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Toxics Regulation: A Brave New World Catching Many Off Guard

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TSCA Regulation of Articles

Given the passage of time since the Toxic Substances Control Act (TSCA) was enacted in 1976, the public's growing awareness of the potential for exposure from chemicals in "articles," or finished goods, during use, and greater focus on the implications of end-of-life product disposal, the U.S. Environmental Protection Agency's (EPA) regulation of articles under TSCA has shifted significantly. Historically, EPA elected not to regulate articles for the most part. EPA's more recent announcement of its intent to regulate chemicals in articles to a much greater extent has caught many off guard and reflects a significant shift in U.S. chemical regulation policy.¹

¹ See, e.g., TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 86 Fed. Reg. 33,926 (proposed June 28, 2021) (to be codified at 40 C.F.R. 705), <https://www.federalregister.gov/documents/2021/06/28/2021-13180/tsca-section-8a7-reporting-and-recordkeeping-requirements-for-perfluoroalkyl-and-polyfluoroalkyl>.

TSCA requires that EPA protect the public from risks from chemicals determined to pose unreasonable risks, including risks from chemicals in “articles,” generally a finished product or manufactured good. Under TSCA, an “article” is:

[A] manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article ... except that fluids and particles are not considered articles regardless of shape or design.²

There is an exceedingly broad range of products in commerce qualifying as articles. These include simple products like metal fixtures, plastic sheets, or wire, and far more complex products like transformers, automobiles, and electronic devices.

Over the past four decades, EPA has exempted the regulation of chemicals in articles and focused its attention instead on chemical substances and chemical mixtures. This decision may have been based on EPA’s view that articles are unlikely to pose a risk because the possibility of exposure is low since the chemical is embedded in a product and often in a solid matrix of some sort. EPA may have believed that articles are better regulated by other federal laws, including the Consumer Product Safety Act of 1972 and the Occupational Safety and Health Act of 1970. For whatever reason, EPA used its authority to regulate chemicals in articles sparingly before Congress amended TSCA in 2016, and EPA-regulated chemicals in articles under Significant New Use Rules (SNUR) in only a handful of cases.

EPA’s authority under TSCA to regulate articles is explicit in several sections of the law. Under TSCA Section 5(a)(5), EPA is required to regulate new chemicals in articles to the extent EPA makes an affirmative finding that there is a reasonable potential for exposure to a chemical in an article.³ Under Section 6(a), EPA is required to regulate existing chemicals in articles, but only to the extent necessary to address

² 40 C.F.R. § 704.3, <https://www.ecfr.gov/current/title-40/chapter-I/subchapter-R/part-704/subpart-A#704.3>.

³ TSCA § 5(a)(5), 15 U.S.C. § 2604(a)(5), <https://www.govinfo.gov/content/pkg/USCODE-2020-title15/html/USCODE-2020-title15-chap53-subchapI-sec2604.htm>.

identified risk of exposure to the chemical from the article.⁴ Section 6(h) authorizes EPA to regulate certain persistent, bioaccumulative, and toxic (PBT) chemicals in articles to the extent necessary to address identified risk of exposure to the chemical from the article.⁵ Section 8(a)(7), and EPA's proposed rule implementing this provision, authorizes EPA to collect information on per- and polyfluoroalkyl substance (PFAS) chemicals.⁶ EPA has interpreted TSCA as authorizing it to include PFAS in articles that are subject to reporting.

What does this mean as a practical matter? It means many more commercial entities historically not regulated under TSCA now are regulated. Take, for example, the January 2021 final rule regulating PIP (3:1) (and four other PBT chemicals) in articles.⁷ The rule caught many in the sprawling electronics and electronic device

⁴ TSCA § 6(c)(2)(E), 15 U.S.C. § 2605(c)(2)(E), <https://www.govinfo.gov/content/pkg/USCODE-2020-title15/html/USCODE-2020-title15-chap53-subchapI-sec2605.htm>.

⁵ TSCA § 6(h), 15 U.S.C. § 2605(h), <https://www.govinfo.gov/content/pkg/USCODE-2020-title15/html/USCODE-2020-title15-chap53-subchapI-sec2605.htm>.

⁶ TSCA § 8(a)(7), 15 U.S.C. § 2607(a)(7), <https://www.govinfo.gov/content/pkg/USCODE-2020-title15/html/USCODE-2020-title15-chap53-subchapI-sec2607.htm>.

⁷ Phenol, Isopropylated Phosphate (3:1) (PIP 3:1); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h), 86 Fed. Reg. 894 (Jan. 6, 2021), <https://www.federalregister.gov/documents/2021/01/06/2020-28692/phenol-isopropylated-phosphate-31-pip-31-regulation-of-persistent-bioaccumulative-and-toxic>; Decabromodiphenyl Ether (DecaBDE); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h), 86 Fed. Reg. 880 (Jan. 6, 2021), <https://www.federalregister.gov/documents/2021/01/06/2020-28686/decabromodiphenyl-ether-decabde-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under> (for decabromodiphenyl ether (decaBDE)); 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h), 86 Fed. Reg. 866 (Jan. 6, 2021), <https://www.federalregister.gov/documents/2021/01/06/2020-28690/246-tristert-butylphenol-246-ttbp-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under> (for 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP)); Hexachlorobutadiene (HCBd); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h), 86 Fed. Reg. 922 (Jan. 6, 2021), <https://www.federalregister.gov/documents/>

industry by surprise. PIP (3:1)'s uncelebrated profile as a ubiquitous chemical, let alone a PBT chemical specifically regulated under TSCA Section 6(h), may have contributed to the 2019 proposed rule's general lack of recognition as a potential showstopper.

EPA issued a final rule on January 6, 2021, prohibiting the processing and distribution in commerce of PIP (3:1), and the products or articles containing the chemical substance, for all uses, except for a handful of specific exemptions or prohibition phase-ins. The final rule also required manufacturers, processors, and distributors of PIP (3:1) to notify their customers of these restrictions. The rule contained other prohibitions, which were to be effective as of March 8, 2021. The industry essentially lost its collective mind in that just about anything that plugs into a wall contains PIP (3:1).

Advocates eventually persuaded EPA to issue a rare "No Action Assurance."⁸ These administrative expedients advised regulated entities that EPA would not pursue legal action for a specified duration to allow affected parties to comply, in this case until September 5, 2021, for violation of the prohibitions pertinent to the processing and distribution of PIP (3:1) in commerce. EPA has since proposed to extend the compliance date for certain PIP (3:1) containing articles to October 31, 2024, in recognition of the severe supply chain disruptions occasioned by the 2021 final rule.⁹

[2021/01/06/2020-28693/hexachlorobutadiene-hcbd-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under-tsca](https://www.federalregister.gov/documents/2021/01/06/2020-28693/hexachlorobutadiene-hcbd-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under-tsca) (hexachlorobutadiene (HCBDD)); and Pentachlorothiophenol (PCTP); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h), 86 Fed. Reg. 911 (Jan. 6, 2021), <https://www.federalregister.gov/documents/2021/01/06/2020-28689/pentachlorothiophenol-pectp-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under-tsca> (pentachlorothiophenol (PCTP)).

⁸ Memorandum from Lawrence E. Starfield, Acting Assistant Adm'r, U.S. Env't Prot. Agency, to Michal Freedhoff, Acting Assistant Adm'r, Off. of Chem. Safety & Pollution Prevention (Mar. 8, 2021), https://www.epa.gov/sites/default/files/2021-03/documents/oeca_naa_tsca_pip_3-1_rule_3_8_21.pdf.

⁹ 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), <https://www.federalregister.gov/documents/2022/03/08/2022->

EPA issued the PIP (3:1) rule pursuant to TSCA Section 6(h), a provision targeting PBT chemical substances. EPA is also regulating articles under TSCA Section 6(a), a provision authorizing EPA to regulate high-priority existing chemical substances. The Agency expressed its intent to regulate certain articles containing chrysotile asbestos, the very first Section 6(a) risk management rule where EPA has met its legal burden of identifying risk, but only to the extent necessary to ensure the unreasonable risk no longer exists.¹⁰ Similarly, EPA has signaled its intent to regulate Cyclic Aliphatic Bromide Cluster (HBCD) found in articles believed to pose unreasonable risks and, again, only to the extent necessary to ensure the unreasonable risk no longer exists.¹¹ This means importers, processors, and possibly others in the supply chain in the automotive aftermarket will need to address restrictions on asbestos-containing brakes, among other uses of asbestos in articles. Similarly, TSCA regulation will apply to certain commercial activities relating to extruded polystyrene and expanded polystyrene foam insulation in public and commercial buildings, residences, and other structures.

EPA has also greatly expanded its regulation of articles under TSCA Section 5. Prior to TSCA's reform in 2016, EPA had seldom included manufactured or imported articles containing a chemical subject to a SNUR. This situation has changed, and

[04945/regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under-tsca-section-6h-phenol](https://www.federalregister.gov/documents/2022/04/12/2022-07601/asbestos-part-1-chrysotile-asbestos-regulation-of-certain-conditions-of-use-under-section-6a-of-the-toxic-substances-control-act). For more information, *see* EPA Will Extend Compliance Dates for Articles Containing PIP (3:1), BERGESON & CAMPBELL, P.C. (Mar. 7, 2022), <https://www.lawbc.com/regulatory-developments/entry/epa-will-extend-compliance-dates-for-articles-containing-pip-31>.

¹⁰ Asbestos Part 1: Chrysotile Asbestos; Regulation of Certain Conditions of Use Under Section 6(a) of the Toxic Substances Control Act (TSCA), 87 Fed. Reg. 21,706 (proposed Apr. 12, 2022) (to be codified at 40 C.F.R. 751), <https://www.federalregister.gov/documents/2022/04/12/2022-07601/asbestos-part-1-chrysotile-asbestos-regulation-of-certain-conditions-of-use-under-section-6a-of-the-toxic-substances-control-act>.

¹¹ Cyclic Aliphatic Bromide Cluster (HBCD); Revision to the Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability, 87 Fed. Reg. 38,747, 38,752 (June 29, 2022) ("Processing: Incorporation into Articles is one of the conditions of use that drives the HBCD unreasonable risk and will be subject to risk management action."), <https://www.federalregister.gov/documents/2022/06/29/2022-13805/cyclic-aliphatic-bromide-cluster-hbcd-revision-to-the-toxic-substances-control-act-tsca-risk>.

EPA now carefully assesses the exposure potential of a SNUR substance to determine if there is a “reasonable potential for exposure” of the chemical from the article.

EPA is also using its authority under TSCA Section 8, TSCA’s information gathering provision. The fiscal year 2020 (FY2020) National Defense Authorization Act (NDAA) amended TSCA to add Section 8(a)(7), mandating that EPA promulgate a rule “requiring each person who has manufactured a chemical substance that is a [PFAS] in any year since January 1, 2011” to report certain information.¹² EPA’s June 2021 proposed rule would require all manufacturers (including importers) of PFAS in any year since 2011 to report information related to chemical identity, categories of use, volumes manufactured and processed, byproducts, environmental and health effects, worker exposure, and disposal.¹³ EPA states that the proposed rule will help it better understand the sources and quantities of PFAS manufactured in the United States and support its research, monitoring, and regulatory efforts.

EPA proposed that manufacturers report information to the extent that the information is known to or reasonably ascertainable by the manufacturer. The proposed rule states that “known to or reasonably ascertainable by” would be defined to include “all information in a person’s possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.”¹⁴ This would require reporting entities to evaluate their current level of knowledge about their manufactured products (including imports) and to evaluate whether there is additional information that a reasonable person, similarly situated, would be expected to know, possess, or control.

This reporting standard would require submitters to conduct a reasonable inquiry within the full scope of their organization, not just the information known to managerial or supervisory employees. This standard may also entail inquiries outside the organization to fill gaps in the submitter’s knowledge. Such activities may include

¹² National Defense Authorization Act for Fiscal Year 2020, Pub. L. 116-92, 133 Stat. 1198 (2019), <https://www.congress.gov/public-laws/116th-congress>.

¹³ TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 86 Fed. Reg. 33,926 (proposed June 28, 2021) (to be codified at 40 C.F.R. 705), <https://www.federalregister.gov/documents/2021/06/28/2021-13180/tsca-section-8a7-reporting-and-recordkeeping-requirements-for-perfluoroalkyl-and-polyfluoroalkyl>.

¹⁴ *Id.* at 33,928.

phone call or e-mail inquiries to “upstream suppliers or downstream users or employees or other agents of the manufacturer, including persons involved in the research and development, import or production, or marketing of the PFAS.”¹⁵

Examples of types of information that are considered to be in a manufacturer’s possession or control, or that a “reasonable person” similarly situated might be expected to possess, control, or know, include files maintained by the manufacturer, such as marketing studies, sales reports, or customer surveys; information contained in standard references showing use information or concentrations of chemical substances in mixtures, such as a safety data sheet (SDS) or a supplier notification; and information from the Chemical Abstracts Service (CAS) or from Dun & Bradstreet. The proposed rule states that this information may also include knowledge gained through discussions, conferences, and technical publications.

EPA intends to use the reported information to support assessments under TSCA of new and existing chemicals. EPA will also use the information to fulfill additional environmental protection mandates beyond the TSCA program, such as regulatory activities under the Safe Drinking Water Act (SDWA), the Resource Conservation and Recovery Act (RCRA), and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA states that data on PFAS manufacturing sites and disposal methods may support contaminant characterizations conducted to support contaminated site work and solid waste management programs. As widely noted in CERCLA remediation circles, EPA’s enhanced focus on PFAS may well invite the reopening of CERCLA sites now believed fully remediated.

EPA’s stepped-up regulation of chemicals in articles has three broad implications. First, EPA is using its new authority under TSCA frequently and will continue to do so. This will expand the universe of entities subject to TSCA, many of which are unfamiliar with the law and its requirements, and thus EPA’s jurisdiction over them under TSCA. A commercial entity’s lack of familiarity with TSCA and its relevance to thousands of products in commerce is certain to be an enforcement target.

Second, this expansion will further press commercial entities to know exactly what chemicals are included in the products sourced to them and accelerate the demand for transparency in product sourcing. The familiar assertions that article importers and others just “don’t know” what chemicals are included in their finished goods does not

¹⁵ *Id.*

cut it anymore and certainly will not suffice as a defense to an assertion of liability under TSCA.

Third, this expansion will accelerate product deselection and product reformulation initiatives and generate more competitive pressure. This is in part due to the fact that product manufacturers will be disinclined to bear the cost, potential reputational injury, and enforcement scrutiny invited by the regulation of articles under TSCA.

Preparing for Risk Management Rules

On April 12, 2022, EPA proposed risk management standards applicable to chrysotile asbestos, the first such TSCA Section 6(a) rule.¹⁶ EPA proposed to prohibit ongoing uses of chrysotile asbestos, the only known form of asbestos currently imported into the United States. EPA notes that the proposed rule will be “the first-ever risk management rule issued under the new process for evaluating and addressing the safety of existing chemicals under the Toxic Substances Control Act (TSCA) that was enacted in 2016.”¹⁷ EPA proposed to prohibit manufacture (including import), processing, distribution in commerce, and commercial use of chrysotile asbestos for all ongoing uses of chrysotile asbestos. EPA also proposed to target disposal and recordkeeping requirements in line with industry standards, Occupational Safety and Health Administration (OSHA) requirements, and the asbestos National Emission Standards for Hazardous Air Pollutants (NESHAP).

EPA has broad authority under TSCA to manage unreasonable risks associated with the uses of existing chemicals. EPA proposed the rule under TSCA Section 6(a) to prohibit manufacture (including import), processing, distribution in commerce, and

¹⁶ Asbestos Part 1: Chrysotile Asbestos; Regulation of Certain Conditions of Use Under Section 6(a) of the Toxic Substances Control Act (TSCA), 87 Fed. Reg. 21,706 (proposed Apr. 12, 2022) (to be codified at 40 C.F.R. 751),

<https://www.federalregister.gov/documents/2022/04/12/2022-07601/asbestos-part-1-chrysotile-asbestos-regulation-of-certain-conditions-of-use-under-section-6a-of-the>.

¹⁷ Press Release, U.S. Env't. Prot. Agency, EPA Proposes to Ban Ongoing Uses of Asbestos, Taking Historic Step to Protect People from Cancer Risk (Apr. 5, 2022),

<https://www.epa.gov/chemicals-under-tsca/epa-proposes-ban-ongoing-uses-asbestos-taking-historic-step-protect-people>.

commercial use of chrysotile asbestos in bulk or as part of chrysotile asbestos diaphragms used in the chlor-alkali industry and chrysotile asbestos-containing sheet gaskets used in chemical production. EPA proposed that these prohibitions take effect two years after the effective date of the final rule, a timeframe considered by many in industry to be entirely too tight.

Asbestos is, of course, a special chemical in TSCA law and lore, and the proposed risk management rule may not be illustrative of EPA's approach to other risk management rules for this reason. There are a few takeaway thoughts based on a review of this first risk management proposal. First, EPA will use its TSCA Section 6 authority broadly, including regulating articles, as appropriate. Second, entities relying upon targeted chemicals for product formulations must be aware of the risk evaluation process and plan accordingly. Products reliant upon high-priority chemicals will need to justify their continued use if EPA determines a use poses unreasonable risk or persuade EPA to grant a long phaseout period. Third, managing shareholder expectations and reputational issues is challenging during the protracted period of risk evaluation and risk management, as downstream users and the public tend to prejudge the outcome of the risk evaluation process (and not in a good way) and quit the chemical early in the process. Failure to be aware of these initiatives and/or engage in them can be commercially catastrophic.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA): Update on Enforcement of Imported Pesticides and Devices

Importers of pesticides and devices are required to comply with regulations set forth by EPA and the U.S. Customs and Border Protection (CBP). These requirements include providing information set forth in EPA's Notice of Arrival (NOA) form and providing copies of pesticide and device labels and accompanying labeling (e.g., user manuals). In the more recent past, EPA regions across the United States have greatly stepped up their review of import documentation for pesticide products and devices. These reviews resulted in an increase in enforcement actions through issuances of Notices of Detention, Notices of Refusal of Admission (NORA), Stop Sale, Use, or Removal Order (SSURO), and/or penalties.

Part of EPA's interest can be traced to the pandemic. As EPA stated in its Compliance Advisory, "What You Need to Know Regarding Products Making Claims to Kill the Coronavirus Causing COVID-19 (UPDATE)," it was receiving a "steady stream of tips/complaints concerning potentially false or misleading claims, including

efficacy claims, associated with pesticides and devices.”¹⁸ EPA Region 2’s press release in October 2020, for example, noted it had issued twenty-nine Advisory Letters, eight Notices of Warning, and fifty-two NORAs to address pesticide products and devices that were found to be marketed with unsubstantiated claims of efficacy against the coronavirus that causes COVID-19 and other pathogens.¹⁹

EPA’s review of imported pesticides and devices was not limited to products making claims related to the coronavirus, however. EPA reviewed and compared labels submitted through import procedures with those EPA-approved labels on file. EPA considers label language that does not match with EPA-approved labels as “misbranding” violations of FIFRA Section 12(a)(1)(E), so any discrepancies between label versions could give rise to enforcement action.

In 2022, EPA has continued to focus on imported pesticides and devices. Importation of pesticide devices has additional complications. Under FIFRA, a pesticidal “device” is any instrument or contrivance (other than a firearm) that is intended for trapping, destroying, repelling, or mitigating any pest.²⁰ Products that may qualify as pesticidal devices include ultraviolet lights, air treatment units, water filters, and insect traps. These devices do not require registration under FIFRA and have not been an EPA priority until recently. In the absence of robust guidance on device compliance, particularly related to claims, many pesticide device shipments are put “on hold” while EPA regions review the documentation, sometimes with varying decisions as to compliance.

Adding to the complexity of this area, in the past when EPA has detected an issue, there often would be opportunities to remedy any issue to allow the shipment of the product into the United States. That possibility is now less prevalent. In particular, if there are discrepancies between the imported label and an EPA-approved label, or an issue with the NOA, EPA is more likely to issue a NORA.

¹⁸ U.S. Env’t. Prot. Agency, Compliance Advisory: What You Need to Know Regarding Products Making Claims to Kill the *Coronavirus* Causing COVID-19 (UPDATE) (Jan. 2021) at 3, <https://www.epa.gov/sites/default/files/2020-05/documents/coronavirus-compliance-advisory.pdf>.

¹⁹ Press Release, U.S. Env’t. Prot. Agency, EPA Takes Action to Protect Public from Coronavirus Protection Scams (Oct. 15, 2020), <https://www.epa.gov/newsreleases/epa-takes-action-protect-public-coronavirus-protection-scams>.

²⁰ FIFRA § 2(h), 7 U.S.C. § 136(h).

PFAS and Pesticide Containers

In September 2020, EPA became aware that a mosquito control product used in Massachusetts was contaminated with PFAS.²¹ In December 2020, EPA studied the fluorinated high-density polyethylene (HDPE) containers used to store and transport the product, and they determined the fluorination process used may have been the source of the contamination. In March 2021, EPA became aware of a second mosquito product used in Maryland that may have been contaminated with PFAS and released testing data showing that PFAS contamination in the containers was extremely small.²²

EPA sent a letter in March 2022 to manufacturers (including importers), processors, distributors, users, and those that dispose of fluorinated HDPE containers and similar plastics about the potential for PFAS to form and migrate from these items.²³ EPA intended the letter to raise awareness in the commercial sector to help prevent unintended PFAS formation and contamination and to outline the requirements under the PFAS SNURs. EPA notes on its website that these efforts “are in line with EPA’s PFAS Strategic Roadmap, which includes steps to further the science and research to restrict these dangerous chemicals from impacting human health and the environment.”²⁴ Released in October 2021, the PFAS Strategic

²¹ Press Release, U.S. Env’t. Prot. Agency, EPA Takes Action to Investigate PFAS Contamination (Jan. 14, 2021), <https://www.epa.gov/newsreleases/epa-takes-action-investigate-pfas-contamination>.

²² Press Release, U.S. Env’t. Prot. Agency, EPA Releases Testing Data Showing PFAS Contamination from Fluorinated Containers (Mar. 5, 2021), <https://www.epa.gov/newsreleases/epa-releases-testing-data-showing-pfas-contamination-fluorinated-containers>.

²³ Letter from Tala R. Henry, Deputy Dir., Off. of Pollution Prevention & Toxics, U.S. Env’t Prot. Agency, to Manufacturers, Processors, Distributors, Users, & Those that Dispose of Fluorinated Polyolefin Containers (Mar. 24, 2022), https://www.epa.gov/system/files/documents/2022-03/letter-to-fluorinated-hdpe-industry_03-16-22_signed.pdf.

²⁴ U.S. Env’t. Prot. Agency, Per- and Polyfluoroalkyl Substances (PFAS) in Pesticide and Other Packaging (last updated Sept. 14, 2022), <https://www.epa.gov/pesticides/pfas-packaging>.

Roadmap outlines EPA's commitments to action for PFAS from 2021 through 2024.²⁵ Although this Roadmap does not reference PFAS in pesticide containers, the issue continues to be the focus of EPA attention in 2022.

Enforcement Trends

EPA enforcement has ticked up, perhaps making up for perceived lost time under the prior Administration. Administrative penalties are not trivial, and EPA may assert noncompliance going back five years. The current maximum penalty per violation under FIFRA is \$21,805, while the current maximum penalty per violation under TSCA is \$43,600.²⁶ Since reporting requirements arising under legislative provisions are often compiled on a daily, weekly, monthly, annual, or quadrennial basis, penalties rack up quickly. Assessed penalties in the hundreds of thousands or millions of dollars are common. While various EPA administrative "penalty policies" offer opportunities to reduce these penalties by rewarding good-faith efforts to comply, how these policies are applied varies considerably, and needing to retain counsel to argue they *should* apply adds to the bottom line.

Payment of sticker shock-inducing penalties is only one of the pain points. The reputational damage a company may incur is equally painful, more lasting thanks to social media, and far more difficult to remedy. EPA tends to broadcast settlement of enforcement actions in press releases and/or in EPA compilations of enforcement actions issued by EPA regional offices. Print and social media outlets pick up these releases and distribute the news broadly, ensuring that employees, neighbors, shareholders, and competitors are aware of the infractions.

In addition to reputational injury, often overlooked is the probability that EPA and/or state enforcement agencies are likely to scrutinize a company more closely post-enforcement. Its chances of being on the receiving end of an inspection request also

²⁵ U.S. Env't. Prot. Agency, PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024 (Oct. 2021), https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.

²⁶ Civil Monetary Penalty Inflation Adjustment, 87 Fed. Reg. 1676 (Jan. 12, 2022), <https://www.federalregister.gov/documents/2022/01/12/2022-00349/civil-monetary-penalty-inflation-adjustment>.

increase. Opportunities for penalty mitigation diminish under the penalty policies noted above once a company has a record of noncompliance.

There are also significant commercial consequences, and none of them is good. Financing may be more difficult to secure, due diligence will be more complicated if one of the parties to a transaction was party to a high-profile enforcement action, and negotiating supplier agreements could be adversely impacted as some companies just do not want to do business with a perceived “bad actor.” Other companies may be disallowed from doing business with “violators” as a result of company policies. Stock prices could be impacted, shareholders agitated, and, depending upon materiality levels, public reporting could be required, creating a lasting stain on a company’s reputation. Competitors, too, find these casualties a target-rich area for corporate misinformation mischief.

There is some good news. The Biden Administration in May 2022 reinstated the ability to mitigate penalties with Supplemental Environmental Projects, or SEPs.²⁷ In 2017, the prior Administration prohibited SEPs. EPA intends these projects to allow a violator to undertake a project to provide a tangible environmental or public health benefit to the affected community. SEPs can go a long way in assuaging the ill will a high-profile, high-dollar enforcement action can generate. This is because a SEP is uniquely local, and a project that area residents can see and relate to reaps significant benefits with respect to shoring up the reputational damage occasioned by a high-profile enforcement action.

E-Commerce Enforcement Uptick

E-commerce platforms are not immune to enforcement, particularly in the FIFRA space. Noncompliance with FIFRA requirements can result in significant fines to the online retailer as well as the seller. On February 14, 2018, for example, EPA and Amazon entered into a Consent Agreement and Final Order (CAFO) whereby Amazon agreed to pay \$1,215,700 in civil penalties for approximately four thousand alleged violations under FIFRA Section 3 for the distribution of unregistered pesticide

²⁷ Press Release, U.S. Dep’t of Just., Justice Department Launches Comprehensive Environmental Justice Strategy (May 5, 2022), <https://www.justice.gov/opa/pr/justice-department-launches-comprehensive-environmental-justice-strategy>.

products.²⁸ In 2021, Amazon paid a \$2.5 million civil penalty to the state of Washington for violations of sales and distributions of pesticides.²⁹ Since then, Amazon and other online marketers (e.g., eBay) have been subject to additional SSUROs regarding unregistered or misbranded pesticide products and devices sold on their platforms.

As more FIFRA-regulated products are sold through online means, online retailers are looking to minimize their liability while encouraging sellers to become educated on their federal and state labeling, registration, and reporting responsibilities. In the most notable move toward this emergent practice, Amazon notified sellers of its updated requirements to sell pesticides and pesticide devices through its online platform.

In its updated policy and notice, Amazon informed sellers of products that qualify as pesticides or pesticide devices that they will need to complete an online eLearning training and successfully pass a short exam based on that material by June 8, 2019.³⁰ The course covers a wide range of topics, including an overview of EPA regulations and definitions, various labeling requirements for pesticidal products, common exemptions, and guidance for E-commerce sales. Sellers electing not to complete Amazon's eLearning course risk removal of their existing offers and will be barred from creating new offers of pesticides and pesticidal devices.

It is uncertain how, or if, other online retailers will follow suit; registrants and distributors alike, however, can take proactive measures to ensure that their products are sold legally and in a compliant manner.

Environmental Justice

When the Biden Administration took office in 2021, it announced an “all-of-government” commitment to achieving environmental justice. In his January 27, 2021, Executive Order, “Tackling the Climate Crisis at Home and Abroad,” President Biden directed the Attorney General to ensure “comprehensive attention” to environmental

²⁸ In the Matter of Amazon Services LLC, Docket No. FIFRA-10-2018-0202 (Feb. 14, 2018), <https://www.epa.gov/sites/default/files/2018-02/documents/amazonserviesllc-cafo.pdf>.

²⁹ State of Washington v. Amazon.com, Inc., Docket No. 21-2-15448-1 SEA Consent Decree (Nov. 22, 2021), <https://agportal-s3bucket.s3.amazonaws.com/uploadedfiles/Another/News/Amazon-Entered.pdf>.

³⁰ Amazon Seller Central, Pesticides and Pesticide Devices, <https://sellercentral.amazon.com/gp/help/external/202115120>.

justice throughout the DOJ and to develop a “comprehensive environmental justice enforcement strategy.”³¹ DOJ did so and released it on May 5, 2022.³² The eight-page “Comprehensive Environmental Justice Enforcement Strategy” (Strategy) is interesting and a must-read for corporations.³³ It comes at a time when DOJ and the Administration are under heavy fire from civil rights advocates for a perceived failure to deliver on President Biden’s commitment to environmental justice. The DOJ Strategy seeks to change the narrative, if not turn the ship around. It also goes a long way in answering the question of how the government intends to promote environmental justice through enforcement scrutiny. Noted below are a few practical implications of the Strategy.

First, under the Strategy, DOJ and EPA will target for enforcement “overburdened and underserved communities.”³⁴ What this means is DOJ and EPA will make good use of a growing number of mapping tools to identify targets on which to focus its enforcement resources. These tools include EPA’s EJScreen 2.0 and the White House Council on Environmental Quality’s (CEQ) Climate and Economic Justice Screening Tool (CEJST), a new tool CEQ released in February of this year to measure the cumulative effects of pollution on disadvantaged communities.³⁵ Importantly, EPA also recently released an updated “roadmap” identifying all the legal tools it intends to

³¹ Exec. Order No. 14,008, Tackling the Climate Crisis at Home and Abroad, 86 Fed. Reg. 7619 (Jan. 27, 2021), <https://www.federalregister.gov/documents/2021/02/01/2021-02177/tackling-the-climate-crisis-at-home-and-abroad>.

³² *See supra* note 27.

³³ Memorandum from the Assoc. Att’y Gen., U.S. Dep’t of Just., to Heads of Dep’t Components, U.S. Att’ys (May 5, 2022), <https://www.justice.gov/asg/page/file/1499286/download>.

³⁴ *See supra* note 27.

³⁵ Press Release, White House, CEQ Publishes Draft Climate and Economic Justice Screening Tool, Key Component in the Implementation of President Biden’s Justice40 Initiative (Feb. 18, 2022), <https://www.whitehouse.gov/ceq/news-updates/2022/02/18/ceq-publishes-draft-climate-and-economic-justice-screening-tool-key-component-in-the-implementation-of-president-bidens-justice40-initiative/>.

use to promote environmental justice.³⁶ The document updates a 120-page document the Obama Administration issued in 2011.

Second, DOJ intends to creatively and expansively use its authority under other enforcement tools “outside of the traditional environmental statutes.”³⁷ Specifically, DOJ notes actions “under the civil rights laws, worker safety and consumer protection statutes, and the False Claims Act (FCA).”³⁸ The FCA is interesting because it provides for treble (triple) damages that, according to DOJ, “may provide significantly greater deterrence than penalties under the environmental statutes alone.”³⁹ The FCA allows the government to use civil investigative tools to investigate potential violations of material public health-related grant or contract conditions pertaining to impacted communities. This would allow DOJ to take on some of the investigative burden that otherwise would fall exclusively on the administrative agencies.

Third, the DOJ Strategy will promote accountability and transparency in terms of how exactly the government is measuring up to achieving the Administration’s goals. Release of the Strategy set off a relentless push to deliver on a promise, and the best way to show progress is to do so quantitatively—by the numbers. Enforcement will intensify.

Finally, heightened outreach by the government to engage communities, particularly those underserved traditionally, will jump-start enhanced community awareness and thus increased activism. This activism could well energize a new wave of environmental/community/worker awareness of chemical releases and real or perceived environmental and human health harm.

State Product Regulatory Initiatives

Preemption was one of the most debated aspects of TSCA reform, and the Lautenberg Act significantly changed when states cannot establish new laws or continue to enforce existing laws. Specifically, while states’ actions taken before April

³⁶ U.S. Env’t Prot. Agency, EPA Legal Tools to Advance Environmental Justice (May 2022), <https://www.epa.gov/system/files/documents/2022-05/EJ%20Legal%20Tools%20May%202022%20FINAL.pdf>.

³⁷ *See supra* note 33.

³⁸ *Id.*

³⁹ *Id.*

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22, 2016, or any action taken pursuant to a state law that was in effect on August 31, 2003, are grandfathered and remain in effect regardless of any EPA action, states are prohibited from establishing or continuing to enforce statutes, administrative actions, or, in some cases, criminal penalties that would:

- Require information already required under a TSCA Section 4, 5, or 6 rule, consent agreement, or order;
- Prohibit or restrict a chemical after EPA has made a Section 6(i)(1) determination or issued a final Section 6(a) rule; or
- Subject a chemical to the same notification of use already established in a Section 5 SNUR.

Although the goal of the preemption revision was to avoid a patchwork of state regulations targeting different chemicals, the reality is that since the Lautenberg Act was enacted, a number of states have enacted or are considering chemical-specific legislation. According to Safer States, at the time of publication of this article, “32 states are considering 271 policies to protect people from toxic chemicals,” and “289 state policies have been adopted in 38 states.”⁴⁰ While a number of these initiatives concern monitoring and reporting PFAS in water, a variety of states have enacted legislation since 2016 that prohibits the use of specific chemicals in consumer products:

- Bisphenol A (BPA)-containing paper may not be manufactured, distributed, or sold in Illinois, including paper distributed and used for business and banking records;⁴¹

⁴⁰ SAFER STATES, States Are Leading the Way to Safer Chemicals, <https://saferstates.org/> (last visited Sept. 26, 2022).

⁴¹ H.B. 2076 (enacted in 2019 and codified at 415 III. COMP. STAT. § 5/22.61, <https://www.ilga.gov/legislation/ilcs/ilcs4.asp?DocName=041500050HTit%2E+V&ActID=1585&ChapterID=36&SeqStart=30350000&SeqEnd=40000000>).

- Flame retardants have been banned in California,⁴² Maine,⁴³ Maryland,⁴⁴ Minnesota,⁴⁵ Nevada,⁴⁶ New Hampshire,⁴⁷ New York,⁴⁸ and Rhode Island;⁴⁹ and

⁴² A.B. 2998 (enacted in 2018 and codified at CAL. BUS & PROF. CODE §§ 19100-19104, https://leginfo.ca.gov/faces/codes_displayText.xhtml?lawCode=BPC&division=8.&title=&part=&chapter=3.&article=5.5) (bans flame retardants in juvenile products, upholstered furniture, and mattresses).

⁴³ LD 182 (enacted in 2017 and codified at ME. REV. STAT. ANN. tit. 38, § 1609-A, <https://legislature.maine.gov/statutes/38/title38sec1609-A.html>) (banning the sale of residential upholstered furniture containing chemical flame retardants). In 2021, Maine enacted LD 1662, amending the statute to include electronic components and retailer indemnification. (Codified at ME. REV. STAT. ANN. tit. 38, §§ 1609-A.3(D), 1609-A.3-A, <https://legislature.maine.gov/statutes/38/title38sec1609-A.html>).

⁴⁴ S.B. 0447 (enacted in 2020 and codified at MD. CODE ANN., HEALTH-GEN. § 24-306, <https://mgaleg.maryland.gov/mgawebsite/Laws/StatuteText?article=ghg§ion=24-306&enactments=false>) (prohibiting the sale of any juvenile product, mattress, upholstered furniture, or reupholstered furniture that contains more than 0.1 percent of a flame-retardant chemical by mass).

⁴⁵ H.F. 359 (enacted in 2019 and codified at MINN. STAT. § 325F.071, <https://www.revisor.mn.gov/statutes/cite/325F.071>) (prohibiting the use of certain flame-retardant chemicals in children's products, upholstered residential furniture, residential textiles, and mattresses).

⁴⁶ A.B. 97 (enacted in 2021 and codified at NEV. REV. STAT. 597.7131 - 597.7141, <https://www.leg.state.nv.us/nrs/nrs-597.html>) (prohibiting flame retardants in the manufacture, sale, and distribution of children's products, mattresses, residential textiles, and upholstered residential furniture).

⁴⁷ S.B. 193 (enacted in 2019 and codified at N.H. REV. STAT. §§ 359-Q:1 - 359-Q:7, <https://www.gencourt.state.nh.us/rsa/html/NHTOC/NHTOC-XXXI-359-Q.htm>) (prohibiting the sale of certain furniture and carpeting with flame retardant chemicals).

⁴⁸ S.B. 4630 (enacted in 2021 and codified at N.Y. ENV. LAW §§ 37-1001 - 37-1013, <https://www.nysenate.gov/legislation/laws/ENV/A37T10>) (prohibiting the use of hazardous

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- PFAS have been banned in California,⁵⁰ Colorado,⁵¹ Maryland,⁵² and Vermont.⁵³

In 2019, New York enacted A. 6296, requiring manufacturers of children's products containing dangerous chemicals to notify the state and retailers and banning the sale of children's products containing dangerous chemicals.⁵⁴ As of January 1, 2023, the distribution and sale of children's products containing tris(1,3-dichloro-2-propyl)phosphate, benzene, or asbestos is prohibited. The bill designates the following

chemicals contained in flame retardants to be used in upholstered furniture, mattresses, and electronic enclosures).

⁴⁹ H. 5082 (enacted in 2017 and codified at R.I. GEN. LAWS §§ 23-26-1 - 23-26-31, <http://webserver.rilegislature.gov//Statutes/TITLE23/23-26/INDEX.htm>) (prohibiting the manufacture and sale of residential upholstered bedding and furniture containing toxic flame retardants).

⁵⁰ A.B. 652 (enacted in 2021 and codified at CAL. HEALTH & SAFETY CODE §§ 108945 - 108947, https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=104.&title=&part=3.&chapter=12.5.&article=) (banning the entire class of PFAS from a wide array of juvenile products, including booster seats, changing pads, crib mattresses, infant carriers, and nursing pillows, and requiring manufacturers to use the least toxic alternative when replacing PFAS chemicals in juvenile products).

⁵¹ H.B. 22-1345 (enacted in 2022, <https://leg.colorado.gov/bills/hb22-1345>) (restricting the sale and distribution of consumer products containing intentionally added PFAS chemicals; consumer products including carpets or rugs, cosmetics, fabric treatments, food packaging, juvenile products, oil and gas products, textile furnishings, and upholstered furniture).

⁵² H.B. 0275 (enacted in 2022, <https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/HB0275>) (prohibiting a person from manufacturing, selling, or distributing a certain rug or carpet).

⁵³ S. 20 (enacted in and codified at VT. STAT. ANN. tit. 18, §§ 1661 - 1671, <https://legislature.vermont.gov/statutes/chapter/18/033>) (prohibits the manufacture, sale, and distribution of a residential rug or carpet, aftermarket stain or water resistant treatment for rugs or carpets, and ski wax to which PFAS have been intentionally added in any amount).

⁵⁴ Codified at N.Y. ENV. LAW §§ 37-0901 - 37-0917, <https://www.nysenate.gov/legislation/laws/ENV/A37T9>.

as high-priority chemicals: tris(1,3-dichloro-2-propyl)phosphate; benzene; mercury and mercury compounds, including methyl mercury; asbestos; arsenic and arsenic compounds, including arsenic trioxide and dimethyl arsenic; cadmium (other than toy coatings); and organohalogen flame retardants in upholstered bedding or furniture. The bill provides New York State Department of Environmental Conservation (NYSDEC) the authority to prohibit children's products containing high-priority chemicals. The bill requires NYSDEC to promulgate a list of chemicals of concern within two years and directs NYSDEC to consider a number of specific chemicals.

In 2019, Washington enacted S.B. 5135, which directs the Washington Department of Ecology (WDOE) to identify and take regulatory action on consumer products that are a significant source of chemicals that are a concern for sensitive populations and species.⁵⁵ The bill prioritizes the following chemicals for initial consideration: PFAS; phthalates; flame retardants, including organohalogen flame retardants; phenolic compounds (alkylphenol ethoxylates and bisphenols), and polychlorinated biphenyls (PCB).

Perhaps the best example of where the aspirations of the Lautenberg Act fall to the realities of federal rulemaking is trichloroethylene (TCE). Although EPA included TCE in its first batch of chemicals for review under the Lautenberg Act, it has yet to propose or adopt a final risk management rule. In 2020, New York enacted legislation prohibiting the use of TCE as a vapor degreaser, an intermediate chemical to produce other chemicals, a refrigerant, or an extraction solvent or in any other manufacturing cleaning process beginning December 1, 2021.⁵⁶

⁵⁵ Codified at WASH. REV. CODE §§ 70A.350.010 - 70A.350.900, <https://app.leg.wa.gov/RCW/default.aspx?cite=70A.350>.

⁵⁶ A. 8829/S. 6829 (codified at N.Y. ENV. LAW § 37-0119, <https://www.nysenate.gov/legislation/laws/ENV/37-0119>).

Conclusion

The chemical regulatory space is rapidly evolving, and many new commercial entities may be subject to TSCA regulation because of EPA's shift in the regulation of chemicals in articles. Enforcement efforts have stepped up, and penalties are high. Chemical product regulation in general has entered a new era of relevance, and legal counsel and other commercial advisors need to remain informed and prepared to advise their clients as appropriate.

Lynn L. Bergeson, Managing Partner of Bergeson & Campbell, P.C., has earned an international reputation for her deep and expansive understanding of the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), European Union Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), and especially how these regulatory programs pertain to nanotechnology, industrial biotechnology, synthetic biology, and other emerging transformative technologies. Her knowledge of and involvement in the policy process allows her to develop client-focused strategies whether advocating before Congress, the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), or other governance and standard-setting bodies. Lynn presented [Toxics Regulations](#) at PLI's [Environmental Regulation in Practice 2022: New Challenges and Priorities](#) program, available from PLI Programs On Demand.
