

Chapter H: PESTICIDES, CHEMICAL REGULATION, AND RIGHT-TO-KNOW 2020 Annual Report¹

I. TOXIC SUBSTANCES CONTROL ACT (TSCA)

TSCA initiatives and controversies continued to dominate the chemical regulatory landscape in 2020 as the U.S. Environmental Protection Agency (EPA) continued its relentless press to meet statutory deadlines imposed under the 2016 Lautenberg Amendments. For the most part, EPA stayed on track. As eventful as 2020 was, 2021 will likely meet and exceed the frantic pace as “new TSCA” is poised to experience its second administrative transition.

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

In 2020, EPA continued to evolve and adapt its New Chemicals Program in response to statutory changes in the [Frank R. Lautenberg Chemical Safety for the 21st Century Act \(Lautenberg\)](#).² “EPA has made significant progress in resolving older cases” (those more than six months past the submission date), although some cases continue to languish. The reorganization of EPA’s Office of Pollution Prevention and Toxics (OPPT) will help diminish the backlog of cases now that the scientific risk assessment teams and regulatory risk management teams (both dedicated to new chemicals) report to a single division director in the OPPT New Chemicals Division. Notably, the EPA continues to use “non-order SNURs” in lieu of section 5(e) orders for cases in which EPA does not find unreasonable risk under the intended conditions of use. The approach, still controversial to some stakeholders, offers administrative streamlining because it reduces the number of section 5(e) orders that EPA must produce, while implementing SNUR requirements that would presumably have been required under section 5(f)(4) after an order is signed. EPA also continued its efforts to address backlogged SNURs. EPA proposed 136 non-order SNURs in fiscal year 2020.³

EPA also continued to evolve the new chemical review process and published for comment its current approach to new chemical review as it has gained experience working under the amended statute,⁴ and on March 18, 2020, a coalition of non-governmental organizations filed suit in the U.S. District Court for the District of Columbia, claiming that EPA fails to disclose required information about new chemical substances under TSCA. According to the [plaintiffs’ complaint](#), EPA fails to publish full and complete notices of its receipt of new chemical applications in a timely fashion and does not disclose all non-confidential information, including health and safety studies, supporting such applications. The plaintiffs argue that TSCA requires that EPA conduct its review of new

¹Margaret Barry and Larry Culleen, Arnold & Porter Kaye Scholer LL; Lynn Bergeson, Christopher Blunck and Richard Engler, Ph.D., Bergeson & Campbell, P.C.; Matthew Allen, Brunini, Grantham, Grower & Hewes, PLLC; Warren Lehrenbaum, Crowell & Moring LLP; Mia Lombardi and Dottie Watson, Foley & Lardner LLP; Tom Berger and James Votaw, Keller and Heckman LLP; and Keith Matthews, Wiley Rein LLP.

²Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No.114-182, 130 Stat 448 (2016).

³Some of the prospectives offered in Section I.A. and I.B.3. can also be found at [Forecast for U.S. Federal and International Chemical Regulatory Policy 2021](#), 8, BERGESON & CAMPBELL, P.C. (Jan. 8, 2021).

⁴Updated Working Approach to Making New Chemical Determinations Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment, [85 Fed. Reg. 99](#) (Jan. 2, 2020).

chemicals transparently, providing the public: (1) access to information about the new chemical, including potential uses, effects, and exposures; and (2) an opportunity to participate in EPA's decision-making process.⁵

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

1. Prioritization for Risk Evaluation

TSCA section 6(b)(2)(B) required EPA to designate by December 22, 2019, at least 20 chemicals as high-priority for risk evaluation, for which the three- to three-and-a-half-year risk evaluation process would immediately commence, and 20 low-priority chemicals. EPA announced [the final designation of 20 high-priority chemicals](#) on December 20, 2019,⁶ and [the final designation of 20 low-priority substances](#) on February 20, 2020.⁷ The low-priority designations were final agency actions that were subject to [judicial review](#).⁸ However, there were no judicial challenges to these designations. There have been no chemicals undergoing prioritization for risk evaluation since the February 20, 2020, low-priority designations. The next high-priority chemical designations are not anticipated until late 2022 or early 2023, when EPA is expected to complete the risk evaluations for the 20 chemicals designated as high priority in December 2019 that are now undergoing risk evaluation.

2. Risk Evaluation for Existing Chemicals

In 2020, EPA completed the first risk evaluations for existing chemicals under the new procedures and standards of amended TSCA. As required by TSCA section 6(b)(2)(A), EPA commenced risk evaluations for an initial ten chemicals in December 2016.⁹ In accordance with TSCA section 6(b)(4)(G),¹⁰ this caused final risk evaluations for all ten to be due no later than June 2020, the end of the three-year statutory period, plus the six-month statutory maximum extension.

By the June 2020 extended deadline, EPA had completed a final risk evaluation for only one of the first ten chemicals, [methylene chloride](#).¹¹ Final risk evaluations were

⁵See Complaint, Env't Def. Fund v. Wheeler, No. 1:20-cv-762 (Mar. 18, 2020 U.S.D.C.); see also Bergeson & Campbell, P.C., [NGOs File Suit Against EPA for Failing to Disclose Information About New Chemical Substances](#), 11 NAT'L L. REV. 59 (Mar. 23, 2020).

⁶Press Release, Env'tl. Prot. Agency, EPA Finalizes List of Next 20 Chemicals to Undergo Risk Evaluation Under TSCA (Dec. 20, 2019); see also High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability, [84 Fed. Reg. 71,924](#) (Dec. 30, 2019).

⁷*Low Priority Substances Under TSCA*, ENVTL. PROT. AGENCY (last updated Apr. 6, 2020); Final Designation of Low-Priority Substances Under the Toxic Substances Control Act (TSCA); Notice of Availability, [85 Fed. Reg. 11,069](#) (Feb. 26, 2020).

⁸See 15 U.S.C. § 2618(a)(1)(C)(i) (2016).

⁹*Id.* § [2605\(b\)\(2\)\(A\)](#); Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act, [81 Fed. Reg. 91,927](#) (Dec. 19, 2016).

¹⁰[15 U.S.C. § 2605\(b\)\(4\)\(G\)](#).

¹¹Press Release, Env'tl. Prot. Agency, EPA Releases First Final Chemical Risk Evaluation (June 19, 2020).

subsequently completed for [1-bromopropane](#),¹² the [Cyclic Aliphatic Bromide Cluster \(HBCD\)](#),¹³ [carbon tetrachloride](#),¹⁴ and [trichloroethylene \(TCE\)](#).¹⁵ By December 2020, EPA still expected to complete the remaining risk evaluations before the end of the year. Each of the completed risk evaluations have found unreasonable risks for certain, but not all conditions of use have been evaluated, as generally described below.

The development of risk evaluations for these ten chemicals presented challenges for EPA, partly because they were the first to be conducted under the amended statute and the TSCA risk evaluation procedures regulation.¹⁶ Many of the chemicals have been the subject of EPA's attention for years, have large information sets, raised complex scientific issues during the evaluation, and/or have an abundance of conditions of use that had to be evaluated. Litigation, too, has affected the timing and substance of the development of certain of the risk evaluations. The U.S. Court of Appeals for the Ninth Circuit, in its November 2019 [decision](#)¹⁷ on challenges to the TSCA section 6 prioritization and risk evaluation regulations, limited EPA's discretion in determining the conditions of use to be considered as part of the risk evaluation. The court held that potential risks of future activities associated with past, discontinued uses (legacy uses) of a substance must be considered as part of the risk evaluation for the substance. Referring to an example used by EPA in the risk evaluation rule's preamble, the court stated that the conditions of use for the asbestos risk evaluation must include the risks of future disposal of asbestos insulation previously installed in a building because those activities are known or reasonably foreseeable, even if asbestos is no longer known or reasonably foreseen to be manufactured, processed, or distributed for insulation uses. In contrast, the court agreed with EPA that the statute does not require the agency to evaluate risks of disposals of a substance that have already occurred (legacy disposals).¹⁸ This decision forced EPA to revisit and revise its risk evaluations.

3. A Summary of the Final Risk Evaluations

The [final risk evaluation for methylene chloride](#)¹⁹ found that there are unreasonable risks to workers, occupational non-users, consumers, and bystanders under 47 out of 53 conditions of use. EPA did not find unreasonable risk to the environment. EPA did not evaluate hazards or exposures to the general population in the risk evaluation, and as such the unreasonable risk determinations for relevant conditions of use do not account for exposures to the general population.

The [1-bromopropane, the final risk evaluation](#)²⁰ identified unreasonable risks to workers, occupational non-users, consumers, and bystanders under 16 out of 25 conditions

¹²Press Release, Env'tl. Prot. Agency, EPA Releases Final Chemical Risk Evaluation for 1-BP (Sept. 1, 2020).

¹³Press Release, Env'tl. Prot. Agency, EPA Releases Final Chemical Risk Evaluation for HBCD (Sept. 25, 2020).

¹⁴Press Release, Env'tl. Prot. Agency, Releases Final Chemical Risk Evaluation for Carbon Tetrachloride (Nov. 3, 2020).

¹⁵Press Release, Env'tl. Prot. Agency, EPA Releases Final Chemical Risk Evaluation for TCE (Nov. 23, 2020).

¹⁶Procedures for Chemical Risk Evaluation Under Amended TSCA, [82 Fed. Reg. 33,726](#) (July 20, 2017) (to be codified at 40 C.F.R. pt. 702) (direct final rule).

¹⁷*See* Safer Chems. v. U.S. Env'tl. Prot. Agency, 943 F.3d 397, 400 (9th Cir. 2019).

¹⁸*Id.* at 424-26.

¹⁹ENVTL. PROT. AGENCY, EPA-740-R1-8010, RISK EVALUATION FOR METHYLENE CHLORIDE (DICHLOROMETHANE, DCM) (JUNE 2020).

²⁰ENVTL. PROT. AGENCY, EPA-740-R1-8010, RISK EVALUATION FOR 1-BROMOPROPANE (N-PROPYL BROMIDE) (Aug. 2020).

of use. EPA did not find unreasonable risks to the environment or the general population from the evaluated uses. EPA did not evaluate risk to the general population from ambient air and disposal pathways for any conditions of use, and the no unreasonable risk determinations do not account for exposures to the general population from ambient air and disposal pathways.

The [final risk evaluation for HBCD](#)²¹ determined that there are unreasonable risks to the environment for six out of 12 conditions of use. EPA found unreasonable risks to workers and occupational non-users from the use and disposal of HBCD in building and construction materials. EPA did not find unreasonable risks to the general population or consumers. EPA did not evaluate risk to the general population from disposal pathways for any conditions of use, and the no unreasonable risk determinations do not account for exposures to the general population from disposal pathways.

The [final risk evaluation for carbon tetrachloride](#)²² determined that there are unreasonable risks to workers and occupational non-users for 13 out of 15 conditions of use. EPA found no unreasonable risks to the environment. EPA states that there are no consumer uses of this chemical. EPA did not evaluate hazards or exposures to the general population in the risk evaluation, and as such the unreasonable risk determinations for relevant conditions of use do not account for exposures to the general population.

The [final risk evaluation for TCE](#)²³ shows that there are unreasonable risks to workers, occupational non-users, consumers, and bystanders for 52 out of 54 conditions of use. For two conditions of use (distribution in commerce and consumer use in pepper spray), EPA found they do not present an unreasonable risk. EPA also found no unreasonable risks to the environment. EPA did not evaluate risk to the general population from ambient air, water and disposal, and pathways for any condition of use, and the unreasonable risk determinations do not account for exposures to the general population.

In the completed risk evaluations, EPA did not evaluate some, or in some cases any, exposure pathways concerning general population exposure, and as such the unreasonable risk determinations for the relevant conditions of use do not account for those exposures to the general population. EPA explains in each of the final risk evaluations that “it believes ‘it is both reasonable and prudent’ to tailor TSCA risk evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA.”²⁴ According to EPA:

coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with the statutory text and legislative history, particularly as they pertain to TSCA’s function as a ‘gap-filling’ statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadlines for completing Risk Evaluations.²⁵

EPA states it therefore tailored the scope of the risk evaluation for the chemical substances using authorities in TSCA sections 6(b) and 9(b)(1). Suits challenging EPA’s final risk

²¹ENVTL. PROT. AGENCY, EPA, 740-R1-8006, RISK EVALUATION FOR CYCLIC ALIPHATIC BROMIDE CLUSTER (HBCD) (Sept. 2020).

²²ENVTL. PROT. AGENCY, EPA-740-R1-8014, RISK EVALUATION FOR CARBON TETRACHLORIDE (METHANE, TETRACHLORO) (Oct. 2020).

²³ENVTL. PROT. AGENCY, EPA-740-R1-8008, RISK EVALUATION FOR TRICHLOROETHYLENE (Nov. 2020).

²⁴*See, e.g., id.* at 39.

²⁵*Id.*

evaluation for methylene chloride were filed in different courts and were consolidated in the U.S. Court of Appeals for the Ninth Circuit in November 2020. On July 16, 2020, a coalition of environmental and labor organizations filed [suit](#) in the U.S. Court of Appeals for the Ninth Circuit for review of EPA’s final risk evaluation and order determining that methylene chloride does not present an unreasonable risk of injury to health or the environment under certain conditions of use and declining to consider certain uses and pathways through which members of petitioners are exposed and face risks of exposure to methylene chloride.²⁶ Notably, several industry groups moved to intervene on the side of EPA, and the court granted their motions.

On August 18, 2020, a group of state and municipal petitioners filed [suit](#) in the U.S. Court of Appeals for the Second Circuit for review of EPA’s “final agency action,” whereby EPA issued an order determining that methylene chloride “does not present an unreasonable risk of injury to health or the environment.”²⁷ On November 4, 2020, the court granted EPA’s motion to transfer the case to the U.S. Court of Appeals for the Ninth Circuit.

On October 16, 2020, the Alaska Community Action on Toxics filed [suit](#) in the U.S. Court of Appeals for the Ninth Circuit, seeking review of EPA’s “final risk evaluation and order,” determining that the cyclic aliphatic bromide cluster (HBCD) does not present an unreasonable risk of injury to health or the environment under certain conditions of use and declining to consider certain uses and pathways through which Petitioner’s members are exposed and face risks of exposure to HBCD.²⁸

In October 2020, EPA published a revised draft risk evaluation for C.I. Pigment Violet 29,²⁹ which included significant revisions to the draft risk evaluation published in November 2018. Changes to the draft risk evaluation include:

- (1) the addition of data from 24 full study reports and associated systematic review that were originally considered as Confidential Business Information (CBI); (2) two sets of particle size distribution (PSD) data for C.I. Pigment Violet 29; (3) two sets of data for breathing zone monitoring of dust in the domestic manufacturer’s workplace; and (4) solubility testing.³⁰

EPA received “some of the added data used in the revised draft risk evaluation under two section 4(a)(2) TSCA Test Orders, including solubility testing of [C.I. Pigment Violet 29](#) in water and octanol, and a [dust monitoring study of Particulates Not Otherwise Regulated](#) at the domestic manufacturer’s workplace.”³¹ Significantly, these TSCA section 4 Orders are the first and to date the only TSCA section 4 testing actions taken by EPA under amended TSCA. As a result of the updated analysis, the revised draft risk evaluation now shows

²⁶Neighbors for Env’tl. Justice v. Env’tl. Prot. Agency, No. 20-72091 (9th Cir. July 16, 2020).

²⁷New York v. Wheeler, No. 20-2729 (2nd Cir. Aug. 17, 2020).

²⁸Alaska Cmty. Action on Toxics v. Env’tl. Prot. Agency, No. 20-73099 (9th Cir. Oct. 16, 2020).

²⁹C.I. Pigment Violet 29; Revised Draft Toxic Substances Control Act (TSCA) Risk Evaluation; Notice of Availability, Letter Peer Review and Public Comment, [85 Fed. Reg. 68,873](#) (Oct. 30, 2020).

³⁰*Bergeson & Campbell Forecast*, at 9-10.

³¹*Id.*; see ENVTL. PROT. AGENCY, EPA-HQ-OPPT-2020-0070-0002, TSCA SECTION 4(A)(2) TEST ORDER FOR C.I. PIGMENT VIOLET 29 - BASF COLORS & EFFECTS USA (Mar. 1, 2020); see also, ENVTL. PROT. AGENCY, EPA-HQ-OPPT-2020-0070-0003, TSCA SECTION 4(A)(2) TEST ORDER FOR C.I. PIGMENT VIOLET 29 – SUN CHEM. CORP., (Mar. 1, 2020).

unreasonable risk to workers for 11 out of 14 conditions of use; the November 2018 initial draft risk evaluation showed no unreasonable risk.

On November 20, 2020, EPA [announced](#) the availability of a supplemental analysis to the draft risk evaluation for 1,4-dioxane and provided a twenty-day public comment period.³² The supplemental analysis includes eight consumer uses where 1,4-dioxane is present as a byproduct. The supplemental analysis also assesses exposure to the general population from 1,4-dioxane in surface water. In the supplemental analysis to the draft risk evaluation, EPA preliminarily found no unreasonable risk to consumers from the eight conditions of use assessed. The agency also preliminarily found no unreasonable risks under any of the conditions of use to the general population from exposure to 1,4-dioxane.

In regards to the ongoing risk evaluations of the twenty (20) chemicals designated as “high priority” in December 2019, EPA [announced](#) the availability of the final scope documents.³³ As required under TSCA section 6(b)(4)(D), the scope document for each chemical substance includes the conditions of use, hazards, exposures, and the potentially exposed or susceptible subpopulations that EPA plans to consider in conducting the risk evaluation for the chemical substance.

In addition, on October 6, 2020, EPA granted a manufacturer request under TSCA section 6(b)(4)(C)(ii) for a risk evaluation of octamethylcyclotetra-siloxane (D4), a chemical used to make other silicone chemicals and as an ingredient in some personal care products.³⁴ It is the second such request granted by EPA. In the request,

[t]he requesting manufacturers asked that EPA evaluate conditions of use, including manufacture of D4, processing of D4 as a reactant or by incorporation into a formulation, mixture, or reaction product, and commercial/consumer uses of products that include D4 in their manufacture . . . and disposal. EPA determined that the circumstances identified in the request constitute conditions of use but also identified additional possible conditions of use for D4 that it may consider in conducting the risk evaluation.³⁵

As with risk evaluations for high-priority chemicals, EPA has three years to complete manufacturer-requested risk evaluations, with an extension available for up to six months.³⁶

On November 27, 2020, EPA announced the availability of the draft risk evaluation scopes for diisodecyl phthalate (DIDP) and diisononyl phthalate (DINP), which were the subjects of the first manufacturer request for risk evaluations granted by EPA.³⁷

4. Risk Management for Existing Chemicals

On July 29, 2019, EPA published proposed TSCA section 6(a) risk management rules for five substances listed on the TSCA Work Plan that EPA found were persistent,

³²1,4-Dioxane; Supplemental Analysis to the Draft Toxic Substances Control Act (TSCA) Risk Evaluation; Notice of Availability and Public Comment, [85. Fed. Reg. 74,341](#) (Nov. 20, 2020).

³³See Final Scopes of the Risk Evaluations To Be Conducted for Twenty Chemical Substances Under the Toxic Substances Control Act; Notice of Availability, 85 Fed. Reg. 55,281 (Sept. 4, 2020).

³⁴[Letter](#) from Yvette C. Reyes, Dir. of the Office of Pollution Prevention & Toxics, to Karluss Thomas, Am. Chem. Council (Oct. 6, 2020).

³⁵*Bergeson & Campbell Forecast*, at 11.

³⁶[15 U.S.C. § 2605\(b\)\(4\)\(G\)](#).

³⁷[Letter](#) from Jeffery T. Morris, Dir. of the Office of Pollution Prevention & Toxics, to Eileen Conneely, Am. Chem. Council (Dec. 2, 2020).

bioaccumulative, and toxic (PBT).³⁸ TSCA section 6(h) required EPA to propose such rules without the subject chemicals needing to go through a prior risk evaluation and to issue final rules by December 2020 that would go beyond reducing any unreasonable risks and reduce all exposure to the PBTs to the extent practicable.³⁹ EPA concluded that existing rules were sufficient to meet this standard for one substance (hexachlorobutadiene) (HCBd), but proposed to ban manufacture and/or processing and distribution of the four other substances in commerce, whether alone or in products, subject to certain exceptions for uses for which there were no practicable alternatives (decabromodiphenyl ether (decaBDE), Phenol, isopropylated phosphate (3:1), pentachlorothiophenol (PCTP), and 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP). When issued in final, these rules will be the first risk management rules promulgated under the new procedures of the amended statute. However, given the absence of underlying risk evaluations, they may provide only limited useful precedent for future section 6(a) risk management rules.

As required by TSCA section 6(c)(1), as it completed risk evaluations for the first ten chemicals, EPA promptly commenced the development of TSCA section 6(a) risk management rules for each of the initial ten chemicals selected by EPA for risk evaluation that found to present an unreasonable risk for one or more uses. EPA has been engaging actively with stakeholders to inform the rulemakings.⁴⁰

C. Other Developments

1. Fees Rule

On January 27, 2020, EPA published preliminary lists of manufacturers (including importers) of the 20 chemical substances designated as High-Priority for risk evaluation in December 2019.⁴¹ This publication triggered the first application of the 2018 rule⁴² requiring manufacturers of chemicals subject to EPA-initiated risk evaluations under TSCA section 6 to jointly pay a fee of \$1.35 million.

After widespread industry complaints that the scope of the rule was too broad because it did not contain the exemptions for R&D, coincidentally manufactured chemicals and chemicals in articles found in other TSCA rules, EPA issued a [No Action Assurance memorandum](#) regarding Self-Identification Requirement for Certain “Manufacturers” Subject to the TSCA Fees Rule.⁴³ The No Action Assurance communicated that EPA would exercise its enforcement discretion for certain manufacturers’ failure to self-identify for purposes of the fees rule. This No Action Assurance only applies to manufacturers who (i) import the chemical substance in an “article;” (ii) produce the chemical substance as a “byproduct;” or (iii) produce or import the chemical substance as an “impurity” as each of those terms are defined under TSCA.⁴⁴ The No Action Assurance memorandum also

³⁸Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h), [84 Fed. Reg. 36,728](#) (July 29, 2019) (to be codified at 40 C.F.R. pt. 751).

³⁹[15 U.S.C. § 2605 \(h\)](#).

⁴⁰See [Risk Management for Existing Chemicals under TSCA](#), ENVTL. PROT. AGENCY (last updated Mar. 16, 2021).

⁴¹Preliminary Lists Identifying Manufacturers Subject to Fee Obligations for EPA-Initiated Risk Evaluations under Section 6 of the Toxic Substances Control Act; Notice of Availability and Request for Comment, [85 Fed. Reg. 4661](#) (Jan. 27, 2020).

⁴²[40 C.F.R. § 700.45](#).

⁴³Memorandum from Susan Bodine, Assistant Adm’r, Office of Enf’t & Compliance Assurance, to Alexandra Dapolito Dunn, Esq., Assistant Adm’r, Office of Chem. Safety and Pollution Prevention regarding No Action Assurance Regarding Self-Identification Requirement for Certain “Manufacturers” Subject to TSCA Fees Rule (Mar. 24, 2020).

⁴⁴[40 C.F.R. § 720.3](#).

communicated EPA’s intent to begin rulemaking to amend the TSCA Fees Rule to propose permanent exemptions to the self-identification requirements associated with EPA-initiated risk evaluations for manufacturers in these three categories.

On August 26, 2020, EPA published the “final list” of companies subject to fees for the Section 6 risk evaluations for the High Priority Substances identified in 2019. This list was updated in a further [final list](#) issued on November 25, 2020.⁴⁵

2. TSCA Inventory and Confidential Business Information (“CBI”)

EPA issued a rule establishing a plan for EPA to review all existing for chemical identity CBI claims for chemicals on the TSCA Inventory.⁴⁶ Required by TSCA section 8(b)(4)(C), the plan included procedures for companies to resubstantiate their existing chemical identity CBI claims prior to EPA review. Manufacturers that had renewed their CBI claims without substantiation in 2018 in connection with the Inventory reset process⁴⁷ by submitting an NOA Form A were given until by November 1, 2020 to resubstantiate their chemical identity CBI claims. Those that had provided substantiation with their NOA Forms A in 2018 were given until November 1, 2020 to supplement their substantiation by addressing two new questions regarding the ability to determine a chemical’s CBI identity by reverse engineering as a result of the 2019 decision in [Envtl. Def. Fund v. EPA](#).⁴⁸

3. Chemical Data (TSCA Inventory Update) Reporting

2020 was a reporting year under EPA’s Chemical Data Reporting (CDR) regulations for updating the TSCA Chemical Substances Inventory of chemicals in commerce. Ahead of the reporting period, EPA amended the reporting rules,⁴⁹ including changing requirements for asserting confidentiality claims, replacing certain processing and use codes with codes based on the functional use and product and article use codes of the Organisation for Economic Co-operation and Development (OECD), modifying how recycled streams are reported, requiring more chemical function information from secondary submitters of a joint submission report, and exempting certain recycled and air pollution control equipment byproducts. The reporting September 30, 2020 deadline was extended multiple times, ultimately until January 29, 2021⁵⁰ in response to concerns raised by stakeholders about technical challenges with electronic reporting.

4. TSCA Section 21 Citizen Petitions

On June 3, 2020, a collection of industry associations filed a [Petition](#) with EPA requesting that EPA initiate a proceeding to Issue a Procedural Risk Management Rule Under Section 6 of the Toxic Substances Control Act. On June 28, 2020, EPA issued a [letter](#) denying the petition because only chemical-specific and not a procedural rulemaking

⁴⁵[Final List of Fee Payers for Next 20 Risk Evaluations](#), ENVTL. PROT. AGENCY (last visited Apr. 15, 2021).

⁴⁶Procedures for Review of Confidential Business Information Claims for the Identity of Chemicals on the Toxic Substances Control Act Inventory, [85 Fed. Reg. 13,062](#) (Mar. 6, 2020) (to be codified at 40 C.F.R. pt. 710).

⁴⁷TSCA Inventory Notification (Active-Inactive) Requirements, [82 Fed. Reg. 37,520](#) (Aug. 11, 2017) (to be codified at 40 C.F.R. pt. 710).

⁴⁸922 F.3d 446 (D.C. Cir. 2019).

⁴⁹TSCA Chemical Data Reporting Revisions Under TSCA Section 8(a), [85 Fed. Reg. 20,122](#) (Apr. 9, 2020) (to be codified at 40 C.F.R. pt. 711) (direct final rule).

⁵⁰Chemical Data Reporting; Final Extension of the 2020 Submission Period, [85 Fed. Reg. 75,235](#) (Nov. 25, 2020) (to be codified at 40 C.F.R. pt. 711) (direct final rule).

is available in response to a Section 21 petition. However, EPA indicated that it would consider the request under the Administrative Procedures Act as a request for a procedural rulemaking.⁵¹

On October 14, 2020, a coalition of six non-governmental organizations filed a [citizen petition](#) with EPA for a rule or order under section 4 of TSCA to require health and environmental effects testing on 54 per- and polyfluoroalkyl substances (PFAS). EPA must grant or deny the petition by January 11, 2021.⁵²

D. National Program Chemicals – Formaldehyde, Mercury, PCBs, LBP, & More

On June 17, 2020, EPA proposed a rule to reduce the amount of lead that can remain in dust on floors and window sills after lead removal activities to protect children from the harmful effects of lead exposure.⁵³ The agency proposed reducing the dust-lead clearance levels (DLCL) from 40 µg/ft² to 10 µg/ft² for floor dust, and from 250 µg/ft² to 100 µg/ft² for window sill dust. This followed EPA's 2019 final rule tightening dust-lead hazard standards (DLHS) for floors and window sills. This rule was promptly [challenged](#) by several environmental and public health groups,⁵⁴ and on October 27, 2020, the U.S. Court of Appeals for the Ninth Circuit [heard oral argument](#) on the petition for review.⁵⁵

EPA published its first mercury inventory report,⁵⁶ which summarizes information on the U.S. mercury supply, use, and trade that is required to be reported by mercury manufacturers, importers, and processors under the Mercury Inventory Reporting rule.⁵⁷ Litigation challenging the Mercury Inventory Reporting rule was decided on June 5, 2020.⁵⁸ The U.S. Court of Appeals for the Second Circuit vacated the reporting exemption for importers of products containing a mercury-added component.⁵⁹ The court upheld the other challenged exemptions in the rule.⁶⁰

The prohibition on export of certain mercury compounds under Section 12 of TSCA became effective January 1, 2020.⁶¹ This prohibition was part of the 2016 amendments to TSCA under the Lautenberg Act.⁶²

⁵¹Petition of the American Coatings Association et al., to Initiate a Proceeding to Issue a Procedural Mgmt. Rule Under Section 6 of the Toxic Substances Control Act, (June 3, 2020); Letter from Alexandra Dapolito Dunn, Esq., Assistant Adm'r, Office of Chem. Safety and Pollution Prevention, to Rachel Jones, Vice President, Energy & Res. Policy (July 28, 2020).

⁵²Petition of Ctr. for Env'tl. Health et al., to Require Health and Environmental Testing Under the Toxic Substances Control Act on Certain PFAS Manufactured by Chemours in Fayetteville, North Carolina (Oct. 13, 2020).

⁵³Review of Dust-Lead Post-Abatement Clearance Levels, [85 Fed. Reg. 37,810](#) (June 24, 2020) (to be codified at 40 C.F.R. pt. 745).

⁵⁴Community Voice v. Env'tl. Prot. Agency, No. 19-71930 (9th Cir. Aug. 1, 2019).

⁵⁵Recording of Hearing, Community Voice v. Env'tl. Prot. Agency, No 19-71930 (9th Cir. Oct. 27, 2020).

⁵⁶Inventory of Mercury Supply, Use, and Trade in the United States 2020 Report; Notice of Availability, [85 Fed. Reg. 18,574](#) (Apr. 2, 2020).

⁵⁷Mercury: Reporting Requirements for the TSCA Mercury Inventory, [83 Fed. Reg. 30,054](#) (June 27, 2018) (to be codified at 40 C.F.R. pt. 713).

⁵⁸Nat. Res. Def. Council, Inc. v. Env'tl. Prot. Agency, No. 18-2121, *consolidated with*, [18-2670-ag](#) (2d Cir. June 5, 2020).

⁵⁹[40 C.F.R. § 713.7\(b\)\(2\)](#).

⁶⁰*Id.* §§ 713.7(b)(3), 713.9(a).

⁶¹TSCA § 12(c)(7)(A), [15 U.S.C. § 2611\(c\)\(7\)\(A\)](#).

⁶²Frank R. Lautenberg Chemical Safety for the 21st Century Act, [Pub. L. No. 114-182, 130 Stat. 448](#).

EPA held a workshop on September 8, 2020, for input on developing guidance for petitioning the agency to exempt certain products from the formaldehyde rule for composite wood products.⁶³

II. PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS)

PFAS continued to be the focus of intense regulatory and legislative activity at the Federal and State levels. EPA revised its regulations to add 172 PFAS substances to the list of chemicals subject to reporting for the [Toxics Release Inventory](#) (TRI), as required under the [2020 National Defense Authorization Act](#).⁶⁴ EPA issued a final rule expanding two Significant New Use Rules (SNURs) to cover certain “long chain” PFAS substances no longer made or in used for commercial purposes in the United States, except for certain narrow use categories excluded from the rule.⁶⁵ First proposed in 2015,⁶⁶ the final regulation notably expanded coverage of the SNURs to include articles containing a SNUR substance as part of a surface coating. Substances in articles usually are excluded from SNUR coverage, along with SNUR substances present only as impurities or produced only as exempt byproducts.⁶⁷ In December 2020, the Agency solicited comments on draft interpretive guidance addressing implementation of this aspect of the rule.⁶⁸

EPA took additional steps to implement its [PFAS Action Plan](#), which was updated in February 2020.⁶⁹ In March 2020 the Agency published a preliminary determination to begin the process of proposing and promulgating national primary drinking water regulations for two long chain PFAS compounds, perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS).⁷⁰ The Agency also issued [interim guidance](#) on destroying and disposing of certain PFAS materials.⁷¹ EPA’s Integrated Risk Information System (IRIS) program continued work on hazard assessment for five PFAS. The National Academies of Sciences, Engineering, and Medicine (NASEM) held a multi-day workshop to review the Government’s PFAS research programs to make recommendations on coordination and research priorities.⁷²

⁶³Public Workshop; Laminated Products-Formaldehyde Emission Standards for Composite Wood Products, [85 Fed. Reg. 40,642](#) (July 7, 2020).

⁶⁴Implementing Statutory Addition of Certain Per- and Polyfluoroalkyl Substances; Toxic Chemical Release Reporting, [85 Fed. Reg. 37,354](#) (June 22, 2020) (to be codified at 40 C.F.R. pt. 372).

⁶⁵Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule, [85 Fed. Reg. 45,109](#) (July 27, 2020) (to be codified at 40 C.F.R. pt. 721) (direct final rule).

⁶⁶Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule, [80 Fed. Reg. 2,885](#) (Jan. 21, 2015) (to be codified at 40 C.F.R. pt. 721).

⁶⁷See 40 C.F.R. §721.45.

⁶⁸Draft Compliance Guide for Imported Articles Containing Surface Coatings Subject to the Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule; Notice of Availability and Request for Comment, [85 Fed. Reg. 81,466](#) (Dec. 16, 2020).

⁶⁹EPA PFAS Action Plan: Program Update, EPA-100K20002 (Feb. 2020).

⁷⁰Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List, [85 Fed. Reg. 14,098](#) (Mar. 10, 2020).

⁷¹Interim PFAS Destruction and Disposal Guidance; Notice of Availability for Public Comment, [85 Fed. Reg. 83,554](#) (Dec. 22, 2020).

⁷²[Press Release](#), Env’tl. Prot. Agency, Federal Partners Kick Off Workshop on Federal Government Human Health PFAS Research with the National Academies of Sciences, Engineering and Medicine (Oct. 26, 2020).

On the legislative front, the [2021 National Defense Authorization Act](#) contained several PFAS-related provisions prohibiting the Department of Defense (DOD) from procuring certain products containing PFOA or PFOS, directing the White House Office of Science and Technology Policy (OSTP) to coordinate federal research on PFAS, and facilitating the phase-out of PFAS-containing firefighting foam by the Department of Defense.⁷³ State legislatures also continued to enact PFAS-related laws at a frenetic pace in 2020. For instance, several states enacted legislation to restrict or ban altogether the use of PFAS chemicals in various types of products, including: [California](#) (cosmetics and [firefighting foam](#)),⁷⁴ [Maryland](#) (firefighting foam),⁷⁵ [Michigan](#) (firefighting foam),⁷⁶ [New York](#) (food packaging and children’s products),⁷⁷ and [Wisconsin](#) (firefighting foam).⁷⁸

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

EPA issued a direct final rule to add certain per- and polyfluoroalkyl substances (PFAS) to the lists of substances subject to annual Toxic Release Inventory (TRI) reporting.⁷⁹ This action implements 2019 [legislation](#) requiring TRI reporting beginning with the 2020 reporting year for some 600 PFAS, including PFOA, PFOS and their salts; GenX, PFNA, and PFHxS; and the TSCA Inventory-listed PFAS subject to two particular SNURs.⁸⁰ The Agency also issued certain technical corrections to the TRI regulations.⁸¹

VI. BIOTECHNOLOGY AND NANOTECHNOLOGY DEVELOPMENTS

A. *Biotechnology*

There were several significant Federal regulatory actions related to non-pharmaceutical biotechnology in 2020. On April 30, the U.S. Environmental Protection Agency (EPA) approved an experimental use permit under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for releases of the OX5034 genetically engineered *Aedes aegypti* mosquito in the Florida Keys.⁸² The *Aedes aegypti* mosquito is the vector for Dengue Fever and the Zika virus. The OX5034 mosquito has demonstrated efficacy in substantially reducing populations of this disease-causing pest. On May 18, USDA’s Animal Plant Health Inspection Service (APHIS) published a final rule amending the 7 C.F.R. Part 340 regulations governing the interstate movement of certain genetically engineered organisms that are or may present risks as plant pests.⁸³ The final rule largely tracks APHIS’ June 6, 2019 proposed rule and significantly streamlines APHIS’ regulatory approach to certain products of agricultural biotechnology, including a limited subset of genome edited

⁷³H.R. 6395, 116th Cong. (2019-2020).

⁷⁴Assem. B. 2762, (Cal. 2019-2020).

⁷⁵H.B. 619, 2020 Reg. Sess. (Md. 2020).

⁷⁶H.B. 4389, 2020 Reg. Sess. (Mich. 2020).

⁷⁷H.B. A4739, 2020 Reg. Sess. (N.Y. 2020).

⁷⁸S.B. 310, 2019-2020 Reg. Sess. (Wis. 2020).

⁷⁹Implementing Statutory Addition of Certain Per- and Polyfluoroalkyl Substances; Toxic Chemical Release Reporting, [85 Fed. Reg. 37,354](#) (June 22, 2020) (to be codified at 40 C.F.R. pt. 372) (direct final rule).

⁸⁰S. 1790, 116th Cong., first Reg. Sess. (2020).

⁸¹Community Right-to-Know; Corrections to Toxics Release Inventory (TRI) Reporting Requirements, [85 Fed. Reg. 42,311](#) (July 14, 2020) (to be codified at 40 C.F.R. pt. 372) (direct final rule).

⁸²Issuance of an Experimental Use Permit, [85 Fed. Reg. 35,307](#) (June 9, 2020).

⁸³Movement of Certain Genetically Engineered Organisms, [85 Fed. Reg. 29,790](#) (May 18, 2020) (to be codified at 7 C.F.R. pt. 330, 340, 372) (direct final rule).

products. EPA published for public comment a draft guidance for updating insect resistance management (IRM) requirements for genetically engineered plants protected against certain Lepidopteran pests.⁸⁴ The comment period was the first phase of a multi-stakeholder process to update the Lepidopteran IRM requirements applicable to certain genetically engineered crops. EPA published a long-awaited proposed rule to exempt from most requirements of FIFRA certain crop plants genetically engineered with traits from sexually compatible plants.⁸⁵ Both APHIS's May 18 final rule amending 7 C.F.R. Part 340 and EPA's October 9 proposed rule exempting certain genetically engineered plants from requirements of FIFRA are manifestations of U.S. Coordinated Framework agencies implementing the direction of Executive Order 13874 to revise and make more efficient the regulatory requirements applicable to agricultural biotechnology products.⁸⁶ Indeed, EPA, USDA, and FDA launched a unified website to provide regulatory information for agricultural biotechnology products.⁸⁷

On March 8, 2019, the U.S. Food and Drug Administration (FDA) lifted an "import alert" on entry of the AquaAdvantage genetically engineered salmon into the United States.⁸⁸ On November 5, 2020, the U.S. District Court for the Northern District of California ruled that FDA had failed to properly address potential NEPA and Endangered Species Act concerns when it lifted the AquaAdvantage import alert.⁸⁹ Notwithstanding the agency's failure to conduct sufficiently broad analyses of potential environmental and endangered species impacts, the Court did not vacate FDA's approval of the genetically engineered salmon on the basis that "the short-term threat to the environment from engineered salmon" produced at the currently approved production facilities is low.⁹⁰

B. *Nanoscale Materials*

EPA [registered](#) a new nanosilver active ingredient, "NSPW Nanosilver" as a materials preservative.⁹¹ This represents EPA's second registration of an acknowledged nanosilver active ingredient. This is also the second time around for this product. It was originally conditionally registered in 2015 under the name "NSPW-L30SWS"; however, the U.S. Court of Appeals for the Ninth Circuit vacated the registration in 2017.⁹² Petitioners challenged the sufficiency of the "public interest" finding necessary for conditionally registering new active ingredients. The court rejected EPA's determination the registration was in the public interest as an alternative to comparable silver products

⁸⁴EPA Draft Proposal to Improve Lepidopteran Resistance Management; Notice of Availability, [85 Fed. Reg. 55,448](#) (Sept. 8, 2020) (to be codified at 40 C.F.R. pt. 174).

⁸⁵Pesticides; Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived from Newer Technologies, [85 Fed. Reg. 64,308](#) (Oct. 9, 2020) (to be codified at 40 C.F.R. pt. 174).

⁸⁶Executive Order No. 13874, Modernizing the Regulatory Framework for Agricultural Biotechnology Products, [84 Fed. Reg. 27,899](#) (June 14, 2019).

⁸⁷[Press release](#), Env'tl. Prot. Agency, EPA, USDA, and FDA Launch Joint Website to Streamline Information about Agricultural Biotechnology Products (Jan. 9, 2020).

⁸⁸[Press Release](#), U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on Continued Efforts to Advance Safe Biotechnology Innovations, and the Deactivation of an Import Alert on Genetically Engineered Salmon (Apr. 18, 2019).

⁸⁹Inst. for Fisheries Res. v. U.S. Food & Drug Admin., [Case No. 16-cv-01574-VC](#) (N.D. Cal. Nov. 5, 2020).

⁹⁰*Id.* at 15.

⁹¹ENVTL. PROT. AGENCY, EPA-HQ-O-PP-2020-0043, REGISTRATION DECISION FOR A NEW ACTIVE INGREDIENT, NSPW NANOSILVER FINAL DECISION (July 5, 2020).

⁹²Nat'l Res. Def. Council v. U.S. Env'tl. Prot. Agency, No. 15-72308 (9th Cir. May 30, 2017).

that release more silver to the environment. The court held that the mere potential for lower silver release was insufficient and the agency was obligated instead to show by substantial evidence that users would in fact substitute the new, lower emitting product for existing silver products.

VII. CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD (CSB)

The Chemical Safety and Hazard Investigation Board (CSB) issued final rule requiring accidental release reporting by chemical manufacturers.⁹³ Reporting is required for releases to the air of hazardous substances from stationary sources that cause a fatality, serious injury or substantial property damage. [CSB was required to issue reporting rules](#) by a decision of the U.S. District Court for the District of Columbia, to fulfill CSB's long-standing mandate under section 112(r) of the Clean Air Act.⁹⁴

VIII. STATE DEVELOPMENTS OF NOTE

In 2020, California and New York enacted new laws regulating or requiring disclosure of chemicals in consumer products. California, Maine, and Washington—which have existing programs regulating chemicals in consumer products—took additional steps to implement those programs.

California enacted [Assembly Bill 2762](#), which bans the sale and manufacture of cosmetic products containing certain intentionally added ingredients, including PFOA, PFOS, certain other PFAS, formaldehyde, and mercury, beginning in 2025.⁹⁵ Two other new laws require disclosure of fragrance or flavor ingredients in cosmetic products ([Senate Bill 312](#))⁹⁶ and ingredient labels on boxes of menstrual products ([Assembly Bill 1989](#)).⁹⁷

A California court declined to dismiss a lawsuit challenging the listing of spray polyurethane foam (SPF) systems as a Priority Product in the Safer Consumer Products Program,⁹⁸ and the Department of Toxic Substances Control rejected manufacturers' Alternatives Analysis for SPF systems.⁹⁹ Other developments in the Safer Consumer Products Program included the proposed listing of carpets and rugs containing PFAS as a

⁹³Accidental Release Reporting, [85 Fed. Reg. 10,074](#) (Feb. 21, 2020) (to be codified at 40 C.F.R. pt. 1604) (direct final rule).

⁹⁴*Air All. of Houston v. U.S. Chem. Safety and Hazard Investigation Bd.*, 365 F. Supp. 3d 118, 132 (D.D.C. Feb. 4, 2019).

⁹⁵2020 Cal. Legis. Serv., ch. 314 (A.B. 2762) (West) (codified at CAL. HEALTH & SAFETY CODE § 108980).

⁹⁶2020 Cal. Legis. Serv., ch. 315 (S.B. 312) (West) (codified at CAL. HEALTH & SAFETY CODE § 111792.6).

⁹⁷2020 Cal. Legis. Serv., ch. 272 (A.B. 1989) (West) (codified at CAL. HEALTH & SAFETY CODE §§ 111822–111822.8).

⁹⁸*Am. Chem. Council v. Cal. Dep't of Toxic Substances Control (DTSC)*, No. 19CECG02938 (Cal. Super. Ct. Jan. 15, 2020).

⁹⁹[News Release](#), Dep't of Toxic Substances Control, California to Spray Foam Insulation Makers: Look Harder for Safer Alternatives; DTSC Issues Notice of Deficiency; Orders Response in 60 Days (July 1, 2020).

Priority Product¹⁰⁰ and the pre-regulatory identification of nail products containing methyl methacrylate¹⁰¹ and of food packaging containing PFAS as Priority Products.¹⁰²

In Maine, PFOS and its salts were designated as priority chemicals under the state's Safer Chemicals in Children's Products Law, triggering requirements for manufacturer reporting about the presence of PFOS in certain categories of products, including clothing, cosmetics, craft supplies, toys, cookware, and other household goods.¹⁰³

New York Governor Andrew M. Cuomo signed legislation (Chapters [756](#) and [757](#)) creating a comprehensive program to regulate toxic chemicals in children's products.¹⁰⁴ The governor's office indicated that the governor signed the bill pursuant to a chapter agreement that will involve amendments to the law.

The Washington state Department of Ecology identified 11 priority consumer products as part of the Safer Products for Washington program.¹⁰⁵

V. FEDERAL INSECTICIDE FUNGICIDE AND RODENTICIDE ACT (FIFRA)

A. *Endangered Species Act Consultations on Pesticide Registrations*

EPA issued [new guidelines for conducting biological evaluations](#) under the Endangered Species Act (ESA),¹⁰⁶ and, together with its sister agencies, submitted its second annual [report to Congress](#) detailing progress in improving the pesticide impact review process.¹⁰⁷ EPA released draft Biological Evaluations (BEs) for Carbaryl, Methomyl, Atrazine, Propazine, Simazine, and Glyphosate over the course of 2020.¹⁰⁸ The schedule for conducting these BEs was negotiated as part of a partial settlement agreement in [Center for Biological Diversity v. EPA](#) and entered by the court on October 22, 2019.¹⁰⁹ On November 19, 2020, the Center for Biological Diversity filed a petition with the EPA to withdraw two ecological risk assessment guidance documents alleged to be inconsistent

¹⁰⁰[Proposed Priority Product: Carpets and Rugs with Perfluoroalkyl and Polyfluoroalkyl Substances \(PFASs\)](#), D.T.S.C. (last visited Apr. 15, 2021).

¹⁰¹DEP'T OF TOXIC SUBSTANCES COUNCIL, PRODUCT-CHEMICAL PROFILE FOR NAIL PRODUCTS CONTAINING METHYL METHACRYLATE: [DISCUSSION DRAFT](#) (Feb. 2020).

¹⁰²DEP'T OF TOXIC SUBSTANCES COUNCIL, PRODUCT – CHEMICAL PROFILE FOR FOOD PACKAGING CONTAINING PERFLUOROALKYL OR POLYFLUOROALKYL SUBSTANCES: [DISCUSSION DRAFT](#) (July 2020).

¹⁰³ME. CODE R. § 890 (2020).

¹⁰⁴S.B. 501, 2019-2020, Reg. Sess. 2020 (codified at N.Y. ENVTL. CONSERV. LAW § 37-9113); S.B. 5349, 2019-2020, Reg. Sess. (codified at N.Y. ENVTL. CONSERV. LAW § 37-0901).

¹⁰⁵WASH. DEP'T OF ECOL., [20-04-019](#), PRIORITY CONSUMER PRODUCTS REPORT TO THE LEGISLATURE (July 2020).

¹⁰⁶EPA, REVISED METHOD FOR NATIONAL LEVEL LISTED SPECIES BIOLOGICAL EVALUATIONS OF CONVENTIONAL PESTICIDES, [EPA-HQ-OPP-2019-0185-0084](#) (Mar. 12, 2020).

¹⁰⁷E.P.A. et al., Progress Report to Congress on Improving the Consultation Process Required Under Section 7 of the Endangered Species Act for Pesticide Registration and Registration Review (June 2020).

¹⁰⁸Carbaryl and Methomyl Registration Review; Draft Endangered Species Act Biological Evaluations; Notice of Availability, [85 Fed. Reg. 15,168](#) (Mar. 17, 2020); Atrazine, Simazine, and Propazine Registration Review; Draft Endangered Species Act Biological Evaluations; Notice of Availability, [85 Fed. Reg. 71,071](#) (Nov. 6, 2020). *See also* [Protecting Endangered Species from Pesticides](#), E.P.A. (last updated Nov. 24, 2020).

¹⁰⁹Proposed Stipulated Partial Settlement Agreement, Ctr. for Biological Diversity v. Env'tl. Prot. Agency, No 3:11-cv-00293 (N.D. Cal. Oct. 22, 2019).

with the Endangered Species Act.¹¹⁰ The petition was submitted under the authority of EPA's new rules for formally adopting amending and withdrawing Agency guidance documents.¹¹¹ The U.S. District Court for the District of Columbia in *Center for Biological Diversity v. Bernhardt*¹¹² dismissed a citizen suit action brought by an environmental group that alleged the EPA failed to provide public notice of and an opportunity for comment on programmatic guidelines for species-specific species status assessments (SSA's). The district court held the group failed to establish injury-in-fact necessary to informational and associational standing. An appeal was filed on April 13, 2020. EPA proposed to settle litigation challenging several pesticide registrations for failing to consult under the ESA by committing to complete certain BEs and effects findings on agreed schedule. Registrations involved include those for flupyradifurone, bicyclopyrone, benzovindiflupyr, cuprous iodide, and haluaxifen-methyl,¹¹³ and imidacloprid.¹¹⁴

B. Pollinator Protection

The EPA updated pollinator risk assessments and released proposed interim decisions in January 2020 for four neonicotinoid pesticide registrations (Imidacloprid, Clothianidin, Thiamethoxam, and Dinotefuran), and released a proposed interim decision for one other without a notation of an updated risk assessment (Acetamiprid).¹¹⁵ An environmental organization petitioned EPA to revoke all tolerances for residues of the neonicotinoid pesticides acetamiprid, clothianidin, dinotefuran, imidacloprid, and thiamethoxam, alleging that the analyses underlying these tolerances are flawed.¹¹⁶ Still pending before the Ninth Circuit is a 2019 suit brought by environmental organizations against EPA's [challenging the registration of new uses for sulfoxaflor](#) on several crops, including those that attract bees, with amicus briefs having been recently filed.¹¹⁷ Of the course of the year, EPA sponsored a series of webinars addressing pollinator health and habitat protection issues.¹¹⁸

C. Particular Products and Uses

EPA issued an interim registration review decision for glyphosate – the most widely used pesticide in the U.S. - finding again that it poses no human health risks as used.¹¹⁹ This decision drew a petition for review filed in the Ninth Circuit by environmental

¹¹⁰Press Release, Ctr. for Biological Diversity, [EPA Petitioned to Rescind Industry-friendly Guidance Document That Oks Ignoring Pesticides' Harms to Endangered Species](#) (Nov. 19, 2020).

¹¹¹EPA Guidance; Administrative Procedures for Issuance and Public Petitions, [85 Fed. Reg. 66,230](#) (Oct. 19, 2020) (to be codified at 40 C.F.R. pt. 2) (direct final rule).

¹¹²442 F. Supp. 3d 97 (D.D.C. 2020).

¹¹³Proposed Settlement Agreement; Biological Evaluations, [85 Fed. Reg. 81,205](#) (Dec. 15, 2020).

¹¹⁴Proposed Stipulated Partial Settlement Agreement, Endangered Species Act Claims, [85 Fed. Reg. 765,64](#) (Nov. 30, 2020).

¹¹⁵Pesticide Registration Review; Proposed Interim Decisions for Several Neonicotinoid Pesticides; Notice of Availability, [85 Fed. Reg. 5953](#) (Feb. 3, 2020).

¹¹⁶Petition To Revoke All Neonicotinoid Tolerances; Notice of Availability, [85 Fed. Reg. 45,883](#) (July 30, 2020).

¹¹⁷*Pollinator Stewardship Council v. Wheeler*, No. 19-72280 (9th Cir. Sept. 6, 2019).

¹¹⁸[EPA Offers Webinars on Pollinator Health and Habitat](#), E.P.A. (last visited Apr. 15, 2021).

¹¹⁹Pesticide Registration Review; Interim Decision for Glyphosate; Notice of Availability, [85 Fed. Reg. 5957](#) (Feb. 3, 2020).

organizations.¹²⁰ EPA also completed a draft biological evaluation for glyphosate, which tentatively concluded that glyphosate is likely to adversely affect a significant percentage of endangered species and critical habitat.¹²¹

In June, the U.S. Court of Appeals for the Ninth Circuit [vacated](#) EPA's 2018 decision to continue [dicamba registrations](#) for use on dicamba-resistant crops¹²² for a flawed decisional process that failed to consider a number of adverse effects for which there was support in the record.¹²³ However, EPA promptly issued new registrations for the affected products, bolstering its analysis to address the deficiencies identified by the court.¹²⁴ Environmental advocates again [challenged](#) EPA's latest dicamba registration decision in the Ninth Circuit.¹²⁵ However, the registrations were also challenged by cotton and soybean growers as unlawfully restrictive.¹²⁶

EPA issued a draft risk assessment and proposed interim registration review decision for [chlorpyrifos](#), finding no risks of concern for residential uses, but imposing new mitigation measures to address remaining drinking water and occupational risks.¹²⁷

Final interim reregistration decisions were adopted for [atrazine, propazine, and simazine](#),¹²⁸ followed by the publication for public comment of a proposed biological evaluation for the three active ingredients.¹²⁹ The interim decision was promptly [challenged](#) by farmworker advocate organizations in the U.S. Court of Appeals for the Ninth Circuit.¹³⁰

D. *Agricultural Worker Protection Standard*

EPA issued [guidance](#) regarding the annual pesticide safety training requirements under the Agricultural Worker Protection Standard (WPS) that offered flexibility during the COVID-19 pandemic.¹³¹ EPA also finalized revisions to the Application Exclusion Zone (AEZ) provisions of the WPS, including changes that would reduce the size of the exclusion zone in many circumstances, which may be less protective for workers.¹³² The

¹²⁰Nat. Res. Def. Council v. Env'tl. Prot. Agency, [No. 20-70787](#) (9th Cir. Mar. 20, 2020).

¹²¹Glyphosate Registration Review; Draft Endangered Species Act Biological Evaluations; Notice of Availability, [85 Fed. Reg. 76,071](#) (Nov. 27, 2020).

¹²²*Registration Decision for the Continuation of Uses of Dicamba on Dicamba Tolerant Cotton and Soybean*, ENVTL. PROT. AGENCY (Oct. 27, 2020).

¹²³Opinion, Nat'l Family Farm Coal. v. Env'tl. Prot. Agency, No. 19-70115 (9th Cir. June 3, 2020).

¹²⁴[Press Release](#), Env'tl. Prot. Agency, Env'tl. Prot. Agency Announces 2020 Dicamba Registration Decision (Oct. 27, 2020).

¹²⁵Nat'l Family Farm Coal. v. Env'tl. Prot. Agency, No. 20-73750 (9th Cir. Dec. 21, 2020).

¹²⁶Am. Soybean Ass'n v. Env'tl. Prot. Agency, No. 20-CV-03190 (D.D.C. 2020).

¹²⁷Pesticide Registration Review; Proposed Interim Decision for Chlorpyrifos; Notice of Availability, [85 Fed. Reg. 78,849](#) (Dec. 7, 2020).

¹²⁸[Press Release](#), Env'tl. Prot. Agency, EPA Administrator Wheeler Meets with Farmers and Local Officials on Efforts to Provide Regulatory Certainty (Sept. 18, 2020).

¹²⁹Atrazine, Simazine, and Propazine Registration Review; Draft Endangered Species Act Biological Evaluations; Notice of Availability, [85 Fed. Reg. 71,071](#) (Nov. 6, 2020).

¹³⁰Rural Coal. v. Env'tl. Prot. Agency, No 20-73220 (9th Cir. Oct. 30, 2020).

¹³¹Memorandum from Richard Keigwin, Dir., Office of the Pesticide Programs, to Agric. emp'rs, handler emp'rs & trainers of agric. workers & pesticide handlers re: Guidance on Satisfying the Annual Pesticide Safety Training Requirement under the Agric. Worker Prot. Standard during the COVID-19 Emergency (June 18, 2020).

¹³²Pesticides; Agricultural Worker Protection Standard; Revision of the Application Exclusion Zone Requirements, [85 Fed. Reg. 68,760](#) (Oct. 30, 2020) (to be codified at 40

rule was challenged in suits initiated by New York, California, Maryland and Minnesota state attorneys general¹³³ and farm worker advocacy groups.¹³⁴

E. Other Regulatory Developments

The Agency issued a final rule revising crop groupings for certain herbs and spices in manner that will permit registered products to be used on a wide range of commodities.¹³⁵ It issued new [policy permitting voluntary disclosure of inert ingredients](#) in pesticide labels,¹³⁶ and continued efforts to reduce animal testing with new policy on [waiving avian dietary toxicity tests](#),¹³⁷ reducing the number of treatment concentrations needed for [BCF studies in fish](#),¹³⁸ and [waiving toxicity tests using animal skin](#).¹³⁹ Other new guidance included three new methods to improve drinking water impact assessments for conventional pesticides,¹⁴⁰ and an [overall framework](#) for conducting surface water impact assessments;¹⁴¹ and updated aquatic life benchmarks.¹⁴² EPA proposed to modify the list of active ingredients eligible for the minimum risk pesticide exemption by adding chitosan, a naturally occurring substance that is found in the cell walls of crustaceans and the exoskeletons of most insects.¹⁴³ EPA published for public comment a second draft of a guidance document clarifying the claims that differentiate [plant regulator pesticides](#) from

C.F.R. pt. 170); *see also* Press Release, Env'tl. Prot. Agency, [EPA Finalizes Improvements to Pesticide Application Exclusion Zone Requirements](#) (Oct. 29, 2020).

¹³³New York v. Env'tl. Prot. Agency, [Case 1:20-cv-10642](#) (S.D.N.Y. Dec. 16, 2020); New York v. Env'tl. Prot. Agency, [No. 20-4174](#) (2d Cir. Dec. 18, 2020).

¹³⁴Rural & Migrant Ministry v. U.S. Env'tl. Prot. Agency, [1:20-cv-10645](#) (S.D.N.Y. Dec. 16, 2020); Rural & Migrant Ministry v. U.S. Env'tl. Prot. Agency, [No. 20-4203](#) (2d Cir. Dec. 17, 2020).

¹³⁵Tolerance Crop Grouping Program V, [85 Fed. Reg. 70,976](#) (Nov. 6, 2020) (to be codified at 40 C.F.R. pt. 180) (direct final rule).

¹³⁶Memorandum from A. Dunn, Assistant Adm'r, to Ed Messina, Acting Dir., OP, Voluntary Antimicrobial Pesticide Inert Ingredient Disclosure Process (Dec. 10, 2020).

¹³⁷ENVTL. PROT. AGENCY, FINAL GUIDANCE FOR WAIVING SUB-ACUTE AVIAN DIETARY TESTS FOR PESTICIDE REGISTRATION AND SUPPORTING RETROSPECTIVE ANALYSIS (Feb. 2020).

¹³⁸ENVTL. PROT. AGENCY ET AL., FISH BIOCONCENTRATION DATA REQUIREMENT: GUIDANCE FOR SELECTION OF NUMBER OF TREATMENT CONCENTRATIONS (July 15, 2020).

¹³⁹ENVTL. PROT. AGENCY ET AL., GUIDANCE FOR WAIVING ACUTE DERMAL TOXICITY TESTS FOR PESTICIDE TECHNICAL CHEMICALS & SUPPORTING RETROSPECTIVE ANALYSIS (Dec. 31, 2020).

¹⁴⁰[Press Release](#), Env'tl. Prot. Agency, EPA Finalizes Methodologies to Improve Drinking Water Assessments for Conventional Pesticides (Sept. 18, 2020).

¹⁴¹ENVTL. PROT. AGENCY, FRAMEWORK FOR CONDUCTING PESTICIDE DRINKING WATER ASSESSMENTS FOR SURFACE WATER (Sept. 2020).

¹⁴²[Aquatic Life Benchmarks and Ecological Risk Assessments for Registered Pesticides](#), ENVTL. PROT. AGENCY (last updated Mar. 1, 2021).

¹⁴³Pesticides; Proposal To Add Chitosan to the List of Active Ingredients Permitted in Exempted Minimum Risk Pesticide Products, [85 Fed. Reg. 69,307](#) (Nov. 2, 2020) (to be codified at 40 C.F.R. pt. 152).

unregulated fertilizer products,¹⁴⁴ and proposed updates to its 2002 list of [pests of significant health importance](#).¹⁴⁵

F. Response to COVID 19

Pesticide products have played an important role in the response to the novel corona virus (2019-nCoV), and EPA has taken several measures to increase the availability and public awareness of pesticides expected to be effective against the virus. EPA activated its 2016 [emerging viral pathogens guidance](#)¹⁴⁶ for antimicrobial pesticides for the first time in late January 2020.¹⁴⁷ Subject to important limits, the policy permits registrants to distribute antimicrobial products with claims of expected effectiveness against an emerging viral pathogen identified by EPA without efficacy testing against the emerging pathogen and without label changes based on prior efficacy testing against viral pathogens expected to be harder to kill than the emerging pathogen and generic emerging pathogen language on the label. Products permitted to make the limited COVID claims were quickly listed on [List N](#) on EPA's website to help purchasers identify suitable products.¹⁴⁸

EPA expedited label amendment applications to add the emerging pathogen claims and increase the supply of suitable products.¹⁴⁹ EPA added all products already on List G (products against norovirus) and List L (products effective against the Ebola Virus) to List N.¹⁵⁰ To help keep a large supply of disinfectants available, EPA authorized registrants to change sources of commodity inerts without revising their confidential statements of formula (CSFS) or other prior agency approval.¹⁵¹ EPA expanded this approach to active ingredients, [temporarily amending PR Notice 98-10](#) to allow registrants without amending the CSFs to source a limited number of active ingredients from any source to formulate their existing registered, List N products, provided that the substitution did not change the character of the end product.¹⁵² EPA subsequently authorized List N disinfectants with registered sources of active ingredients to quickly add additional registered sources of eh active ingredient and to manufacture the registered product at new establishments without

¹⁴⁴Pesticides; Updated Draft Guidance for Pesticide Registrants on Plant Regulator Products and Claims, Including Plant Biostimulants; Notice of Availability and Request for Comment, [85 Fed. Reg. 76,562](#) (Nov. 30, 2020).

¹⁴⁵Pesticides; Draft Guidance for Pesticide Registrants on the List of Pests of Significant Public Health Importance, [85 Fed. Reg. 70,146](#) (Nov. 4, 2020).

¹⁴⁶ENVTL. PROT. AGENCY, GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING VIRAL PATHOGENS NOT ON EPA-REGISTERED DISINFECTANT LABEL (Aug. 19, 2016).

¹⁴⁷Press Release, Env'tl. Prot. Agency, [Coronavirus Cases Trigger EPA Rapid Response](#) (Jan. 29, 2020).

¹⁴⁸[Press Release](#), Env'tl. Prot. Agency, EPA Releases List of Disinfectants to Use Against COVID-19 (Mar. 5, 2020).

¹⁴⁹See, e.g., [Press Release](#), Env'tl. Prot. Agency, EPA Expediting Emerging Viral Pathogens Claim Submissions (Mar. 9, 2020).

¹⁵⁰See, e.g., [Press Release](#), Env'tl. Prot. Agency, EPA Continues to Add New Surface Disinfectant Products to List N in Effort to Combat COVID-19 (Apr. 2, 2020).

¹⁵¹See, e.g., [Press Release](#), Env'tl. Prot. Agency, EPA Continues Efforts to Help Increase the Availability of Disinfectant Products for Use Against the Novel Coronavirus (Mar. 26, 2020).

¹⁵²See, e.g., [Press Release](#), Env'tl. Prot. Agency, EPA Takes Action to Assure Availability of Disinfectant Products for Use Against the Novel Coronavirus (March 31, 2020); ENVTL. PROT. AGENCY, REVISED TEMPORARY AMENDMENT TO PESTICIDE REGISTRATION (PR) NOTICE 98-10 (MAY 11, 2020).

prior EPA approval.¹⁵³ The Agency subsequently established temporary procedures to streamline registration amendments to add application by electrostatic spray methods.¹⁵⁴ In July, EPA approved the first products with SARS-CoV-2 label claims based on testing against the virus,¹⁵⁵ and in August, it approved an emergency exemption to the state of Texas permitting it to allow an airline to use a new product that [kills SARS-CoV-2 on surfaces for up to seven days](#). This approval is also notable because it represents the first product with approved residual efficacy claims against a public health pest (99.9% reduction over two hours).¹⁵⁶ EPA subsequently issued guidance to assist other companies to demonstrate residual effectiveness against public health pests¹⁵⁷ and associated test protocols.¹⁵⁸

¹⁵³See, e.g., [Press Release](#), Env'tl. Prot. Agency, EPA Continues Efforts to Increase the Availability of Disinfectant Products for Use Against the Novel Coronavirus (Apr. 14, 2020).

¹⁵⁴[Expedited Review for Adding Electrostatic Spray Application Directions for Use to Antimicrobial Product Registrations](#), ENVTL. PROT. AGENCY (2020); [Press Release](#), Env'tl. Prot. Agency, EPA takes action to help Americans disinfect indoor spaces efficiently and effectively (July 7, 2020).

¹⁵⁵[Press Release](#), Env'tl. Prot. Agency, EPA Approves First Surface Disinfectant Products Tested on the SARS-CoV-2 Virus (July 6, 2020).

¹⁵⁶Master Label, Allied BioScience SurfaceWise®2, Unregistered Product for Sale, Distribution, and Use only in the State of Texas under FIFRA §18 Public Health Emergency Exemption Number 20TX05 (Aug. 24, 2020).

¹⁵⁷ENVTL. PROT. AGENCY, INTERIM GUIDANCE - EXPEDITED REVIEW FOR PRODUCTS ADDING RESIDUAL EFFICACY CLAIMS (Oct. 14, 2020).

¹⁵⁸ANTIMICROBIAL TESTING METHODS & PROCEDURES: [INTERIM GUIDANCE - EXPEDITED REVIEW FOR PRODUCTS ADDING RESIDUAL EFFICACY CLAIMS](#) (Oct. 2, 2020); [INTERIM METHOD FOR EVALUATING THE EFFICACY OF ANTIMICROBIAL SURFACE COATINGS](#) (Oct. 2, 2020).