in a new section under 40 CFR Part 703 (except for other modified provisions). Significant changes concern data protected from disclosure under other statutes, changes to the definition of “health and safety study,” and preventing waiver of CBI status by submitters that do not know the underlying confidential information. Finally, the rule requires companies to submit health and safety information using OECD templates, when available, in addition to the full study report.

#### *F. National Program Chemicals*

EPA finalized an expanded set of extraction and determinative methods used to characterize and verify the cleanup of polychlorinated biphenyl (PCB) waste under TSCA, and made changes to the PCB remediation rules, including harmonizing the general disposal requirements for PCB remediation wastes and removing provisions allowing PCB bulk product waste to be disposed of as roadbed material.<sup>59</sup>

EPA proposed “to lower the dust-lead hazard standards (DLHS) from 10 mg/ft<sup>2</sup> and 100 mg/ft<sup>2</sup> for floors and windowsills,” respectively, “to any reportable level as analyzed by a laboratory recognized by EPA’s National Lead Laboratory Accreditation Program.”<sup>60</sup>

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[FRAMEWORK FOR TSCA NEW CHEMICALS REVIEW OF PFAS PREMANUFACTURE NOTICES \(PMNs\) AND SIGNIFICANT NEW USE NOTICES \(SNUNs\)](#) (June 28, 2023).

<sup>55</sup>OECD Environment Directorate Chemicals and Biotechnology Committee, [Reconciling Terminology of the Universe of Per-and Polyfluoroalkyl Substances: Recommendations and Practical Guidance](#), U.N. Doc. ENV/CBC/MONO (2021)25 (July 9, 2021).

<sup>56</sup>40 C.F.R. §§ 705.5, 705.10 (2023).

<sup>57</sup>40 C.F.R. § 705.20 (2023).

<sup>58</sup>Confidential Business Information Claims Under the Toxic Substances Control Act (TSCA), [88 Fed. Reg. 37,155](#) (June 7, 2023) (to be codified at 40 C.F.R. pts. 2, 702-04, 707, 716-17, 720, 723, 725, 729).

<sup>59</sup>Alternate PCB Extraction Methods and Amendments to PCB Cleanup and Disposal Regulations, [88 Fed. Reg. 59,662](#) (Aug. 29, 2023) (to be codified at 40 C.F.R. pt. 761).

<sup>60</sup>Reconsideration of the Dust-Lead Hazard Standards and Dust-Lead Post-Abatement Clearance Levels, [88 Fed. Reg. 50,444](#) (proposed Aug. 1, 2023) (to be codified at 40 C.F.R. pt. 745).

EPA also proposed to lower the dust-lead clearance levels (DLCL) to 3 mg/ft<sup>2</sup> (floors), 20 mg/ft<sup>2</sup> (window-sills), and 25 mg/ft<sup>2</sup> (window troughs).

## II. EMERGENCY PLANNING AND COMMUNITY RIGHT-TO-KNOW (EPCRA)

EPA added several chemicals to the list of those subject to reporting under the Toxics Release Inventory (TRI) regulations. EPA added nine PFAS chemicals to the TRI list by direct final rule pursuant to National Defense Authorization Act for Fiscal Year 2020,<sup>61</sup> which causes individual PFAS chemicals automatically to be added to the TRI list after EPA makes any of several determinations with respect to the substances (e.g., EPA finalizes a toxicity value for the PFAS).<sup>62</sup> EPA also added a category of diisononyl phthalate (DINP) plasticizers to the TRI list in response to a petition submitted in 2000.<sup>63</sup>

EPA amended the TRI list of “chemicals of special concern” to add several PFAS already subject to TRI reporting. All chemicals on this list are ineligible the Form A, de minimis exemption, and range-reporting TRI reporting burden-reduction options.<sup>64</sup> The amendments also eliminated the availability of the de minimis exemption from supplier notification requirements for all chemicals of special concern.

The Agency began the process of reconsidering its 2019 rule exempting all farms from reporting air emissions from animal waste under EPCRA reporting. The rule had been challenged in the District Court for the District of Columbia and remanded to EPA without vacatur.<sup>65</sup> EPA issued a notice soliciting comment on the particular costs and benefits of removing the exemption.<sup>66</sup>

## III. BIOTECHNOLOGY AND NANOTECHNOLOGY DEVELOPMENTS

Building on President Biden’s 2022 executive order creating the National Biotechnology and Biomanufacturing Initiative (NBBI),<sup>67</sup> the White House Office of Science and Technology Policy (OSTP) developed and published an agenda of particular

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<sup>61</sup>[National Defense Authorization Act for Fiscal Year 2020](#), Pub. L. 116-92, § 7321, 133 Stat. 1198, 2277 (2019).

<sup>62</sup>Implementing Statutory Addition of Certain Per- and Polyfluoroalkyl Substances (PFAS) to the Toxics Release Inventory Beginning With Reporting Year 2023, [88 Fed. Reg. 41,035](#) (June 23, 2023) (to be codified at 40 C.F.R. pt. 372) (adding nine PFAS with final toxicity values or added to a SNUR).

<sup>63</sup>Addition of Diisononyl Phthalate Category; Community Right-to-Know Toxic Chemical Release Reporting, [88 Fed. Reg. 45,089](#) (July 14, 2023) (to be codified at 40 C.F.R. pt. 372).

<sup>64</sup>Changes 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, [88 Fed. Reg. 74,360](#) (Oct. 31, 2023) (to be codified at 40 C.F.R. pt. 372).

<sup>65</sup>See [Memorandum Order](#), Rural Empowerment Assn. for Cmty. Help v. EPA, No. 18-2260 (TJK) (D.D.C. Feb. 14, 2022).

<sup>66</sup>Potential Future Regulation for Emergency Release Notification Requirements for Animal Waste Air Emissions Under the Emergency Planning and Community Right-to-Know Act (EPCRA), [88 Fed. Reg. 80,222](#) (proposed Nov. 17, 2023)(to be codified at 40 C.F.R. pt. 355).

<sup>67</sup>Exec. Order 14,081, Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy, [87 Fed. Reg. 56,849](#) (Sept. 15, 2022).

policy goals and priorities designed to advance U.S. biotechnology and biomanufacturing,<sup>68</sup> and an action plan to expand U.S. biotechnology and biomanufacturing education and job training.<sup>69</sup> EPA, U.S. Department of Agriculture’s Animal and Plant Health Inspection Service (APHIS), and the Food and Drug Administration (FDA) together issued a new, plain-language guidance document for new entrants to the U.S. biotechnology regulatory system and the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework)<sup>70</sup> responding to a review of stakeholders’ perceived uncertainties about regulation under the Coordinated Framework.<sup>71</sup> EPA and FDA announced plans to seek public input on the best approaches for updating their respective oversight responsibilities for specific products, including genetically engineered pest animals utilized for pest control purposes.<sup>72</sup>

APHIS issued its final Regulatory Status Review (RSR) Guide, detailing the procedures for preparing and submitting an RSR request under the revised biotechnology regulations at 7 C.F.R. Part 340,<sup>73</sup> and released a revised draft of its permitting guide for microorganisms developed using genetic engineering.<sup>74</sup> It proposed to exempt five new types of plant genetic modifications from regulation under the Plant Protection Act on the basis that the modifications could otherwise be achieved through conventional breeding methods.<sup>75</sup> APHIS also published a new five-year strategic plan that includes biotechnology-related objectives.<sup>76</sup>

EPA promulgated a new exemption from FIFRA registration requirements and pesticide tolerance requirements under the Federal Food, Drug, and Cosmetic Act for plant-incorporated protectants (PIPs). The new rules exempt PIPs created from sexually

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<sup>68</sup>[Press Release](#), The White House, Fact Sheet: Biden-Harris Administration Announces New Bold Goals and Priorities to Advance American Biotechnology and Biomanufacturing (Mar. 22, 2023).

<sup>69</sup>[Building the Bioworkforce of the Future](#), MFG. USA (last visited Mar. 30, 2024).

<sup>70</sup>U.S. DEPT. OF AG., U.S. ENVTL. PROT. AGENCY, U.S. FOOD AND DRUG ADM., [THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY PLAIN LANGUAGE INFORMATION ON THE BIOTECHNOLOGY REGULATORY SYSTEM](#) (Nov. 2023).

<sup>71</sup>U.S. DEPT. OF AG., U.S. ENVTL. PROT. AGENCY, U.S. FOOD AND DRUG ADM., [REPORT ON STAKEHOLDER OUTREACH RELATED TO AMBIGUITIES, GAPS, UNCERTAINTIES IN REGULATION OF BIOTECHNOLOGY UNDER THE COORDINATED FRAMEWORK](#) (Mar. 2023).

<sup>72</sup>See [EPA and FDA to Seek Public Input on Modernizing Their Approach to Oversight of Certain Products](#), U.S. ENVTL. PROT. AGENCY (last updated Apr. 25, 2023).

<sup>73</sup>See [Press Release](#), U.S. Dep’t of Agric.: Animal and Plant Health Inspection Serv., APHIS Announces Final Regulatory Status Review Guide (Dec. 20, 2022).

<sup>74</sup>ANIMAL AND PLANT HEALTH INSPECTION SERV., U.S. DEP’T OF AGRIC., [GUIDE FOR SUBMITTING PERMIT APPLICATIONS FOR MICROORGANISMS DEVELOPED USING GENETIC ENGINEERING UNDER 7 CFR PART 340](#) (Oct. 13, 2023).

<sup>75</sup>Movement of Organisms Modified or Produced Through Genetic Engineering; Notice of Proposed Exemptions; [88 Fed. Reg. 78,285](#) (Nov. 15, 2023).

<sup>76</sup>ANIMAL AND PLANT HEALTH INSPECTION SERV., U.S. DEP’T OF AGRIC., [FISCAL YEARS 2023–2027 STRATEGIC PLAN](#) (Apr. 25, 2023).

compatible plants and “loss-of-function PIPs.”<sup>77</sup> EPA registered a first-of-its-kind sprayable interfering RNA (RNAi) pesticide product.<sup>78</sup>

OSTP published an RFI seeking public input in updating the National Nanotechnology Initiative (NNI) Environmental, Health, and Safety (EHS) Research Strategy.<sup>79</sup>

#### IV. FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

##### A. *Pesticide Regulatory Developments*

EPA published an advance notice of proposed rulemaking to solicit comment on whether to initiate regulatory action on seeds and paint treated with preservatives.<sup>80</sup> Articles of this type are generally exempt from FIFRA registration when prepared and sold consistent with the treated articles exemption. Stakeholders have raised questions about the clarity and enforceability of instructions related to treated seed products, and whether treated paints warrant instructions for use to protect professional painters.

The agency developed antimicrobial registration guidance to address several particular pests and application scenarios. In response to strong interest in antimicrobial products with approved public health claims to reduce bacteria and viruses on soft, porous surfaces, EPA developed and released final [guidance](#) for evaluating the efficacy of and registering such products, but only for use in clinical and institutional (non-residential) environments.<sup>81</sup> In a significant policy shift, the EPA issued draft guidance for approving virucidal claims to sanitizer products.<sup>82</sup> Approval will be limited to seven years, when the guidance and registrations will be reviewed. EPA released for comment [draft guidance](#)<sup>83</sup> for evaluating efficacy claims to reduce planktonic *Legionella pneumophila* in cooling tower water systems and extended its Emerging Viral Pathogen Guidance to allow

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<sup>77</sup>Pesticides; Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived From Newer Technologies, [88 Fed. Reg. 34,756](#) (May 31, 2023)(to be codified at 40 C.F.R. pt. 174).

<sup>78</sup>REGISTRATION DECISION FOR THE NEW ACTIVE INGREDIENT LEDPRONA (LEPTINOTARSA DECEMLINEATA-SPECIFIC RECOMBINANT DOUBLE-STRANDED INTERFERING OLIGONUCLEOTIDE GS2) (CAS NUMBER: 2433753-68-3), U.S. ENVTL. PROT. AGENCY (Dec. 21, 2023).

<sup>79</sup>Request for Information; National Nanotechnology Initiative Environmental, Health, and Safety Research Strategy, [88 Fed. Reg. 20,194](#) (Apr. 5, 2023).

<sup>80</sup>Pesticides; Review of Requirements Applicable to Treated Seed and Treated Paint Products; Request for Information and Comments, [88 Fed. Reg. 70,625](#) (proposed Oct. 12, 2023) (to be codified at 40 C.F.R. pt. 152).

<sup>81</sup>Pesticides; Antimicrobial Product Efficacy Claims on Soft Surface Textiles in Non-Residential Settings; Guidance, Methods, and Response to Comments; Notice of Availability [88 Fed. Reg. 59,522](#) (Aug. 29, 2023).

<sup>82</sup>Draft Guidance for the Evaluation of Products for Claims Against Viruses; Notice of Availability and Request for Comments, [88 Fed. Reg. 45,417](#) (July 17, 2023); U.S. ENVTL. PROT. AGENCY, [DRAFT GUIDANCE FOR THE EVALUATION OF PRODUCTS FOR CLAIMS AGAINST VIRUSES](#) (June 1, 2023).

<sup>83</sup>Pesticides; Draft Guidance and Proposed Method for Antimicrobial Product Efficacy Claims Against Planktonic Legionella Pneumophila in Cooling Tower Water; Notice of Availability and Request for Comments, [88 Fed. Reg. 67,749](#) (Oct. 2, 2023); U.S. ENVTL. PROT. AGENCY, EPA Releases Draft Guidance on Testing the Efficacy of Antimicrobial Pesticides Against Legionella Pneumophila in Cooling Towers (Oct. 2, 2023).

registrants to make limited off-label efficacy claims for a limited time for [Marburg virus](#)<sup>84</sup> without organism-specific efficacy data or label amendments.

EPA proposed framework to strengthen the assessment of antimicrobial resistance (AMR) efficacy risks for human and animal drugs associated with pesticide use,<sup>85</sup> a growing global public health threat. The [framework](#) was developed jointly by EPA, USDA, and the U.S. Department of Health and Human Services (HHS).

EPA proposed [updates to its Safer Choice Standard](#),<sup>86</sup> which was last updated in 2015.<sup>87</sup> The standard identifies the requirements that products and their ingredients must meet to earn EPA's Safer Choice certification. The DfE program, related to the Safer Choice Standard, is used by EPA for the purpose of helping consumers and commercial buyers identify antimicrobial products that meet this Standard and are registered under FIFRA. The proposed updates include updates to the packaging criteria, allowing certification of cleaning service providers, and adding several product and functional use class requirements.

## *B. Endocrine Disruptors*

EPA released its long-awaited strategic plan to complete screening all pesticide ingredients for potential endocrine-disrupting effects in humans through the 1998 Endocrine Disruptor Screening Program (EDSP)<sup>88</sup> as required by section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA).<sup>89</sup> Among other things, the plan provides that EPA will defer action on all List 2 chemicals and prioritize review of conventional pesticide active ingredient chemicals currently in registration or registration review proceedings,<sup>90</sup> including a data call-in for thirty of these. The plan also describes the endocrine-related data needed to register a new active ingredient and how it will address data deficiencies.

## *C. Developments: Particular Products and Uses of National Significance*

The U.S. Court of Appeals for the Eighth Circuit held that EPA's August 2021 revocation of all food tolerances for chlorpyrifos<sup>91</sup> was arbitrary and capricious because EPA failed to recognize its discretion to cancel less than all tolerances, although canceling

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<sup>84</sup>[Emerging Viral Pathogen Guidance and Status for Antimicrobial Pesticides](#), U.S. ENVTL. PROT. AGENCY (last updated Dec. 18, 2023).

<sup>85</sup>Pesticides; Concept for a Framework To Assess the Risk to the Effectiveness of Human and Animal Drugs Posed by Certain Antibacterial or Antifungal Pesticides; Notice of Availability and Request for Comment, [88 Fed. Reg. 65,998](#) (Sep. 26, 2023).

<sup>86</sup>Modifications to the Safer Choice Standard and Potential Implementation of a Safer Choice Cleaning Service Certification Program; Notice of Availability, Webinar and Request for Comment, [88 Fed. Reg. 78,017](#) (Nov. 14, 2023).

<sup>87</sup>U.S. ENVTL. PROT. AGENCY, [EPA'S SAFER CHOICE STANDARD](#) (revised Feb. 2015).

<sup>88</sup>Endocrine Disruptor Screening Program (EDSP); Near-Term Strategies for Implementation; Notice of Availability and Request for Comment, [88 Fed. Reg. 73,841](#) (Oct. 27, 2023).

<sup>89</sup>FFDCA § 408(p); [21 U.S.C. § 346a\(p\)](#).

<sup>90</sup>U.S. ENVTL. PROT. AGENCY, [LIST OF CONVENTIONAL REGISTRATION REVIEW CHEMICALS FOR WHICH AN FFDCA SECTION 408\(P\)\(6\) DETERMINATION IS NEEDED](#) (Oct. 2023).

<sup>91</sup>Chlorpyrifos; Tolerance Revocations, [86 Fed. Reg. 48,315](#) (Aug. 30, 2021) (to be codified at 40 C.F.R. pt. 180).

some would reduce exposure sufficiently to keep certain high-benefit agricultural uses “safe.”<sup>92</sup>

EPA announced that some organophosphate uses of diazinon,<sup>93</sup> ethoprop, tribufos, and phosmet were determined to have unacceptable risks, and registrants agreed to voluntary mitigation measures years before EPA completed its registration review.<sup>94</sup>

#### D. *Endangered Species Act (ESA) Developments*

EPA continued implementation of its 2022 ESA-FIFRA [workplan](#), which describes how the agency will handle new registration applications and registration review cases while meeting its obligations under the ESA to ensure that pesticide registrations do not jeopardize endangered species or adversely modify critical habitat.<sup>95</sup> Certain elements of the workplan were given court-enforceable deadlines as part of [the landmark settlement of the long-running, so-called “Mega” litigation](#).<sup>96</sup> The final settlement of the Mega litigation obligates EPA to complete Biological Evaluations for several organophosphates by 2027 and to publish certain class-wide “strategies” and presumptive remedies that are part of the “workplan” (*i.e.*, for herbicides, rodenticides, and insecticides) by dates certain. EPA completed and released the [draft herbicide strategy](#)<sup>97</sup> and [draft rodenticide biological evaluation](#), which will serve as the rodenticide strategy when finalized.<sup>98</sup> The Insecticide Strategy draft is due in July of 2024. The Mega settlement also set a date for the issuance of the EPA [Vulnerable Species Pilot Program](#), or VSPP document, designed to move toward a more programmatic and less chemical-by-chemical approach to protect a suite of 12 particular species.

Notably, the strategies and the VSPP do not alter product use requirements themselves; rather, they provide a framework to be applied during the registration review or evaluation of new applications. A major component of how EPA intends to implement these frameworks is through [Bulletins Live Two](#).<sup>99</sup>

The Mega case settlement did not eliminate all ESA litigation. The Center for Food Safety challenged EPA’s assertion that it may grant a registration prior to the completion of consultation with FWS and NMFS because doing so (imposing early mitigation if needed in EPA’s view pending completion of consultation) does not constitute an “irreversible or irretrievable commitment of resources” and is therefore permissible under

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<sup>92</sup>[Red River Valley Sugarbeet Growers Ass’n v. Regan](#), No. 22-1422 (8th Cir. Nov. 2, 2023).

<sup>93</sup>[Press Release](#), U.S. Evtl. Prot. Agency, EPA Reaches Agreement on Early Mitigation Measures Initiative for an Organophosphate Pesticide (Apr. 27, 2023).

<sup>94</sup>[Press Release](#), U.S. Evtl. Prot. Agency, EPA Reaches Agreements on Early Mitigation Measures for Three More Organophosphate Pesticides (May 25, 2023).

<sup>95</sup>[EPA’s Workplan and Progress Toward Better Protections for Endangered Species](#), U.S. ENVTL. PROT. AGENCY (last updated July 11, 2023).

<sup>96</sup>Proposed Stipulated Settlement Agreement, Ctr. for Biological Diversity v. EPA, No. 3:11-cv-00293 (N.D. Cal. Sept. 21, 2023).

<sup>97</sup>[Press Release](#), U.S. Evtl. Prot. Agency, Draft Strategy to Better Protect Endangered Species from Herbicide Use (July 24, 2023).

<sup>98</sup>[Press Release](#), U.S. Evtl. Prot. Agency, EPA Releases Draft Biological Evaluation of 11 Rodenticides’ Effects on Endangered Species (Dec. 1, 2023); *see also* U.S. ENVTL. PROT. AGENCY, [UPDATE ON VULNERABLE SPECIES PILOT](#) (Nov. 2023).

<sup>99</sup>[Bulletins Live! Two -- View the Bulletins](#), U.S. ENVTL. PROT. AGENCY (last updated Jan. 10, 2024).

ESA Section 7(d).<sup>100</sup> A challenge was also filed to EPA’s application of the treated articles exemption to certain neonicotinoid-treated seeds, arguing in part, that EPA had failed to properly evaluate the effects of treated seeds under the ESA.<sup>101</sup>

In *Maine Lobstermen’s Ass’n v. Nat’l Marine Fisheries Serv.*,<sup>102</sup> the D.C. Circuit Court of Appeals [vacated](#) a NMFS biological opinion (BiOp) concerning the effects of certain fisheries on the Right Whale. Instead of making “an empirical judgment” about whether fishery activities were “likely” to jeopardize the whales, NMFS had relied on worst-case assumptions. If NMFS “lacks a clear and substantial basis for predicting an effect is reasonably certain to occur... [then] the effect must be disregarded in evaluating the agency action.”<sup>103</sup>

In *Migrant Clinicians Network v. U.S. Env’tl. Prot. Agency*,<sup>104</sup> the Court [vacated](#) an amended registration of streptomycin. The Court rejected a claim that EPA did not properly assess possible antibiotic resistance concerns but agreed that EPA failed to adequately assess effects on pollinators. EPA did not contest an additional complaint that it had failed to comply with ESA screening requirements and asked for remand without vacatur, but court vacated the registration when EPA could not commit to a relatively short timeline (180 days) to come into compliance with the ESA, a benchmark the Court had used in a recent case.<sup>105</sup>

#### E. *Agricultural Worker Protection Standard*

In March 2023, EPA [issued](#) a proposed rule revising certain application exclusion zone (AEZ) requirements of the Agricultural Worker Protection Standards (WPS).<sup>106</sup> EPA had initially revised the AEZ requirements in a final rule published on October 30, 2020 (2020 AEZ Rule),<sup>107</sup> but that rule remains stayed pursuant to a court order. Since then, EPA has determined that certain requirements in the 2020 AEZ Rule do not adequately protect public health, including limiting the applicability of the AEZ to the agricultural employer’s property and the distance determination criteria. EPA has therefore proposed rulemaking to reconsider the 2020 AEZ Rule. The proposed rule would reinstate certain requirements in the 2015 WPS standards<sup>108</sup> while retaining some standards in the 2020

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<sup>100</sup>Complaint, *Ctr. for Food Safety v. EPA*, No. 23-cv-1633 (D.D.C. June 6, 2023).

<sup>101</sup>Complaint, *Ctr. for Food Safety v. EPA*, No. 23-cv-02714 (N.D. Cal. May 31, 2023).

<sup>102</sup>70 F.4th 582 (D.C. Cir. 2023).

<sup>103</sup>Notably, the Court’s reference to the “reasonably certain to occur” standard implicates a separate ongoing rulemaking process by FWS and NMFS concerning the consultation regulations that will likely result in updates to the interagency consultation regulations in 2024. The Proposed Rule was issued only a week after the *Maine Lobstermen’s* decision. See *Endangered and Threatened Wildlife and Plants; Revision of Regulations for Interagency Cooperation*, [88 Fed. Reg. 40,753](#) (proposed June 22, 2023) (to be codified at 50 C.F.R. pt. 402).

<sup>104</sup>No. 21-70719, 2023 WL 8613493 (9th Cir. Dec. 13, 2023).

<sup>105</sup>*Ctr. for Food Safety v. Regan*, 56 F.4th 648, 669 (9th Cir. 2022).

<sup>106</sup>Pesticides; Agricultural Worker Protection Standard; Reconsideration of the Application Exclusion Zone Amendments, [88 Fed. Reg. 15,346](#) (proposed Mar. 13, 2023) (to be codified at 40 C.F.R. pt. 170).

<sup>107</sup>Pesticides; Agricultural Worker Protection Standard; Revision of the Application Exclusion Zone Requirements, [85 Fed. Reg. 68,760](#) (Oct. 30, 2020) (codified at 40 C.F.R. pt. 170).

<sup>108</sup>Pesticides; Agricultural Worker Protection Standard Revisions, [80 Fed. Reg. 67,496](#) (Nov. 2, 2015) (to be codified at 40 C.F.R. pt. 170).



AEZ Rule. For example, EPA’s 2023 proposed rule would [reinstate](#) the 2015 requirement that pesticide handlers suspend application if a person, other than appropriately trained and equipped applicators, enters an AEZ regardless of whether they are within the property’s boundaries that are under the agricultural employer’s control.<sup>109</sup> EPA’s 2023 proposed rule also would reinstate the 2015 requirements that specify: (1) a 100 feet AEZ for ground-based fine spray applications, (2) a 25-foot AEZ for ground-based applications using medium or large droplet sizes sprayed above 12 inches, and (3) all applicable determination criteria from the 2015 WPS standards with the exception of the Volume Median Diameter (VMD) droplet size criterion when making distance determinations.

*F. State Developments of National Significance*

In *National Association of Wheat Growers v. Bonta*,<sup>110</sup> the Ninth Circuit entered a permanent injunction enjoining the California Attorney General from enforcing California’s Proposition 65’s (Prop 65) carcinogen warning requirement for the herbicide glyphosate, finding that requiring the warning was unconstitutional as a violation of First Amendment free speech rights.<sup>111</sup> In so holding, the Ninth Circuit determined that: (1) the government’s proposed Prop 65 warning as applied to glyphosate was not purely factual and uncontroversial, as the use of the word “risk” was still “factually misleading because a reasonable person reading it would understand this to mean that glyphosate poses a *risk* not a *hazard*[,]” and therefore, the warning was subject to intermediate scrutiny;<sup>112</sup> and (2) there were “less burdensome ways for [California] to convey its message than to compel plaintiffs to convey it for them,” (e.g., California could post information about glyphosate on its own website or conduct an advertising campaign).<sup>113</sup>

California’s Department of Pesticide Regulation (DPR) issued a notice of proposed regulatory action on November 3, 2023, which would impose additional requirements for notices of intent (NOI) for the agricultural use of restricted materials.<sup>114</sup>

*G. Pesticide Registration Improvement Act (PRIA) developments*

The Pesticide Registration Improvement Act of 2022 (PRIA 5) reauthorized EPA’s ability to collect pesticide maintenance fees through FY2027 and registration services fees through FY2029.<sup>115</sup> PRIA 5 increased the average annual maintenance fee collection target and raised the registration service fees and added new categories. The PRIA 5 pesticide registration service fee schedule became effective February 27, 2023.<sup>116</sup> EPA also is working on implementing other provisions of PRIA 5 including: (1) Section 3(f)(5) of FIFRA, which directs EPA to require some sections of the pesticide product labeling to be translated into Spanish; (2) the establishment of the Vector Expedited Review Voucher

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<sup>109</sup>Pesticides; Agricultural Worker Protection Standard; Reconsideration of the Application Exclusion Zone Amendments, 88 Fed. Reg. at 15,347.

<sup>110</sup>85 F.4th 1263 (9th Cir. 2023).

<sup>111</sup>*Id.*

<sup>112</sup>*Id.* at 1281.

<sup>113</sup>*Id.* at 1283.

<sup>114</sup>Statewide Notification of Agricultural Use of Restricted Materials, [44-Z Cal. Regulatory Notice Reg. 1402](#) (Nov. 3, 2023).

<sup>115</sup>Consolidated Appropriations Act of 2023, Pub. L. No. 117-328, § 703, [136 Stat. 4459](#), 5999 (2022).

<sup>116</sup>See [FY 2023-2024 Fee Schedule for Registration Applications](#), U.S. ENVTL. PROT. AGENCY (last updated Mar. 5, 2024).

(VERV) Program, which would incentivize expedited review of new insecticides to control the spread of vector-borne disease; and (3) information technology modernization, including an information technology system for electronic submissions and application tracking. EPA estimated that it would be able to accomplish many of these actions by December 29, 2023.<sup>117</sup>

As part of PRIA 5 implementation, EPA has: held a webinar on bilingual pesticide labels and conducted outreach to the states and other stakeholders on bilingual labeling; developed Endangered Species Act (ESA) guidance related to the registration of new active ingredients and outdoor new uses of pesticides;<sup>118</sup> and announced funding opportunities for the Pesticide Safety Education Program<sup>119</sup> and the National Pesticide Information Center.<sup>120</sup>

## V. STATE CHEMICAL CONTROL DEVELOPMENTS

In 2023, at least five states instituted new or revised laws related to PFAS in products. Minnesota enacted legislation requiring the phase-out of intentionally added PFAS in certain consumer products, including cookware, cosmetics, upholstered furniture, and juvenile products, starting in 2025, and then all covered products by 2032.<sup>121</sup> Manufacturers of PFAS-containing products must begin reporting products to the state environmental agency beginning in 2026. The Maine legislature amended that state's PFAS product reporting and restriction law to extend the initial reporting deadline from 2023 to January 1, 2025.<sup>122</sup> Other states adopted bans and disclosure requirements applicable to particular categories of PFAS-containing products. New York banned intentionally-added PFAS in apparel and outdoor apparel for severe wet conditions.<sup>123</sup> Indiana now requires firefighting gear containing PFAS to be labeled.<sup>124</sup> Oregon banned the manufacture, sale, and distribution of cosmetic products containing PFAS or certain other chemicals of concern beginning in 2027,<sup>125</sup> and banning foodware containers containing PFAS beginning in 2025.<sup>126</sup> Maryland will study the use of PFAS in pesticides in the state and determine if other actions are needed.<sup>127</sup>

States have addressed other chemicals in products. Minnesota now restricts the amount of cadmium and lead content in various consumer products.<sup>128</sup> New York banned

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<sup>117</sup>[PRIA 5 Implementation](#), U.S. ENVTL. PROT. AGENCY (last updated Jan. 10, 2024).

<sup>118</sup>[Press Release](#), U.S. Env'tl. Prot. Agency, Register for EPA's Webinar on Bilingual Pesticide Labels (May 18, 2023).

<sup>119</sup>[Press Release](#), U.S. Env'tl. Prot. Agency, EPA Opens Application Period for Grant Supporting Education and Training for Pesticide Applicators (Mar. 13, 2023).

<sup>120</sup>[Press Release](#), U.S. Env'tl. Prot. Agency, EPA Requests Applications for \$10 Million National Pesticide Information Center Agreement (June 23, 2023).

<sup>121</sup>[H.F. 2310](#), 93rd Leg., Reg. Sess. (Minn. 2023), 2023 Minn. Laws Ch. 60, art 3, § 21.

<sup>122</sup>[L.D. 217](#), 131st Leg., 1st Spec. Sess. (Me 2023) (codified at ME STAT. tit. 38, § 1614).

<sup>123</sup>[S.B. 1322](#), 2023-2024 Leg. Sess. (N.Y. 2023) (codified at N.Y. ENVTL. CONSERV. LAW § 37-0121).

<sup>124</sup>[H.B. 1341](#), 123rd Gen. Assemb., 1st Reg. Sess. (Ind. 2023) (codified at IND. CODE § 36-8-27).

<sup>125</sup>[S.B. 546](#), 82nd Leg. Assemb., 2023 Reg. Sess. (Or. 2023), 2023 Or. Laws Ch. 575.

<sup>126</sup>[S.B. 543](#), 82nd Leg. Assemb., 2023 Reg. Sess. (Or. 2023) (to be codified at OR. REV. STAT. § 459.995).

<sup>127</sup>[S.B. 158](#), 2023 Leg. Sess. (Md. 2023), 2023 Md. Laws Ch. 485.

<sup>128</sup>[H.F. 2310](#), 93rd Leg., Reg. Sess. (Minn. 2023), 2023 Minn. Laws Ch. 60, art 3, § 24.

the sale of cosmetics or personal care products containing mercury,<sup>129</sup> and Maine banned the sale of certain mercury-added lamps.<sup>130</sup> California banned the sale of any juvenile product, mattress, or upholstered furniture containing textile fiberglass,<sup>131</sup> and expanded the list of substances prohibited in cosmetic products.<sup>132</sup> Oregon banned the sale of cosmetics containing certain chemicals, and imposed disclosure requirements on the sale of cosmetics containing high priority chemicals designated by the Oregon Health Authority.<sup>133</sup> Oregon also banned food vendors from using polystyrene foam containers when selling or serving food to consumers, and anyone from selling polystyrene foam containers and packaging peanuts.<sup>134</sup> Delaware and Rhode Island passed a similar laws prohibiting food establishments from providing polystyrene foam containers for ready to eat food and beverages.<sup>135</sup>

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<sup>129</sup>[A. 619](#), 2023-2024 Leg. Sess. (N.Y. 2023) (codified at N.Y. ENVTL. CONSERV. LAW § 37-0117).

<sup>130</sup>[L.D. 1814](#), 131st Leg., 1st Spec. Sess. (Me. 2023) (codified at 38 M.R.S.A. § 1672).

<sup>131</sup>[A.B. 1059, 2023-2024 Reg. Sess.](#) (Cal. 2023) (codified at CAL. BUS. & PROF. CODE § 19101.5).

<sup>132</sup>[A.B. 496, 2023-2024 Leg. Sess.](#) (Cal. 2023) (codified at CAL. HEALTH & SAFETY CODE § 108980).

<sup>133</sup>[S.B. 546](#), 82nd Leg. Assemb., 2023 Reg. Sess. (Or. 2023); 2023 Or. Laws Ch. 575.

<sup>134</sup>[S.B. 543](#), 82nd Leg. Assemb., 2023 Reg. Sess. (Or. 2023) (to be codified at OR. REV. STAT. § 459.995).

<sup>135</sup>[S.B. 51, 152. Gen. Assemb., 2023 Leg. Sess.](#) (Del. 2023) (codified at DEL. CODE. ANN. tit. 16, § 122, § 3001Q *et seq.*); [S.B. 14, 2023 Reg. Sess.](#) (R.I. 2023) (codified at R.I. GEN. LAWS tit. 21, § 27.3).