REGULATION OF PRODUCTS WITH PFAS

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SUMMARY

From cookware to dental floss to stain-resistant fabrics, PFAS, or per- and polyfluoroalkyl substances, pervade modern life. PFAS are a family of thousands of synthetic chemicals that have a variety of unique qualities that make them useful in industrial and consumer product applications. Unfortunately, there is a growing scientific recognition that many PFAS come with a cost to public health and the environment. While federal and state action is just beginning for PFAS and the regulatory landscape is changing quickly, the toxicity of many PFAS has been well-established. This Article, adapted from Chapter 3 of the *PFAS Deskbook* (ELI Press 2023), examines the statutory and regulatory frameworks relevant to product manufacturers, including TSCA, FIFRA, state regulations, and marketing claim regulations to consumer products. In addition, it discusses many aqueous film-forming foam-specific regulations in place throughout the country. The authors also examine the growing consumer products litigation landscape relevant to PFAS.

Each day, you encounter countless artificial chemicals and materials. The medicine you take, the keyboard you use to type, the bottle holding your water, or the cosmetics on your face—each product contains a complicated array of chemical components designed and selected to improve the way the product functions. The chemical and material sciences have created an incredible variety of products over the course of the past century that have enhanced our comfort, efficiency, and productivity.

When chemical companies invented per- and polyfluoroalkyl substances (PFAS) in the 1940s, chemical manufacturers lauded the unique carbon-fluorine structure as an exciting and profitable chemical breakthrough. This structure granted PFAS anomalous properties such as simultaneous oil and water repellency, stain resistance, temperature resistance, chemical stability, and friction reduction that made them extremely attractive for a wide variety of industrial, commercial, and consumer product applications. Like many chemicals before them, PFAS stood to provide useful properties in any number of productive applications.

However, the dangers that many PFAS chemicals posed to human and environmental health were not yet known. Their intrinsic structural strength prevents them from breaking down naturally in the environment or biotic systems, resulting in the nickname "forever chemicals." We have now developed a more sophisticated understanding of the risks and harms that at least some PFAS can pose to human health and the environment. Researchers have linked certain PFAS with reduced fertility, pregnancy risk, development effects or delays in children, increased cancer risk, immune deficiency, hormonal imbalances, increased obesity risk, and increased cholesterol levels.[1]

Scientific research and public awareness regarding the toxicity of certain PFAS did not intensify until somewhat recently. As a result, the investigation and regulation of PFAS has only become a priority for federal and state policymakers within the past decade. Various sources of PFAS contamination have triggered more than 6,400 lawsuits since 2005, including at least 1,235 filed in 2021 alone.[2] Those lawsuits have revealed significant information about the development of many PFAS, as well as early conclusions that chemical manufacturers made regarding their health and environmental effects. Despite those revelations, there is still much to be discovered about the effects of PFAS.

The unique properties of PFAS have made it a common chemical in a variety of consumer products. Its grease-repellent properties make it ideal for nonstick cookware and bakeware as well as food packaging. Its water repellency makes it useful for outdoor gear such as rain jackets, tent flies, and water-resistant hiking boots. Its heat absorption makes it useful in batteries and other electronics. Its

1. U.S. Environmental Protection Agency (EPA), *Our Current Understanding of the Human Health and Environmental Risks of PFAS*, https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas (last updated Mar. 16, 2022).
2. Andrew Wallender, *Companies Face Billions in Damages as PFAS Lawsuits Flood Courts*, Bloomberg L. (May 23, 2022), https://news.bloomberglaw.com/pfas-project/companies-face-billions-in-damages-as-pfas-lawsuits-flood-courts. The count includes cases that ended up in the aqueous film-forming foam (AFFF) multidistrict litigation.

high permeability makes it useful for breathable fabrics. Its non-reactivity makes it a useful lubricant for watches and a useful component of long-lasting cosmetics and makeup. Finally, its low surface tension helps to create aqueous film-forming foam (AFFF) for firefighting applications.

In this Article, we cover the statutory and regulatory frameworks relevant to product manufacturers as related to their products (rather than their facilities). Specifically, we highlight the application of the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), state regulations, and marketing claim regulations to consumer products. The one exception is that the Article covers the regulation of AFFF. As one of the most well-documented sources of PFAS contamination, there are many AFFF-specific regulations in place throughout the country that require their own thorough discussion. We also cover the growing consumer products litigation landscape.

There are a variety of federal and state regulations that apply to product manufacturers, retailers, and importers. Some regulations based on the Emergency Planning and Community Right-to-Know Act (EPCRA), the Clean Water Act (CWA), the Resource Conservation and Recovery Act (RCRA), Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and state cleanup laws may also apply to product manufacturers, particularly at the facilities where they produce those products. However, we focus this Article on the regulation of products themselves once they have left manufacturing facilities and entered the market.

I. TSCA

The U.S. Congress adopted TSCA to address the proliferation of chemical substances in the United States.[3] TSCA, as amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act,[4] provides a number of mechanisms that regulate the manufacture, use, and import of chemicals, as well as the products that contain those chemicals. The TSCA Chemical Substance Inventory (TSCA Inventory) lists the chemicals subject to regulation as existing chemicals, and the law provides a pathway for the regulation of new chemicals.

Of particular interest to consumer product manufacturers, TSCA mandates manufacturing and processing notices for new chemicals as well as any "significant new use" of existing chemicals.[5] TSCA also establishes reporting and document retention requirements for the manufacturing and import of chemicals.[6] TSCA represents the clearest set of federal requirements for manufacturers of products containing PFAS. The U.S. Environmental Protection Agency (EPA) is in the process of implementing TSCA regulations. And those regulations may lead to preemption of state reporting requirements.

A. Premanufacture Notice for New Chemicals

A manufacturer that intends to manufacture (including import) a new chemical substance must submit a premanufacture notice (PMN) at least 90 days prior to the manufacture, import, or processing of the chemical.[7] That notice provides EPA with the opportunity to regulate the use of that new chemical. Although these requirements may appear limited in their application to chemical manufacturers, the definition of "manufacture" includes "import."[8] As a result, the PMN provisions also apply to any imported products that contain unlisted chemicals. That broader application can impact any product manufacturer or importer that uses any of the thousands of PFAS not currently on the TSCA Inventory.

EPA has already enforced the PMN provisions against product manufacturers and importers in the PFAS context. Specifically, EPA has publicized its enforcement against ski wax manufacturers. The hydrophobic qualities of PFAS make it a useful chemical in ski waxes to increase glide over the snow. As a result, many manufacturers of ski wax have utilized PFAS, resulting in well-documented contamination in ski areas.[9] Growing criticism of the impact of these waxes has led to competitive bans. U.S. Ski & Snowboard and the Canadian Ski Association have joined the International Ski Federation and International Biathlon Union in phasing out the use of fluorinated ski wax in competition.[10]

In January 2022, EPA issued an enforcement alert regarding the application of TSCA to ski waxes containing unlisted PFAS.[11] On May 13, 2020, Swix Sport USA settled 83 alleged TSCA violations for importing ski wax containing six different unlisted PFAS chemicals.[12] Swix committed to spending $1 million on outreach and training for programs aimed to promote the use of non-PFAS wax alternatives and paid a $375,625 civil penalty.[13] Swix further committed to quarantine and export the offending products to its parent company in Norway.[14] On August 24, 2021, TASR Inc. settled at least four self-disclosed TSCA violations for the import of ski wax including at

3. U.S. Environmental Protection Agency (EPA), *Summary of the Toxic Substances Control Act*, https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act (last updated Oct. 4, 2022).
4. Pub. L. No. 114-182, 130 Stat. 448 (2016).
5. 15 U.S.C. §§2603, 2604, 2605, 2607.
6. *Id.*
7. 15 U.S.C. §2604; 40 C.F.R. §§720.45, 720.50.
8. 15 U.S.C. §2602(9).
9. Gail L. Carlson & Skylar Tupper, *Ski Wax Use Contributes to Environmental Contamination by Per- and Polyfluoroalkyl Substances*, 261 Chemosphere 128078 (2020).
10. Pamela Manson, *Program Aims to Remove Ski Wax That Could Contaminate Water*, Park Rec. (Dec. 9, 2022), https://www.parkrecord.com/news/program-aims-to-remove-ski-wax-that-could-contaminate-water/.
11. U.S. EPA, Enforcement Alert: Violations May Put Ski Wax Users at Risk From Illegal Perfluoroalkyl Substances (2022) (EPA Doc. No. 305S21001) [hereinafter EPA, Ski Wax Enforcement Alert], https://www.epa.gov/system/files/documents/2022-01/pfasskiwax.pdf.
12. *See id.* at 3.
13. *See id.*
14. Final Order, In re Swix Sport USA, No. TSCA-HQ-2020-5005 (EAB May 13, 2020), https://yosemite.epa.gov/oa/EAB_Web_Docket.nsf/RecentAdditionsv2/61788F0B22745FDE8525856700681EA1/$File/Swix%20Sport%20Final%20Order%20Consent%20Agreement%20and%20CoS%20with%20MKL%20Signature.pdf.

least four separate non-listed PFAS.[15] TASR paid a civil penalty of $12,445, quarantined the offending products, and committed to export them to the product manufacturer in Germany.[16]

The EPA enforcement alert reveals several lessons for consumer product manufacturers. It shows the potential enforcement risk should a manufacturer import products containing unlisted PFAS. Each imported product constitutes its own independent violation of TSCA. As a result, TSCA violations can quickly add up. It also shows the potential benefit of independent testing and disclosure. Should product manufacturers or importers discover unlisted PFAS in their product stock, they may want to utilize EPA's audit and disclosure provisions to limit potential penalties for manufacturing or importing unlisted chemicals.

B. *Significant New Use Rule for Existing Chemicals*

In addition to the PMN process described above for new chemicals, TSCA includes provisions that create additional notification requirements for the manufacture, processing, or importation of chemicals already listed in the TSCA Inventory. These chemical-specific rules require a manufacturer, importer, or processor of that chemical to report to EPA before engaging in a "significant new use" of that chemical.[17]

EPA has already adopted several PFAS-related significant new use rules (SNURs) with implications on product manufacturers and importers. On March 11, 2002, EPA published a SNUR that would require notification before the manufacture or import of 13 PFAS chemicals included in a voluntary phaseout of perfluorooctanesulfonic acid (PFOS) by 3M between 2000 and 2002.[18] That SNUR allowed for limited uses of those chemicals that required a low volume of use and for which no alternatives were available.[19] On December 9, 2002, EPA expanded that SNUR to cover 75 PFAS chemicals.[20] On October 9, 2007, EPA issued a SNUR on 183 PFAS chemicals believed to no longer be manufactured, imported, or used in the United States.[21] On October 22, 2013, EPA issued a SNUR that required companies to report new uses of perfluorooctanoic acid (PFOA)-related chemicals in carpets or carpet treatments.[22]

In July 2020, EPA issued its most expansive PFAS-related SNUR to date. The SNUR covers two categories of PFAS: long-chain perfluoroalkyl carboxylate (LCPFAC) and perfluoroalkyl sulfonate chemical substances.[23] The full list of chemicals included is provided in the rule itself. The SNUR identifies several activities that would constitute significant new use requiring notice, including (1) the manufacturing, importing, or processing of a subset of LCPFAC chemical substances for any use that was not an ongoing use as of December 31, 2015; (2) the manufacturing, importing, or processing of all other LCPFAC chemical substances for which there were no ongoing uses as of January 21, 2015; (3) the importing of a subset of LCPFAC chemicals as part of a surface coating on articles; and (4) the importing of perfluoroalkyl sulfonate chemical substances as part of carpets.[24]

The long-chain SNUR's coverage of surface coatings on articles[25] became the subject of significant controversy. EPA's Office of Inspector General (OIG) investigated several changes to the SNUR's application to articles.[26] Then-EPA Administrator Andrew Wheeler signed the final SNUR on June 27, 2020. Between that signing and the final SNUR publication in the *Federal Register* in July 2020, EPA removed language that defined what would constitute a surface coating for imported articles, and replaced it with language previewing a future EPA compliance guide.[27] On January 19, 2021—the day before President Joseph R. Biden's inauguration—EPA issued a compliance guide for imported articles containing surface coatings subject to the July 2020 SNUR.[28] That compliance guide narrowed the scope of the SNUR to include only coatings on the surface of the article that come into direct contact with people or the environment.[29] EPA withdrew that compliance guide in June 2021 as an impermissible narrowing of the scope of the SNUR.[30] EPA has since emphasized that the defining feature of a surface coating is the application of a chemical to a surface, whether interior or exterior, cured, or through

15. EPA, Ski Wax Enforcement Alert, *supra* note 11, at 4.
16. Final Order, In re TASR, Inc., No. TSCA-HQ-2021-5001 (EAB Aug. 24, 2021), https://yosemite.epa.gov/oa/EAB_Web_Docket.nsf/Unpublished~Final~Orders/68751FAD173E1D418525873B007837E2/$File/TASR%20Inc.%20Combined%20CAFO%20(002).pdf.
17. 15 U.S.C. §2604(a)(2).
18. Perfluoroalkyl Sulfonates; Significant New Use Rule, 67 Fed. Reg. 11008 (Mar. 11, 2002).
19. *Id.*
20. Perfluoroalkyl Sulfonates; Significant New Use Rule, 67 Fed. Reg. 72854 (Dec. 9, 2002).
21. Perfluoroalkyl Sulfonates; Significant New Use Rule, 72 Fed. Reg. 57222 (Oct. 9, 2007).
22. Perfluoroalkyl Sulfonates and Long-chain Perfluoroalkyl Carboxylate Chemical Substances; Final Significant New Use Rule, 78 Fed. Reg. 62443 (Oct. 22, 2013).
23. Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule, 85 Fed. Reg. 45109, 45109 (July 27, 2020); 40 C.F.R. §§721.10536, 721.9582.
24. 40 C.F.R. §§721.10536, 721.9582.
25. *Id.* §704.3 (defining an article).
26. OIG, U.S. EPA, The EPA Was Not Transparent About Changes Made to a Long-Chain PFAS Rule After Administrator Signature (2022) (Report No. 22-E-0052) [hereinafter EPA OIG Report], https://www.epa.gov/system/files/documents/2022-07/_epaoig_20220707-22-E-0052.pdf.
27. *Id.* at 2.
28. U.S. EPA, Compliance Guide for Imported Articles Containing Surface Coatings Subject to the Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances Significant New Use Rule (2021) (Doc. ID No. RIN 2070-ZA23), https://www.epa.gov/sites/default/files/2021-01/documents/final_lcpfac-snur_surface-coating-compliance-guide_0.pdf.
29. *Id.* at 8.
30. U.S. EPA, *Risk Management for Per- and Polyfluoroalkyl Substances (PFAS) Under TSCA*, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas (last updated Jan. 26, 2023).

chemical reaction.[31] EPA OIG concluded that EPA's 2021 compliance guide did not follow proper procedures to alter the SNUR's coverage of surface coatings.[32]

Setting that controversy aside, EPA's long-chain SNUR has already spurred questions over compliance issues. EPA issued an open letter on March 24, 2022, to manufacturers, processors, distributors, users, and disposers of fluorinated high-density polyethylene (HDPE) containers.[33] These containers are created by bombarding the plastic with fluorine to create a high-performance barrier that protects against weathering and degradation of the plastic. Testing has revealed that the fluorination process may result in the creation of detectable incidental PFAS. EPA specifically found PFAS in containers of pesticide.[34] EPA emphasized in its open letter that the creation of such incidental PFAS in the manufacturing process, or on containers to be imported, would constitute a significant new use of those PFAS that would trigger a significant new use notice (SNUN) requirement under the long-chain SNUR.[35]

The list of PFAS on the TSCA Inventory will certainly grow over the coming years. And as it does, product manufacturers and importers must keep apprised of the need to submit a SNUN should their products contain listed PFAS subject to a SNUR[36]

C. Certification for Import and Export

Any entity that imports or exports a chemical substance is responsible for complying with TSCA certification and reporting requirements. Importers of chemical substances subject to TSCA must certify upon import that all substances in their shipment comply with all applicable rules and orders under TSCA.[37]

A certification of compliance includes certification with PMN requirements under TSCA. As a result, failure to submit a PMN for the import of a product that includes PFAS not on the TSCA Inventory can constitute a violation of the §12 certification process. In fact, the above-described ski wax violations included not only violations for failure to submit a PMN, but also violations for improper certification of compliance upon import.[38]

Further, certification includes compliance with any existing SNUR. As mentioned above, EPA has adopted several PFAS-related SNURS, including the LCPFAC and perfluoroalkyl sulfonate chemical substances SNUR.[39] As a result, any importer, processor, or distributor in commerce of these chemical substances, mixtures, or articles that are surface-coated with these chemical substances must not only comply with the SNUR, but also certify compliance under TSCA.[40] Exporters of such chemicals or articles are similarly subject to the export notification provisions of TSCA.[41]

The TSCA certification requirement provides importers and exporters alike with an affirmative obligation to stay apprised with the requirements of TSCA. As a result, importers and exporters should stay apprised of the chemical content of their products, the chemicals listed on the TSCA Inventory, as well as any new SNURs in order to ensure proper compliance with certification requirements.

D. TSCA §8 Rulemaking: The PFAS Data Call

The PMN, SNUN, and certification processes together encompass the major PFAS TSCA compliance requirements for product manufacturers as of the writing of the *PFAS Deskbook*. However, a new set of TSCA recordkeeping and reporting requirements were finalized in late 2023.

TSCA §8(a) authorizes EPA to promulgate rules that require people to maintain and submit records to EPA on the production, import, processing, or mixture of particular chemicals.[42] Congress adopted a provision in the National Defense Authorization Act for Fiscal Year 2020 (FY20 NDAA) that required EPA to adopt a PFAS regulation under §8(a) no later than January 1, 2023.[43] EPA finalized its Data Call rule in October 2023.[44]

The finalized Data Call covers a vast array of consumer and industrial products, including apparel, furniture, carpeting, fire-fighting foam, and cookware. It also provides no *de minimis* threshold for reporting on the amount of PFAS that must be present in the material manufactured or imported. The rule covers any person who manufactured or imported PFAS—including anyone who manufactured or imported an *article* that contains PFAS—going back to 2011.[45] The final rule provides a few narrow exclusions from reporting, such as when PFAS is produced solely for use as a pesticide, or in food, in food additives, drugs, cosmetics, or medical devices.[46] In addition, the rule excludes

31. *Id.*
32. EPA OIG Report, *supra* note 26, at 6.
33. Letter From Tala Henry, Deputy Director, EPA Office of Pollution Prevention and Toxics, to Manufacturers, Processors, Distributors, Users, and Those That Dispose of Fluorinated Polyolefin Containers (Mar. 24, 2022) [hereinafter EPA Letter to the Fluorinated Polyolefin Container Industry], https://www.epa.gov/system/files/documents/2022-03/letter-to-fluorinated-hdpe-industry_03-16-22_signed.pdf.
34. U.S. EPA, *Per- and Polyfluoroalkyl Substances (PFAS) in Pesticide and Other Packaging*, https://www.epa.gov/pesticides/pfas-packaging (last updated Dec. 14, 2022).
35. *See* EPA Letter to the Fluorinated Polyolefin Container Industry, *supra* note 33.
36. Since the publication of this chapter in the *PFAS Deskbook*, EPA has finalized a SNUR that prevents anyone from resuming manufacturing or processing inactive PFAS without EPA review of the significant new use. *See* U.S. EPA, Per- and Poly-Fluoroalkyl Chemical Substances Designated as Inactive on the TSCA Inventory; Significant New Use Rule, EPA-HQ-OPPT-2022-0867. The SNUR applies to PFAS that are listed as "Inactive" on the Toxics Substances Control Act (TSCA) Inventory and are not already subject to a SNUR. This "Inactive" designation means that a chemical substance has not been manufactured (including imported) or processed in the United States since June 21, 2006.
37. 40 C.F.R. §707.20(b)(2)(i).
38. EPA, Ski Wax Enforcement Alert, *supra* note 11 at 1-2.
39. 40 C.F.R. §§721.10536, 721.9582.
40. 15 U.S.C. §2612; 19 C.F.R. §12.118.
41. 15 U.S.C. §2611(b); 40 C.F.R. §§707, 721.20.
42. 15 U.S.C. §2607(a).
43. Pub. L. No. 116-92, §7351, 133 Stat. 1198, 2289 (2019).
44. Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 88 Fed. Reg. 70516, 70516 (Oct. 11, 2023) (to be codified at 40 C.F.R. pt. 705) [hereinafter PFAS Data Call].
45. *See id.*
46. 15 U.S.C. §2602(2).

PFAS found in municipal waste. There is no small business exemption, however there is delayed reporting for businesses below a certain size. As a result, the Data Call may be the first time that many manufacturers and importers of consumer products have had to file reports under TSCA.

There is a streamlined reporting form for those businesses that only import articles containing PFAS, which if available slightly decreases a business's reporting obligations.[47] Otherwise, full reports must include:

- company and plant site information for each site where a reportable PFAS is manufactured or imported;
- chemical-specific information, such as the PFAS common or trade name;
- categories of use and concentration ranges for the used PFAS;
- manufactured concentrations and amounts (by volume) for each year;
- byproduct reporting;
- internal environmental and health research;
- worker exposure data for those at the manufacturing site; and
- disposal data for PFAS wastes.

Failure to provide reportable information under the rule may expose the reporting entity to civil and criminal penalties under TSCA. Violations could result in penalties that exceed $45,000 per day, per violation.[48] Reporting companies will no doubt find that the new reporting rule raises numerous questions about how a product manufacturer or importer is expected to collect and report the detailed information that EPA is requiring by the end of next year. EPA has provided limited guidance on the topic. EPA requires a covered business to supply the requested information to the extent any such information is "known to or reasonably ascertainable."[49] When actual data are not available, EPA will require a "reasonable estimate."[50]

The standard of due diligence for PFAS reporting is the same standard EPA uses in its Chemical Data Reporting (CDR) rule. Guidance issued under that program provides that information "[k]nown to or reasonably ascertainable by" the submitter means "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."[51]

Although EPA initially projected minimal costs of complying with the rule,[52] EPA has since revised those cost estimates for the one-time reporting and recordkeeping rule up to $876 million industrywide.[53] Per-firm costs for manufacturers are estimated to range from $6,553 to $1.8 million, while per-firm costs for article importers are estimated to range from $4,046 to $224,734.[54]

The general submission period will begin one year from November 13, 2023, (the effective date of the rule) and be open for six months—November 12, 2024, to May 8, 2025.[55] Certain "small manufacturers" whose reporting obligations under the rule exclusively concern article imports will, however, receive an additional six months to submit the required data—until November 10, 2025.[56] EPA defines "small manufacturer" in this context as: (1) a manufacturer (including importer) whose total annual sales, when combined with those of its parent company, are less than $120 million, *and* the annual production or import volume of a chemical substance at any individual site controlled by the manufacturer is less than 100,000 pounds; or (2) a manufacturer (including importer) whose total annual sales, when combined with those of its parent company, are less than $12 million, regardless of the quantity of chemical substances produced or imported.[57] Businesses subject to the rule must also retain records documenting the reported information for a period of at least five years after the end of the submission period.[58]

The submissions under the Data Call will establish perhaps the largest dataset of PFAS in consumer products ever put together. EPA plans to make portions of the information public so that state and federal agencies may set priorities for regulation and to help consumers avoid specific

47. PFAS Data Call, 88 Fed. Reg. at 70555 (to be codified at C.F.R §705.18). This special reporting provision acknowledges the unique challenges that article importers may face in collecting information. The streamlined report still includes much of the same information described in the full report form, but allows for reporting of volume of the imported articles (by units or weight) rather than an estimation of. It also removes byproduct reporting, environmental and health effects, worker exposure data, and disposal data. Domestic manufacturers are not able to use this short-form reporting framework.
48. *See* 15 U.S.C. §§2614, 2615(a)(1); 40 C.F.R. §19.4. The exact penalty would vary based on the adjustment factors above, as well as the "extent" of the violation, which ranges from minor (a potential for a lesser amount of damage to human health or the environment) to major (potential for serious damage to human health or for major damage to the environment). *See generally* U.S. EPA, TSCA Section 5 Enforcement Response Policy (amended July 1, 1993).
49. PFAS Data Call, 88 Fed. Reg. at 70550 (to be codified at C.F.R §705.18); *see also* 15 U.S.C. §2607(b)(2).
50. PFAS Data Call, 88 Fed. Reg. at 70550 (to be codified at C.F.R §705.18).
51. *Id.* at 70549; *see also* PFAS Data Call, 88 Fed. Reg. at 70548 (to be codified at 40 C.F.R. §705.3).
52. *See* U.S. EPA, Initial Regulatory Flexibility Analysis and Updated Economic Analysis for TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances at 1 (2022).
53. U.S. EPA, Initial Regulatory Flexibility Analysis and Updated Economic Analysis for TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances 1 (2022).
54. *See id.*
55. PFAS Data Call, 88 Fed. Reg. at 70557 (to be codified at 40 C.F.R.§705.20).
56. *Id.*
57. 40 C.F.R. §704.3; PFAS Data Call, 88 Fed. Reg. at 70557 (to be codified at 40 C.F.R. §705.20).
58. PFAS Data Call, 88 Fed. Reg. at 70,558 (to be codified at 40 C.F.R. §705.25).

products. Whether or not EPA makes records public on its own, submissions may become subject to public records requests. EPA expects that the PFAS data it collects could potentially be used by the public, including consumers wishing to know more about the products they purchase, communities with environmental justice concerns, and government agencies to take appropriate steps to reduce potential risk. As a result, consumer product manufacturers may weigh whether to submit a confidential business information (CBI) claim to protect submitted information if proper.

II. Food, Drug, and Cosmetic Regulations

Food, drugs, and cosmetics can be distinguished from other products because they are ingested or otherwise directly applied to the human body. Given these clear exposure pathways, a harmful substance within food, drugs, or cosmetics could pose special risks to consumers. As a result, both the federal government and the states have adopted regulatory schemes that specially govern these consumer products with an eye toward protecting public health. PFAS have been implicated in all three kinds of products. To date, the brunt of the Food and Drug Administration's (FDA's) regulatory efforts regarding PFAS has been on PFAS in food and—particularly—food packaging. Although FDA wields substantial authority that once was entrusted to the states, there remains a significant, "complementary" role for states in the regulation of food, drugs, and cosmetics.[59] Certain states have gone further than FDA, restricting or outright banning PFAS in food packaging and cosmetics. This section provides an overview of federal and state developments in the regulation of PFAS in food, drugs, and cosmetics.

A. Federal Food, Drug, and Cosmetic Act

Congress first adopted food and drug legislation with the Pure Food and Drug Act of 1906.[60] The law primarily acted as a labeling law to provide national standards for the food and drug industries. Congress subsequently adopted the Federal Food, Drug, and Cosmetic Act (FDCA) in 1938.[61] The FDCA grants authority to FDA to regulate these three categories of products to prevent adulteration and misbranding.[62] The agency has enacted a suite of regulations to ensure the safety of food, drug, and cosmetic products in the United States. This section covers how those regulations have covered PFAS chemicals.

1. FDA Food Packaging Regulations

FDA regulates all foods and food ingredients introduced into or offered for sale in interstate commerce.[63] Following the Food Additives Amendment of 1958,[64] the agency also regulates any "food additive" as though it were food itself—including any chemical that migrates into food from food packaging.[65] The FDCA as amended defines a "food additive" as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food."[66] The definition explicitly covers any substance "intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food."[67] As a result, the law covers both direct food additives—those ingredients purposefully added into food to achieve a specific quality—and indirect food additives—those ingredients that become part of the food in trace amounts due to its packaging, storage, or other handling. Food additives must obtain premarket review and approval from FDA unless they meet certain exemptions.[68]

To bring food product packaging to market, the packaging itself must comply with FDA regulations built on the statute's coverage of indirect food additives. Of particular concern are those layers of the food packaging that come into direct contact with the food itself, also known as the food contact substance (FCS). The path to compliance depends on the materials used in the FCS, including the *component* chemicals of the FCS if made of a composite or combination of different materials.

For established food packaging materials, manufacturers may be able to rely on an existing FDA regulation governing the use of that material in food packaging. For example, FDA has already adopted regulations governing the use of many plastics, paper and cardboard, polymeric coatings, adhesives, and other additives in food packaging.[69] Those regulations provide limitations for permissible uses for those materials and chemical additives within those materials, including maximum chemical content or limitations on what kinds of foods those materials may permissibly contain. FDA maintains a full inventory of approved FCS.[70]

For new food packaging materials, FDA has constructed the Food Contact Notification (FCN) Program. The program sets out a formal process that allows manufacturers of FCS materials to register any new FCS materials. The petition must include sufficient information to demonstrate

59. 3 James T. O'Reilly & Katharine A. Van Tassel, Food and Drug Administration §25:1 (2022).
60. Pub. L. No. 59-384, 34 Stat. 768 (1907).
61. Pub. L. No. 75-717, 52 Stat. 1040 (1938).
62. 21 U.S.C. §§301 et seq.
63. With the exception of meat, poultry, certain processed egg products, and catfish, which are regulated by the U.S. Department of Agriculture.
64. Pub. L. No. 85-929, 72 Stat. 1784 (1958).
65. FDA, *What Does FDA Regulate?*, https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate (last updated Jan. 18, 2022).
66. 21 U.S.C. §321(s).
67. *Id.*
68. *Id.* §348.
69. 21 C.F.R. §§174.5-190.6.
70. FDA, *Inventory of Food Contact Substances Listed in 21 CFR*, https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=IndirectAdditives (last updated May 25, 2022).

that the materials are safe, or that there is a "reasonable certainty of no harm."[71] The FCN must include the chemical identity of the FCS, a description of the manufacturing process, a description of the intended conditions of use, the quantity of the substance likely to become components of food under the intended use conditions, an estimated concentration of the additive in the daily diet, and toxicology data showing the safety of that intake level of the substance.[72] Depending on the levels of estimated dietary concentration, the applicant may also need to provide toxicity studies. FDA has 120 days to object to the filed notification, otherwise it becomes effective on the 121st day. FDA may seek additional information from the manufacturer through a deficiency letter. FCNs are considered proprietary and may only be relied upon by the listed manufacturer or supplier and their customers. FDA maintains a database of all effective FCNs.[73]

Finally, a material may qualify for an exemption from the above-described regulatory structure, allowing a food packaging manufacturer to bring a substance to market without premarket review and approval from FDA.[74] The agency's regulations of food additives and food packaging exempt substances from regulation if they are "generally recognized as safe" (GRAS).[75] FDA has defined "safety" as a "reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use."[76] Generally, the safety determination relies primarily on publicly available information, but can be supported by unpublished studies, information, and evidence. As a result of this exemption, the manufacturer of a substance can make its own determination based on the evidence that the substance qualifies for GRAS status, and, without FDA review, bring that substance to market.

In order to formalize the GRAS claim process and to create certainty for entities claiming GRAS designations, FDA has created a voluntary notification process.[77] Under the notification process, the manufacturer of the substance may voluntarily submit a notice to FDA showing that a given substance qualifies for GRAS designation.[78] The GRAS notice requires a number of components, including certifications of compliance, identification of the substance, description of the manufacturing process, estimates of dietary exposure, data on limitations of chemical use based on unpalatability, a narrative that justifies GRAS designation, and a list of supporting data for the designation.[79] The agency generally responds to a notification within 180 days of filing, but may extend that response by 90 days. FDA may respond with a "no questions" letter or with a request for additional information. Critically, the GRAS notification process is voluntary—a manufacturer may bring a substance to market if it meets the GRAS requirements whether or not it notifies FDA.

Another exemption covers those materials that are not reasonably expected to become a component of food. This so-called no migration exemption covers those components of food packaging that never become a component of food itself.[80] A material may meet that exemption through the "functional barrier doctrine," where a surface of a package is separated from the food by a barrier that prevents migration, or through testing that shows lack of transfer from the package to the food. In a rule of thumb known as the "Ramsey Proposal," manufacturers have used 50 parts per billion (ppb) as the threshold for whether a material migrates into food.[81] FDA formalized this in what is known as the Threshold of Regulation (TOR) Rule that provides guidance on whether migration of a substance is "so trivial as not to require regulation of the substance as a food additive."[82] Whether or not a manufacturer uses the formalized TOR process, a material that meets the no-migration exemption does not have to go to FDA for premarket review and approval. The manufacturer can simply bring it to market.

FDA has authorized a variety of PFAS for use in specific food contact applications. Those approved uses include for nonstick cookware, as a resin for food processing equipment, as processing aids to reduce buildup in manufacturing equipment, and for food packaging as a grease-proofing agent like fast-food wrappers and microwave popcorn bags.[83]

FDA regulations of PFAS chemicals date back to the 1960s. Chemical companies filed food additive petitions to permit the use of various PFAS in food packaging. In perhaps the first of this kind of effort, DuPont filed a petition to use Zonyl RP—a mixture of short fluorinated polymers that breaks down into PFOA—as a grease-resistant coating for paper wrappers in 1966.[84] FDA initially denied the petition for lack of toxicity data,[85] but eventually granted the

71. 21 C.F.R. §§70.3(i), 170.3.
72. FDA, Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances (Chemistry Recommendations) (2007) (FDA-2020-D-1925-0001).
73. FDA, *Inventory of Effective Food Contact Substance (FCS) Notifications*, https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=FCN (last updated Dec. 31, 2022).
74. For purposes of this Article (and the *PFAS Deskbook*), we do not cover the "prior sanctioned" exception that grandfathers in materials that pre-date 1958 due to its non-applicability to PFAS.
75. 21 C.F.R. §170.30.
76. *Id.* §170.3(i).
77. *Id.* §§170.203 et seq.; Substances Generally Recognized as Safe, 81 Fed. Reg. 54960 (Aug. 17, 2016).
78. 81 Fed. Reg. at 54961.
79. 21 C.F.R. §§170.225-.255.
80. Monsanto v. Kennedy, 613 F.2d 947, 955 (D.C. Cir. 1979).
81. Lessel L. Ramsey, The Food Additive Problem of Plastics Used in Food Packaging, Presentation to the Society of Plastics Engineers (Nov. 1969).
82. Food Additives; Threshold of Regulation for Substances Used in Food-Contact Articles, 60 Fed. Reg. 36582 (July 17, 1995).
83. FDA, *Authorized Uses of PFAS in Food Contact Applications*, https://www.fda.gov/food/process-contaminants-food/authorized-uses-pfas-food-contact-applications (last updated Feb. 24, 2022).
84. E.A. (Ev) Crunden & Ariel Wittenberg, *Inside FDA's "Forever Chemicals" Catastrophe*, E&E News (Mar. 7, 2022), https://www.eenews.net/articles/inside-fdas-forever-chemicals-catastrophe/; Memorandum From Richard H. Rea, E.I. du Pont de Nemours and Co. Legal Department, to H.A. Lips, E.I. du Pont de Nemours and Co. Organic Chemicals Department (Mar. 23, 1966), https://www.documentcloud.org/documents/21295331-dupont-internal-zonyl-memo.
85. Letter From Willard Orr, Food and Drug Officer, FDA, to Richard Rea, E.I. du Pont de Nemours and Co. Legal Department (Mar. 3, 1966), https://static.ewg.org/reports/2022/pfas-fda-timeline/March-03-1966.pdf?_ga=2.231208221.369684524.1672325704-1348158974.1653340102.

petition.[86] Other chemical companies would seek approval for their own PFAS formulations to be used in food packaging, including 3M[87] and Ciba-Geigy.[88]

In subsequent years, chemical manufacturers frequently utilized the FCN Program to obtain approval for their PFAS formulations.[89] FDA's FCN Program database includes approvals for PFAS formulations submitted by 3M, Arkema, Asahi Glass Company, BASF Corporation, Chemours, Daikin Industries, DuPont, Dyneon, Greene, Tweed, and Company, Inc., Precision Polymer Engineering, Solenis, and Solvay Specialty Polymers among others.[90] The GRAS notice inventory contains no entries for PFAS chemicals—but that notification program is only voluntary. Should a chemical manufacturer find its PFAS formulation meets the GRAS requirements, the manufacturer can unilaterally bring that compound to market without submitting a notification. As a result, it is difficult to estimate how many PFAS chemicals have been introduced through the GRAS exemption.

As scientific consensus grew around the hazardous properties of long-chain or C8 PFAS like PFOA and PFOS, FDA initiated a series of voluntary food packaging PFAS phaseouts beginning in the 2000s. The agency developed a voluntary phaseout plan for long-chain PFAS that had been approved for use in food packaging.[91] FDA obtained letters from BASF Corporation,[92] DuPont,[93] and Clariant[94] committing to no longer use those long-chain PFAS in food contact applications sold in the United States.[95] FDA went on to revoke the FCNs for those as well as other long-chain PFAS.[96] FDA represents that as of November 2016, "long-chain PFAS are no longer used in food contact applications sold in the United States."[97]

In spring 2020, FDA published findings from the agency's scientific review of new data on short-chain PFAS that contain 6:2 fluorotelomer alcohol (6:2 FTOH).[98] The findings raised safety questions regarding potential health risks arising from dietary exposure to 6:2 FTOH.[99] At the time of the findings, four chemical manufacturers held 15 FCNs covering 11 short-chain PFAS compounds containing 6:2 FTOH.[100] One of the chemical manufacturers—Chemours—had already voluntarily ended its production of the short-chain PFAS compounds.[101] The other three manufacturers—Archroma Management,[102] AGC Chemicals Americas, Inc.,[103] and Daikin America, Inc.[104]—each voluntarily agreed to a three-year phaseout of sales of short-chain 6:2 FTOH FCS beginning in January 2021.[105]

Although several PFAS have been phased out through these voluntary FDA programs, many PFAS remain on the FDA FCN Program database, and PFAS may be introduced into the food system through the GRAS or no-migration exemptions. In light of FDA's recent activities, several advocacy organizations filed a petition on June 3, 2021, seeking FDA's removal of all approvals for PFAS and banning the use of short-chain and long-chain PFAS in food contact materials.[106] FDA has not acted on the petition.

Finally, FDA has developed and initiated testing for PFAS in foods to identify potential PFAS contamination in the food system.[107] FDA has developed test methods for 20 different PFAS in food samples, although those methods are only published for 16 PFAS so far.[108] In order to study

86. Memorandum From K.P. Misra & J. McLaughlin Jr., FDA Division of Toxicological Evaluation, to FDA Petitions Control Branch (July 21, 1966), https://www.documentcloud.org/documents/21295354-fda-memo-determining-use-of-zonyl-is-safe; Food Additives Resulting From Contact With Containers or Equipment and Food Additives Otherwise Affecting Food: Paper and Paperboard, 32 Fed. Reg. 12474 (Aug. 29, 1967), *available at* https://static.ewg.org/reports/2022/pfas-fda-timeline/August-29-1967.pdf.
87. Food Additives Resulting From Contact With Containers or Equipment and Food Additives Otherwise Affecting Food: Paper and Paperboard, 33 Fed. Reg. 14544 (Sept. 27, 1968), *available at* https://static.ewg.org/reports/2022/pfas-fda-timeline/September-27-1968.pdf.
88. Indirect Food Additives: Paper and Paperboard Components, 48 Fed. Reg. 51770 (Nov. 14, 1983), *available at* https://static.ewg.org/reports/2022/pfas-fda-timeline/November-14-1983.pdf.
89. FDA, *supra* note 73.
90. *Id.*
91. FDA, *supra* note 83.
92. Letter From Theodore Kelly Jr., Vice President, BASF Corp., to Mitchell Cheeseman, Acting Director, FDA Office of Food Additive Safety (Nov. 28, 2011), https://www.fda.gov/media/127527/download.
93. Letter From John Moriarty, Global Business and Market Director, E.I. du Pont de Nemours and Co., to Mitchell Cheeseman, Acting Director, FDA Office of Food Additive Safety (Nov. 16, 2011), https://www.fda.gov/media/127528/download.
94. Letter From Kenneth L. Golder, President and Chief Executive Officer, Clariant Corp. & Helmut Wagner, Global Head of Business Unit Paper, Clariant Corp., to Mitchell Cheeseman, Acting Director, FDA Office of Food Additive Safety (Sept. 1, 2011), https://www.fda.gov/media/127529/download.
95. *See id.*
96. Indirect Food Additives: Paper and Paperboard Components, 81 Fed. Reg. 5 (Jan. 4, 2016); Indirect Food Additives: Paper and Paperboard Components, 81 Fed. Reg. 83672 (Nov. 22, 2016).
97. FDA, *supra* note 83.
98. Penelope Rice et al., *Comparative Analysis of the Toxicological Databases for 6:2 Fluorotelomer Alcohol (6:2 FTOH) and Perfluorohexanoic Acid (PFHxA)*, 138 Food & Chem. Toxicology (2020); Shruti Kabadi et al., *Characterizing Biopersistence Potential of the Metabolite 5:3 Fluorotelomer Carboxylic Acid After Repeated Oral Exposure to the 6:2 Fluorotelomer Alcohol*, 388 Toxicology & Applied Pharmacology 114878 (2020).
99. Constituent Update, FDA, FDA Announces the Voluntary Phase-Out by Industry of Certain PFAS Used in Food Packaging (July 31, 2020), https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-voluntary-phase-out-industry-certain-pfas-used-food-packaging.
100. FDA, *supra* note 83.
101. Letter From Dennis M. Keefe, Director, FDA Office of Food Additive Safety, to Thomas Band, Global Product Manager, Chemours Co. (July 29, 2020), https://www.fda.gov/media/140611/download.
102. Letter From Carole Mislin, Head of Product Stewardship, Archroma Management GmbH & Silke Wischeropp, General Counsel, Archroma Management GmbH, to Dennis M. Keefe, Director, FDA Office of Food Additive Safety (July 17, 2020), https://www.fda.gov/media/140562/download.
103. Letter From William Lillis, President, AGC Chemicals Americas, Inc., to Dennis M. Keefe, Director, FDA Office of Food Additive Safety (July 17, 2020), https://www.fda.gov/media/140561/download.
104. Letter From Greg Rubin, Vice President of Sales and Commercial Activities, Daikin America, to Dennis M. Keefe, Director, FDA Office of Food Additive Safety (July 17, 2020), https://www.fda.gov/media/140565/download.
105. FDA, *supra* note 83.
106. Citizens Petition to FDA Division of Dockets Management, Re: Citizens Petition Requesting That the Agency Take More Aggressive Action to Protect Consumers From Per- and Poly-Fluoroalkyl Substances (PFAS) by Banning All Forms That Biopersist in the Human Body (June 3, 2021), https://static.ewg.org/reports/2022/pfas-fda-timeline/June-03-2021.pdf.
107. FDA, *Testing Food for PFAS and Assessing Dietary Exposure*, https://www.fda.gov/food/process-contaminants-food/testing-food-pfas-and-assessing-dietary-exposure (last updated July 6, 2022).
108. FDA, FDA Foods Program Compendium of Analytical Laboratory Methods: Chemical Analytical Manual (CAM), Determination of

the risk of dietary exposure to PFAS, FDA has integrated these tests into the agency's Total Diet Study.[109] FDA made public the test results from its first Total Diet Study to integrate PFAS testing. Of the 167 tested foods, 164 contained no detectable levels of PFAS.[110] The three samples with detectable levels of PFAS each implicated seafood: fish sticks (PFOS and perfluorononanoic acid (PFNA)), canned tuna (PFOS and perfluorodecanoic acid (PFDA)), and protein powder (PFOS). Protein powders frequently include proteins sourced from aquatic life. Each of these measurements fell below 150 parts per trillion (ppt), and FDA concluded that there was no "need to avoid any particular foods in the general food supply."[111]

Food packaging regulations at the federal level will continue to evolve in the coming years as FDA begins to reexamine its previous decisions regarding the approval of PFAS in FCS materials, and as the agency develops additional testing methods to examine the potential migration of PFAS from FCS materials. In the meantime, states have become an active site for regulation of food packaging. Those state activities are explored in detail below.

2. FDA Cosmetics Regulations

PFAS are used widely in cosmetics for consistency, texture, and their water-repellant properties.[112] In one study, more than one-half of the 231 cosmetic products tested by researchers contained high fluorine content, strongly indicating the presence of PFAS.[113] The human health risk posed by the dermal exposure pathway is, however, an open question.[114]

Since 1938, FDA has had regulatory authority over cosmetics under the FDCA, which defines "cosmetics" as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance," and the components of such articles, but not soap.[115] Several basic rules govern cosmetics under the FDCA, resembling the basic rules for food and drugs. A cosmetic is deemed "adulterated" if "it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual" or "consists in whole or in part of any filthy, putrid, or decomposed substance."[116] The packaging of cosmetics may render the cosmetics adulterated, too—a cosmetic that "has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health" is adulterated, as is a cosmetic packaged in a container "composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health."[117] In addition, a cosmetic is considered "misbranded" if, inter alia, its labeling is "false or misleading in any particular."[118] A label's failure to reveal material facts, in light of representations made, renders a cosmetic misbranded.[119] If any cosmetic is adulterated or misbranded, FDA has enforcement authority ranging from warning letters to recalls to safety alerts.[120]

At the end of 2022, Congress passed the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), amending the FDCA and revamping the federal regulatory framework for cosmetics.[121] Perhaps the most far-reaching component of MoCRA is a mandatory registration requirement for manufacturers and processers of cosmetics that are distributed in the United States. Existing facilities must register with FDA within one year of MoCRA's enactment, while new facilities must do so within 60 days of their first engaging in cosmetics manufacturing or processing.[122] By forthcoming FDA rule, all registrants will need to submit cosmetic product listings containing information on each cosmetic product's facility registration identification, contact information for responsible persons, product categories, and a list of ingredients in the product, including fragrances, flavors, and colors.[123] Critically, MoCRA provides procedures for FDA to suspend a facility's registration if the agency determines that the facility's cosmetic product

> has a reasonable probability of causing serious adverse health consequences or death to humans and the Secretary has a reasonable belief that other products manufactured or processed by the facility may be similarly affected because of a failure that cannot be isolated to a product or products, or is sufficiently pervasive to raise concerns about other products manufactured in the facility.[124]

Another important development under MoCRA is a set of new recordkeeping and reporting requirements for "adverse events" caused by cosmetics—tiered as "adverse

16 Per and Polyfluoroalkyl Substances (PFAS) in Processed Food Using Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) (2021), https://www.fda.gov/media/131510/download.

109. FDA, *supra* note 107.

110. *Id.*

111. Constituent Update, FDA, FDA Makes Available PFAS Testing Results From First Survey of Processed Foods (Aug. 26, 2021), https://www.fda.gov/food/cfsan-constituent-updates/fda-makes-available-pfas-testing-results-first-survey-processed-foods.

112. Melinda Fulmer, *Is Your Long-Lasting Makeup Toxic? Study Raises Concerns About PFAS in Cosmetics*, Wash. Post (Aug. 11, 2021), https://www.washingtonpost.com/lifestyle/wellness/pfas-cosmetics-forever-chemicals-toxic/2021/08/11/f6475ab4-f9f3-11eb-8a67-f14cd1d28e47_story.html.

113. Heather D. Whitehead et al., *Fluorinated Compounds in North American Cosmetics*, 8 Env't Sci. & Tech. Letters 538 (2021), *available at* https://pubs.acs.org/doi/10.1021/acs.estlett.1c00240.

114. FDA, *Per and Polyfluoroalkyl Substances (PFAS) in Cosmetics*, https://www.fda.gov/cosmetics/cosmetic-ingredients/and-polyfluoroalkyl-substances-pfas-cosmetics (last updated Feb. 25, 2022).

115. 21 U.S.C. §321(i) (2012).

116. *Id.* §361(a), (b).

117. *Id.* §361(c), (d).

118. *Id.* §362.

119. 21 C.F.R. §1.21.

120. FDA, *Cosmetics Compliance & Enforcement*, https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement (last updated Feb. 25, 2022).

121. Consolidated Appropriations Act of 2023, Pub. L. No. 117-328, §§3501 et seq., 136 Stat. 4459 (MoCRA).

122. FDCA §607(a) (2023).

123. *Id.* §607(c).

124. *Id.* §607(f).

events," or any events involving adverse health impacts, and "serious adverse events," those adverse events that result in infection, hospitalization, birth defects, persistent or significant disability or incapacity, or significant disfigurement.[125] Manufacturers, packers, and distributors must maintain records of all adverse events, subject to inspection by FDA.[126] Any serious adverse event must be reported to FDA within 15 days of a manufacturer's, packer's, or distributor's receipt of knowledge of the event.[127] Moreover, FDA now has authority to require disclosure of fragrance and flavor ingredients in cosmetics where there are reasonable grounds to believe that such ingredients caused or contributed to a serious adverse event.[128] Additionally, FDA's reasonable belief that a product is likely adulterated entitles it to inspect *all* records related to the product in question and similarly situated products (not just those records related to adverse events).[129]

Another significant component of MoCRA is a requirement that FDA promulgate current good manufacturing practices on cosmetics, "intended to protect the public health and ensure that cosmetic products are not adulterated," to be issued in a notice of proposed rulemaking by two years after MoCRA's enactment, and a final rule within three years.[130] FDA has never previously promulgated current good manufacturing practices regulations for cosmetics, instead issuing only nonbinding guidance.[131]

Adding to these new substantive and procedural requirements of cosmetics manufacturers, packers, and distributors, MoCRA shores up FDA's enforcement authority over cosmetics, creating a new procedure for FDA to effect mandatory recalls of products for which there is a "reasonable probability" of adulteration or misbranding and for which use or exposure would cause "serious adverse health consequences."[132]

Finally, and directly implicating PFAS, MoCRA directs the Secretary of Health and Human Services to "assess the use of [PFAS] in cosmetic products, and the scientific evidence regarding the safety of such use in cosmetic products, including any risks associated with such use"; the Secretary must publish a report on the same within three years of MoCRA's enactment.[133]

Historically, regulatory oversight of cosmetics has been fairly lax.[134] FDA has always had authority to issue regulations controlling ingredients in cosmetics,[135] including banning ingredients entirely, but it has exercised that authority sparingly, prohibiting only eight and restricting two.[136] Before MoCRA, there were no approval or registration requirements for cosmetics or cosmetics makers until MoCRA's enactment, and FDA obtained information on cosmetics substantially through the Voluntary Cosmetic Registration Program (VCRP), an elective system through which manufacturers, packers, and distributors of cosmetics submitted corporate and product information.[137]

Accordingly, MoCRA represents a sea change in the regulatory framework for cosmetics. To date, FDA has not acted on PFAS in cosmetics beyond promising to "continue to monitor the VCRP data and published research and continue to engage with stakeholders."[138] But after the passage of MoCRA, one can expect from FDA at the very least that the forthcoming congressionally mandated report on the health risks of PFAS in cosmetics will provide new information to FDA and the public. It is likely that this new information will undergird future regulatory steps with respect to PFAS, should FDA determine that the cosmetics exposure pathway is a dangerous one—for instance, FDA could issue regulations or bring enforcement actions to require warning statements on the labels of cosmetics containing PFAS.[139] In addition, the broad new registration, recordkeeping, and reporting procedures for adverse health events will provide rich sources of new data for FDA and the public. Any PFAS-related adverse events from this data will likely spur new litigation, rulemaking, and enforcement actions up to FDA's new mandatory recall authority over cosmetic products posing a reasonable probability of serious health risks.

B. *State Laws on Cosmetics and Food Packaging*

States have begun to regulate PFAS in food packaging and cosmetics. Connecticut, Hawaii, Minnesota, New York, Rhode Island, and Vermont all have banned PFAS in food packaging completely, effective at various points in the next two years.[140] Washington has implemented a ban on food packaging with intentionally added PFAS, if safer alternatives are identified.[141] PFAS in packaging wraps and liners, plates, food boats, and pizza boxes are banned fully in the state since February 2023, and this list will expand to include food bags and sleeves, bowls, flat serviceware, open-top containers, and closed containers beginning May 2024.[142] Maine, California, and Maryland have banned PFAS in food packaging with some limitations, with Cali-

125. *Id.* §604, 605.
126. *Id.* §605(e).
127. *Id.* §605(a), (b)(1).
128. *Id.* §605(f).
129. *Id.* §610.
130. *Id.* §606.
131. FDA Enforcement Manual ¶ 1663 (2015); FDA, Guidance for Industry: Cosmetic Good Manufacturing Practices—Draft Guidance (2013) [hereinafter FDA, Cosmetic Good Manufacturing Practices], https://www.fda.gov/media/86366/download.
132. FDCA §611.
133. MoCRA §3506.
134. Thomas J. Donegan Jr., *Fifty Years of Cosmetic Safety: A Government and Industry Partnership*, 50 Food & Drug L.J. 151 (1995).
135. 21 U.S.C. §§361, 362, 371(a).
136. FDA, Cosmetic Good Manufacturing Practices, *supra* note 131, at 9.
137. 21 C.F.R. pts. 710, 720.
138. FDA, *supra* note 114.
139. 21 C.F.R. §740.1 (FDA may require warning statements on cosmetic product "whenever necessary or appropriate to prevent a health hazard that may be associated with the product").
140. N.Y. Env't Conserv. Law §37-0209 (2022); Vt. Stat. Ann. tit. 18, ch. 33A (2023); Conn. Gen. Stat. Ann. §22a-255i (2023); 23 R.I. Gen. Laws §23-18.13-4 (2024); Haw. Rev. Stat. Ann. §321-602 (2024); Minn. Stat. Ann. §325F.075 (2024).
141. Wash. Rev. Code §70A.222.070.
142. Washington Department of Ecology, *PFAS in Food Packaging*, https://ecology.wa.gov/Waste-Toxics/Reducing-toxic-chemicals/Addressing-priority-toxic-chemicals/PFAS/Food-packaging (last visited Jan. 31, 2023).

fornia implementing a limit at 100 parts per million (ppm) of total organic fluorine (TOF) for plant-based food packaging.[143] Finally, New Hampshire requires bottled water manufacturers to report PFAS levels in water when applying for or renewing beverage licenses.[144]

With the recent passage of Assembly Bill 2771, codified at California Health and Safety Code §108981, California will prohibit the manufacture, sale, delivery, or offer for sale of cosmetic products with intentionally added PFAS after January 1, 2025.[145] It has no exceptions for any type of cosmetics, which are defined as "an article for retail sale or professional use intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance."[146] The law covers all PFAS, and does not provide a minimum threshold for what is considered intentionally added PFAS content. This represents an expansion of a California law enacted in 2020 that banned the use of 13 specific PFAS in cosmetics.[147] Similarly, Colorado will prohibit all intentionally added PFAS in cosmetics by January 1, 2025.[148] Maryland also has enacted a ban on the manufacture, handling, or sale of cosmetics with intentionally added PFAS.[149] The ban, which will go into effect in 2025, does not apply to all PFAS, instead specifying 13 types of PFAS and their salts, including PFOA, PFOS, and PFNA.

III. FIFRA

FIFRA governs the registration, distribution, sale, and use of pesticides in the United States.[150] A "pesticide" is defined as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest; any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant; and any nitrogen stabilizer."[151] FIFRA imposes a variety of requirements to ensure that pesticides will not cause "unreasonable risk to human health or the environment."[152] Chief among these are registration, labeling, and distribution requirements.

Though PFAS is not itself used as a pesticide, there have been concerns regarding the contamination of pesticides from PFAS in fluorinated HDPE storage containers.[153] EPA subsequently developed and released a method for detecting 28 different PFAS compounds to help manufacturers and regulators test their products for PFAS contamination.[154] EPA also issued a letter meant to raise awareness to this issue among pesticide manufacturers.[155] Such contamination could create additional reporting requirements for manufacturers of pesticides. On September 8, 2022, EPA released the results of a new study confirming that several different brands of fluorinated HDPE containers readily leach PFAS from container walls into liquids stored within, including water-based solutions.[156]

Several PFAS were also listed for a time as approved inert ingredients in pesticides designated for non-food uses, meaning that manufacturers could use those listed PFAS in pesticides as inert ingredients without further EPA oversight. EPA recently initiated rulemaking to remove those PFAS from the approved-inert-ingredient list.

A. *Registration and Labeling Requirements*

Under FIFRA, all pesticides must be registered before they may be distributed or sold unless an exception applies.[157] For a pesticide to be registered under the statute, applicants must provide a variety of information, including the name of the pesticide, the pesticide label and use instructions, and the complete formula of the pesticide.[158] Labels must include the name under which the product is sold, its registration number, an ingredient statement, hazardous and precautionary statements, and directions for use, among other things.[159] The labels must be accurate and accompany the product during transportation and storage.[160] If EPA finds the data provided insufficient to make a registration decision, it may order the registrant to provide additional data.[161] Furthermore, in making its decision to approve registration of a pesticide, EPA must conclude that it will not cause any unreasonable adverse effects on the environment.[162]

Relevant to PFAS, pesticide registrants have an ongoing obligation to provide EPA with any additional information the Agency may acquire about their pesticide after registration regarding unreasonable adverse effects on the environment.[163] EPA "considers any level of PFAS to be potentially toxicologically significant."[164] As a result, the presence of PFAS would almost certainly trigger the requirement to

143. Cal. Health & Safety Code §109000; Md. Code Ann., Env't §9-1902; Me. Rev. Stat. Ann. tit. 32, §§1731-1747.
144. N.H. Code Admin. R. He-P 2102.01, He-P 2102.02, He-P 2102.05, He-P 2107.01.
145. Cal. Health & Safety Code §108981.
146. *Id.*
147. *Id.* §108980.
148. Colo. Rev. Stat. §25-15-604.
149. Md. Code Ann., Health-Gen. §21-259.2.
150. U.S. EPA, *Summary of the Federal Insecticide, Fungicide, and Rodenticide Act*, https://www.epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act (last updated Sept. 12, 2022).
151. 7 U.S.C. §136(u).
152. *Id.* §136(bb).
153. News Release, U.S. EPA, EPA Takes Action to Investigate PFAS Contamination (Jan. 14, 2021), https://www.epa.gov/newsreleases/epa-takes-action-investigate-pfas-contamination.
154. Memorandum From Thuy Nguyen, Chief, Analytical Chemistry Branch, Biological and Economic Analysis Division, U.S. EPA, to Kimberly Nesci, Director, Biological and Economic Analysis Division, EPA Office of Pesticide Programs, Re: EPA's Analytical Chemistry Branch Method for the Analysis of PFAS in Oily Matrix, ACB Project B21-02 (Sept. 28, 2021), https://www.epa.gov/system/files/documents/2021-09/epa-pfas-method-in-oil.pdf.
155. EPA Letter to the Fluorinated Polyolefin Container Industry, *supra* note 33.
156. U.S. EPA, *EPA Releases Data on Leaching of PFAS in Fluorinated Packaging*, https://www.epa.gov/pesticides/epa-releases-data-leaching-pfas-fluorinated-packaging (last updated Sept. 12, 2022).
157. 7 U.S.C. §136a(a).
158. *Id.* §136a(c)(1).
159. 40 C.F.R. §156.10(a).
160. *Id.*
161. 7 U.S.C. §136a(c)(2)(B).
162. *Id.* §136a(c)(3).
163. *Id.* §136d(a)(2).
164. U.S. EPA, *supra* note 34.

report to EPA about PFAS contamination in any pesticide.[165] EPA must receive notice about impurities no later than the 30th calendar day after the registrant first possesses or knows of the information.[166] EPA has asked pesticide registrants and companies providing container-fluorination services to investigate their distribution chains for sources of PFAS contamination and to report any relevant information as required by FIFRA.[167] EPA has also indicated that if any contamination has been sourced to packaging, that the pesticide registrant work with EPA on collecting data on alternative packaging prior to distribution of the pesticide in that new packaging.

B. *Distribution Requirements*

FIFRA §19 governs the storage, disposal, transportation, and recall of pesticides.[168] EPA may require the registration applicant to submit data about transportation and storage methods and may require certain procedures be followed by those who store, transport, or dispose of pesticides.[169] Additionally, the Agency may issue requirements to those who store, transport, or dispose of containers that used to contain pesticides, and can require certain recycling procedures to be followed for containers.[170] EPA can issue mandatory recalls of pesticides if a pesticide has been suspended, and is empowered to promulgate regulations for the design of pesticide containers to ensure safe disposal and reuse.[171] Pesticide manufacturers should monitor whether EPA uses these authorities to recall containers or products containing PFAS.

C. *Limiting Use of PFAS as Inert Ingredients*

On September 13, 2022, EPA issued a notice of proposed rulemaking to remove 12 PFAS from the current list of inert ingredients approved for use in pesticide products.[172]

Most pesticide products contain substances in addition to the active ingredient or ingredients, referred to as inert ingredients (or "other ingredients" on some packaging).[173] An inert ingredient is any substance or group of similar substances other than an active ingredient that is intentionally included in a pesticide product.[174] Examples include substances affecting consistency, smell, or color like emulsifiers, solvents, carriers, aerosol propellants, fragrances, and dyes.

EPA maintains a list of approved inert ingredients for use in pesticide products.[175] Inert ingredients on this list may be used in pesticides oriented toward non-food uses without any further approval.[176] Accordingly, removal of the 12 PFAS from this list means that any future proposed uses of the PFAS as inert ingredients in an application for registration of a pesticide product will require approval and payment of a fee in accordance with §33 of FIFRA.[177]

The extent of historical use of these PFAS in pesticides is unclear, but this rule is unlikely to be very disruptive because these 12 PFAS are no longer used in any registered pesticide products.[178] Nevertheless, EPA suggested that manufacturers double-check their records to ensure that the 12 PFAS are, "in fact," no longer used in their products.[179] Pesticide manufacturers should track this space to see whether EPA removes additional PFAS from this approved list.

IV. State Product Regulations

In the relative absence of federal regulations, states have stepped in to either utilize existing state environmental laws or adopt entirely new state laws to address the environmental and health effects of PFAS. State regulations have largely focused on reporting, labeling, and restricting the use of PFAS in certain products. Many states have adopted PFAS regulations, but it is worth highlighting select laws from three states: California, Maine, and Washington. Although this Article will not cover all regulations relevant to consumer product manufacturers—or even all the relevant PFAS laws—within these particular states, these three states provide a useful cross-section of the types of state regulations relevant to product manufacturers.

A. *California: Proposition 65*

California's Safe Drinking Water and Toxic Enforcement Act, also known as Proposition 65, requires product manufacturers, producers, packagers, importers, suppliers, or distributors to place "clear and reasonable" warnings on products that contain chemicals that may cause cancer, birth defects, or other reproductive harms.[180] California maintains a list of chemicals "known to the state to cause cancer or reproductive toxicity" that require such warnings.[181] This list is updated on at least an annual basis as knowledge of existing and new chemicals is developed.[182] Labeling requirements for a newly added chemical take effect one year after the listing.[183] Although this mandate generally applies to the product manufacturer, product

165. 40 C.F.R. §159.179(b).
166. *Id.* §155(a)(5).
167. U.S. EPA, *supra* note 156.
168. 7 U.S.C. §136q.
169. *Id.* §136q(a).
170. *Id.*
171. *Id.* §136q(b), (e).
172. Pesticides; Proposed Removal of PFAS Chemicals From Approved Inert Ingredient List for Pesticide Products, 87 Fed. Reg. 56051 (Sept. 13, 2022).
173. U.S. EPA, *Inert Ingredients Regulation*, https://www.epa.gov/pesticide-registration/inert-ingredients-regulation (last updated May 2, 2022).
174. 40 C.F.R. §158.300.
175. U.S. EPA, *InertFinder*, https://ordspub.epa.gov/ords/pesticides/f?p=INERTFINDER:1:0::NO:1 (last visited Jan. 31, 2023).
176. 87 Fed. Reg. at 56053.
177. 7 U.S.C. §136w-8.
178. 87 Fed. Reg. at 56052.
179. *Id.*
180. Cal. Health & Safety Code Ann. §§25249.5, 25249.6.
181. *Id.* §25249.8.
182. *Id.*
183. *Id.*

manufacturers and retailers may enter into agent arrangements that transfer the responsibility to place and maintain labels from manufacturer to retailer.[184]

The warning requirement is enforced through civil penalties that may be brought by the California attorney general, a district attorney, a city attorney, or a private citizen if no prosecution has been commenced by the government.[185] Those civil penalties can be quite large: a person who is found to violate the reporting requirement is liable for a civil penalty of up to $2,500 per day for each violation.[186] In 2019 alone, there were almost 900 private Proposition 65 settlements for a total of nearly $30,000,000.[187]

California first listed PFAS chemicals under Proposition 65 on November 10, 2017, when the state added both PFOA and PFOS for reproductive toxicity.[188] This listing was based on the formal identification by EPA that the chemicals cause reproductive toxicity.[189] PFOS and PFOA were then subsequently listed as known to cause cancer in December 2021 and February 2022, respectively; the PFOS listing was based on the identification by the Carcinogen Identification Committee that PFOS causes cancer, and the PFOA listing was based on the identification by the National Toxicology Program that PFOA causes cancer.[190] The state listed PFNA as causing reproductive toxicity in December 2021 based on identification by the Developmental and Reproductive Toxicant Identification Committee.[191] The California Office of Environmental Health Hazard Assessment has proposed to list PFDA, perfluorohexanesulfonic acid (PFHxS), and perfluoroundecanoic acid (PFUnDA) as chemicals known to cause reproductive toxicity, although that process is ongoing at the time of this writing.[192] Additional PFAS substances may be added in the future as the understanding of their toxicity progresses over time.

The impacts of current and future listing of PFAS under Proposition 65 are significant given California's size and market share, as well as the active citizen enforcement of the law. This disclosure law will have broad impacts on the market as the science on particular PFAS develops and California continues to expand its list of chemicals.

B. *California: California Health and Safety Code §108945*

A growing set of states have banned categories of products that contain PFAS.[193] On October 5, 2021, California's governor signed into law Assembly Bill 652, a prohibition on the sale and distribution of "juvenile products" containing PFAS.[194] This law provides a useful look at the features that tend to distinguish many of these types of categorical regulations. Generally, these types of state laws target a product category, filter for a particular quantity or quality of PFAS in the product, regulate particular acts with regard to those products (sale, distribution, or advertising), and provide penalties for violation. California was one of the first states to establish such a law.

First, the juvenile products law defines the product category covered by the regulation. For this law, it covers "juvenile products" defined as "a product designed for use by infants and children under 12 years of age."[195] It also provides a list of example products, "including, but not limited to" products such as a "basinet," "crib mattress," "pillow," or "stroller."[196] The law includes exclusions from the broad category of products covered, including medical devices, adult mattresses, and children's electronic products such as a calculator, wireless phone, or game console.[197] Exclusions are a common feature of these kinds of laws.

Second, the juvenile products law clarifies that it covers only juvenile products with certain PFAS qualities. Specifically, it regulates only those juvenile products that contain "intentionally added" PFAS.[198] The law clarifies that the definition covers only those products with TOF measurements at or above 100 ppm.[199] The intentional addition and minimum threshold are both broadly used categories in state laws to distinguish products that may have accidental or background PFAS contamination. Other laws do not provide such accommodations and cover all PFAS in a product—even when that PFAS arises from contamination.

184. *Id.* §25600.2.
185. *Id.* §25249.7(c).
186. *Id.* §25249.7(b)(1).
187. California Department of Justice, Office of the Attorney General, *Annual Reports of Settlements*, https://oag.ca.gov/prop65/annual-settlement-reports (last visited Jan. 31, 2023).
188. *Chemicals Listed Effective November 10, 2017, as Known to the State of California to Cause Reproductive Toxicity: Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)*, Cal. Off. Env't Health Hazard Assessment (Nov. 9, 2017), https://oehha.ca.gov/proposition-65/crnr/chemicals-listed-effective-november-10-2017-known-state-california-cause.
189. *Id.*
190. *Notice to Interested Parties: Chemicals Listed Effective December 24, 2021, as Known to the State of California to Cause Cancer: Perfluorooctane Sulfonic Acid (PFOS) and Its Salts and Transformation and Degradation Precursors*, Cal. Off. Env't Health Hazard Assessment (Dec. 22, 2021), https://oehha.ca.gov/proposition-65/crnr/notice-interested-parties-chemicals-listed-effective-december-24-2021-known; *Notice to Interested Parties: Chemical Listed Effective February 25, 2022, as Known to the State of California to Cause Cancer: Perfluorooctanoic Acid*, Cal. Off. Env't Health Hazard Assessment (Feb. 25, 2022), https://oehha.ca.gov/proposition-65/crnr/notice-interested-parties-chemical-listed-effective-february-25-2022-known-state.
191. *Notice to Interested Parties: Chemicals Listed Effective December 31, 2021, as Known to the State of California to Cause Reproductive Toxicity: Perfluorononanoic Acid (PFNA) and Its Salts*, Cal. Off. Env't Health Hazard Assessment (Dec. 29, 2021), https://oehha.ca.gov/proposition-65/crnr/notice-interested-parties-chemicals-listed-effective-december-31-2021-known.
192. *Chemicals Selected for Consideration for Listing by the DARTIC and Request for Relevant Information on the Reproductive Toxicity Hazards of: PFDA and Its Salts, PFHxS and Its Salts, PFNA and Its Salts, and PFUnDA and Its Salts*, Cal. Off. Env't Health Hazard Assessment (Mar. 26, 2021), https://oehha.ca.gov/proposition-65/crnr/chemicals-selected-consideration-listing-dartic-and-request-relevant-information.
193. For example, Colorado has banned the sale of cosmetics containing PFAS beginning in 2025, Vermont has banned the sale of ski wax containing PFAS starting July 2023, and Washington is finalizing a prohibition on the sale of carpets and rugs containing PFAS starting in 2025.
194. Cal. Health & Safety Code §108945.
195. *Id.* §108945(c)(1).
196. *Id.*
197. *Id.* §108945(c)(2).
198. *Id.* §108945(b).
199. *Id.*

Third, the juvenile products law prohibits a subset of activities connected to the covered products. Specifically, the law prohibits the sale and distribution of covered products within the state on and after July 1, 2023.[200] Different states target different types of activities with the targeted products, such as the manufacture, sale, shipment, distribution, advertisement, or disposal of products containing PFAS. However, California limited this law to only encompass sale and distribution of juvenile products containing PFAS.

Finally, many of the PFAS products laws include sections on enforcement or penalty authority. Those laws frequently draw on existing agencies to issue regulations or enforce the law using existing civil penalty authority. However, not all of these laws include implementation or enforcement authority. The California juvenile products law does not delegate any agency with rulemaking authority and does not provide any enforcement provisions. As a result, any enforcement would be accomplished through private or public litigation. That raises questions of what kinds of damages such litigants could obtain.

California's juvenile products law provides a useful blueprint for similar categorical product prohibitions in California and elsewhere across the country. California has gone on to regulate additional categories of products with PFAS, including food packaging,[201] apparel and other textiles,[202] and cosmetics.[203]

C. *Washington: Pollution Prevention for Healthy People and Puget Sound Act*

Another class of state laws provides broad authority for state regulators to determine chemicals and products for regulation. Washington provides an excellent example of such a law. The state adopted the Pollution Prevention for Healthy People and Puget Sound Act (Puget Sound Act) in May 2019.[204] The law directs the Washington Department of Ecology (Ecology) to regulate classes of "priority chemicals," and then regulate "priority products" that contain those chemicals.[205] The Puget Sound Act sets out a four-stage regulatory process to take place every five years.[206]

First, Ecology must designate at least five priority chemicals that exhibit certain characteristics, such as persistence, bioaccumulative toxicity, or potential harm for children.[207] Rather than allow Ecology to designate the first set of chemicals, the Puget Sound Act designated the first five priority chemicals to include PFAS (regulated as a chemical class), polychlorinated biphenyls (PCBs), phthalates, phenols, and flame retardants.[208]

Second, Ecology must study each chemical and issue a report that identifies priority consumer products that are significant sources of contamination for those priority chemicals based off benchmarks such as units sold and volume of priority chemicals present in the consumer product.[209] The law exempts certain categories of products from designation, including plastic shipping pallets manufactured prior to 2012, food or beverages, tobacco products, drug or biological products regulated by FDA, Federal Aviation Administration- or U.S. Department of Defense (DOD)-certified or regulated products, motorized vehicles, and chemical products used to produce an agricultural commodity.[210]

Third, Ecology must present via a report to the legislature a set of proposed regulations that will increase transparency around those priority chemicals and reduce the use of priority chemicals in priority consumer products.[211] Potential regulatory enforcement actions may include no action, reporting requirements, or limitations on the manufacture, distribution, sale, use, or any combination thereof of a priority chemical or product that contains a priority chemical.[212] However, in order to issue a restriction, Ecology must first identify a safe, feasible, and available alternative for the identified product and the restriction must reduce a significant source or use of a priority chemical or be necessary to protect the health of sensitive populations or species.[213]

Fourth and finally, Ecology must develop and adopt regulations that implement the regulatory actions identified above.[214] Those regulations must undergo the standard notice-and-comment process as provided under state law. Any restrictions adopted by Ecology may be enforced through civil penalty authority.[215] The penalties are set at $5,000 for each violation in the case of a first offense and up to $10,000 for each repeat offense.[216]

Ecology has already begun the process to regulate PFAS added to certain products. The state legislature included PFAS among the first set of priority chemicals. Ecology went on to identify priority consumer products that contain PFAS in a June 2020 report.[217] Ecology ultimately designated carpets and rugs, indoor leather and textile furniture and furnishings, and aftermarket stain- and water-resistance treatments for leather and textile products.[218] In June 2022, Ecology released its report to the legislature on

200. *Id.* §108946.
201. *Id.* §109000.
202. *Id.* §108970.
203. *Id.* §108981.
204. Wash. Rev. Code Ann. §70A.350.020.
205. Washington Department of Ecology, *Safer Products for Washington*, https://ecology.wa.gov/Waste-Toxics/Reducing-toxic-chemicals/Safer-products (last visited Jan. 31, 2023).
206. Wash. Rev. Code Ann. §70A.350.040.
207. *Id.* §70A.350.020.
208. *Id.* §70A.350.010(12).
209. *Id.* §70A.350.030.
210. *Id.*
211. *Id.* §70A.350.040.
212. *Id.*
213. *Id.* §70A.350.040(3).
214. *Id.* §70A.350.050.
215. *Id.* §70A.350.070.
216. *Id.* §70A.350.070(1).
217. Washington Department of Ecology, Priority Consumer Products Report to the Legislature: Safer Products for Washington Implementation Phase 2 (2020), https://apps.ecology.wa.gov/publications/documents/2004019.pdf.
218. *Id.*

regulatory action determinations for the identified priority consumer products for PFAS.[219] The report identified a combination of restrictions and reporting requirements for priority products.[220] Ecology has since finalized its regulations to ban the manufacture, sale, and distribution of intentionally added PFAS in aftermarket stain- and water-resistant treatments and carpets and rugs by January 1, 2025; a ban on intentionally added PFAS in leather and textile furniture and furnishings intended for indoor use by January 1, 2026; and a reporting program for the use of PFAS in leather and textile furniture and furnishings intended for outdoor use by January 1, 2024.[221]

Ecology's rulemaking is only the first set of PFAS consumer product regulations that will be implemented under the Puget Sound Act. Washington has already begun to study the regulation of PFAS in several other product categories, including water-resistant clothing and gear, apparel, ski wax, car wax, floor sealants, nonstick cookware, personal care products, cosmetics, firefighter personal protective equipment (PPE), and several others.[222] As of this writing, Ecology is collecting stakeholder feedback.

D. *Maine: An Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution*

Maine's An Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution was passed into law on July 15, 2021. The Act originally required, beginning January 1, 2023, that a "manufacturer of a product for sale in the State that contains intentionally added PFAS shall submit to the [Maine Department of Environmental Protection (MDEP)] a written notification."[223] After much controversy, the timeline was delayed to January 1, 2025.[224] The written notification must include (1) a brief description of the product; (2) the purpose for including PFAS in the product; (3) the amount of each PFAS in the product or of total organic fluorine in the product; (4) the name and address of the manufacturer; and (5) any additional information established by rule.[225] If a manufacturer fails to provide this information, a person may not sell, offer for sale, or distribute for sale that product in Maine.[226] Further, the manufacturer may also be required to notify persons who sell, offer for sale, or distribute that product that the sale of the product is prohibited in Maine.[227]

Beyond notification requirements, the Act also restricts the sale, offer for sale, and distribution of various products containing PFAS. Effective January 1, 2023, a person may not sell, offer for sale, or distribute for sale in Maine a carpet or rug that contains intentionally added PFAS or a fabric treatment that contains intentionally added PFAS.[228] Further, effective January 1, 2030, a person may not sell, offer for sale, or distribute for sale in Maine *any product* that contains intentionally added PFAS, unless MDEP has determined by rule that the use of PFAS in the product is a "currently unavoidable use."[229] MDEP may determine that specific products or entire product categories present a "currently unavoidable use" through rulemaking.

The Act is unique due to both the scale and timeline of its requirements. The Act's reporting requirements encompass all products that contain any type of PFAS. Furthermore, the deadline for the requirements going into effect (originally January 1, 2023) was one of the first major requirements for manufacturers and sellers of PFAS products in the United States. Finally, the 2030 ban of selling, offering for sale, or distributing all products that contain intentionally added PFAS unless use is "currently unavoidable" is likely the most comprehensive restriction on PFAS to date. Manufacturers, distributors, and sellers of products that contain PFAS in Maine should be prepared to engage with the law and its restrictions. However, it is important to note that the Act does not apply to the sale or resale of used products.[230]

E. *Other State Regulations*

California, Washington, and Maine are not alone in their regulation of consumer products containing PFAS. Colorado adopted a state law that prohibits the sale of juvenile products, carpets or rugs, fabric treatments, food packaging, oil and gas products, cosmetics, and indoor and outdoor furnishings and furniture with intentionally added PFAS.[231] The same law also requires disclosures for cookware with intentionally added PFAS.[232] Minnesota and New York have each adopted a prohibition on intentionally added PFAS in food packaging.[233] Minnesota has also adopted a comprehensive Maine-like reporting framework,[234] while New York has a law prohibiting PFAS in apparel.[235] Vermont banned firefighting foam, PPE, food packaging, rugs, carpets, and ski wax with intentionally

219. Washington Department of Ecology Committees, Board, and Workgroups, *Safer Products for Washington*, https://www.ezview.wa.gov/site/alias__1962/37555/safer_products_for_washington.aspx (last visited Jan. 31, 2023).
220. *Id.*
221. Wash. Admin. Code ch. 173-337, https://ecology.wa.gov/DOE/files/34/34868dd6-a7ea-4944-814f-010df10dde99.pdf.
222. Priority Chemicals in Consumer Products—PFAS Chemicals, 2022 Wash. Sess. Laws 1921, https://lawfilesext.leg.wa.gov/biennium/2021-22/Pdf/Bills/Session%20Laws/House/1694-S.SL.pdf; Washington Department of Ecology, Per- and Polyfluoroalkyl Substances Chemical Action Plan (rev. 2022), https://apps.ecology.wa.gov/publications/documents/2104048.pdf.
223. Me. Rev. Stat. Ann. tit. 38, §1614(2)(A).
224. Public Law 2023, c. 138, An Act to Support Manufacturers Whose Products Contain Perfluoroalkyl and Polyfluoroalkyl Substances (LD 217, 131st Legislature).
225. *Id.*
226. *Id.* §1614(7).
227. *Id.* §1614(8)(B).
228. *Id.* §1614(5).
229. *Id.*
230. *Id.*
231. An Act Concerning Measures to Increase Protections From Perfluoroalkyl and Polyfluoroalkyl Chemicals, Colo. Rev. Stat. Ann. §§25-15-601 et seq.
232. *Id.* §25-15-604.
233. Minn. Stat. Ann. §325F.075; N.Y. Env't Conserv. Law §37-0209.
234. 2023 Minn. Laws Ch. 60.
235. N.Y. Env't Conserv. Law §37-0121 (S1322/AB994).

added PFAS.[236] The list of states continues to grow each legislative session.

V. Marketing Claims

Claims made regarding products containing PFAS or on their PFAS content must comply with federal and state law. Although there are no federal statutes that specifically regulate the marketing of products containing PFAS, the Federal Trade Commission (FTC) has provided guidance on environmental marketing claims through the agency's "Green Guides." Some states like California have gone further, effectuating their own state-specific rules on environmental marketing, including for products containing PFAS. This section reviews federal and state marketing rules with potential impacts on PFAS-containing products.

A. *FTC Guides for the Use of Environmental Marketing Claims*

Under federal law, marketers must ensure their representations are truthful, not misleading, and supported by a reasonable basis.[237] Section 5 of the Federal Trade Commission Act prohibits "unfair or deceptive acts or practices in or affecting commerce."[238] An unfair act or practice "causes or is likely to cause substantial injury to consumers," is not "reasonably avoidable by consumers themselves," and is "not outweighed by countervailing benefits to consumers or to competition."[239] Deceptive acts or practices include material misrepresentations that are likely to mislead customers acting reasonably under the circumstances.[240]

In 1992, the FTC published its Guides for the Use of Environmental Marketing Claims—known more commonly as the agency's Green Guides. The guidance contains general principles that apply to all environmental marketing claims, how consumers are likely to interpret particular claims and how marketers can substantiate those claims, and how marketers can qualify their claims to avoid deceiving consumers.[241] The Green Guides apply broadly to "environmental claims in labeling, advertising, promotional materials, and all other forms of marketing in any medium, whether asserted directly or by implication, through words, symbols, logos, depictions, product brand names, or any other means."[242] The Green Guides were last revised in 2012, and as of this writing, those remain the active guidance on environmental marketing representations.

The Green Guides outline several general principles for environmental marketing. First, qualifications and disclosures should be "clear, prominent, and understandable."[243] Second, unless it is clear from context, environmental marketing claims must specify whether the claim refers to the product, the product's packaging, a service, or just a portion of the product, package, or a service.[244] Third, the Green Guides discourage general claims of environmental benefits and distinguish between consumer-facing claims and environment-facing claims.[245] Consumer-facing claims are those referencing a benefit to the consumer, while environment-facing claims assert that the product confers some type of benefit onto the environment. Marketers must be clear about which type of benefit they are claiming: "marketers should not make unqualified general environmental benefit claims."[246] Moreover, all marketing claims must be supported by a "reasonable basis," which often will require "competent and reliable scientific evidence."[247]

Several categories of environmental marketing are addressed more specifically. For one, the Green Guides include rules on the use of environmental certifications and seals of approval.[248] According to the FTC, it is deceptive to misrepresent that a product, package, or service has been endorsed or certified by an independent third party. If there is a valid third-party certification, it must meet the criteria for endorsements provided in the agency's endorsement guides.[249] Additionally, third-party certification does not eliminate a marketer's obligation to ensure that it has substantiation for all claims reasonably communicated by the certification. Different certification regimes include different requirements for PFAS content—companies should review the chemical requirements of any particular certification to ensure compliance with that representation.

The Green Guides also address "free of" claims, specifying that it is deceptive to misrepresent that a product, package, or service is free of, or does not contain or use, some substance. Even if true, claims that an item is free of a substance may be deceptive if the product, package, or service contains or uses substances that pose the same or similar environmental risk as the substance not present, or the substance has never been associated with the product category.[250] On the other hand, a "free of" claim may be appropriate even for a product that contains or uses a trace amount of a given substance if (1) the level of the specified substance is no more than that which would be found as an acknowledged trace contaminant or background level; (2) the substance's presence does not cause material harm that consumers typically associate with that substance; and (3) the substance has not been added intentionally to the

236. Act No. 36 of 2021, 2021 Vt. Acts & Resolves No. 36.
237. FTC Policy Statement Regarding Advertising Substantiation (Appended to In re Thompson Med. Co., 104 F.T.C. 648 (1984)).
238. 15 U.S.C. §45(a)(1).
239. *Id.* §45(n).
240. Federal Trade Comm'n v. World Travel Vacation Brokers, Inc., 861 F.2d 1020, 1029 (7th Cir. 1988); Federal Trade Comm'n v. Tashman, 318 F.3d 1273, 1277 (11th Cir. 2003).
241. 16 C.F.R. §260.
242. *Id.* §260.1.
243. *Id.* §260.3(a).
244. *Id.* §260.3(b).
245. *Id.* §260.4.
246. *Id.* §260.4(b).
247. *Id.* §260.2.
248. *Id.* §260.6.
249. *Id.* §255.
250. *Id.* §260.9.

product.[251] The "free of" component of the Green Guides will pose particular challenges for PFAS chemicals. The ubiquity of PFAS may lead to the discovery of PFAS in products whether intentionally added or not. Consumer product manufacturers should ensure any claims are specific (do they apply to particular PFAS chemicals, or to all PFAS?), and should ensure they have substantiation for any claims through means like a testing program paired with supplier certifications.

In addition, the Green Guides contain rules on "non-toxic" claims, stating that it is deceptive to misrepresent that a product, package, or service is non-toxic.[252] Marketers making non-toxic claims should have competent and reliable scientific evidence that the product is non-toxic for humans and for the environment or should clearly and prominently qualify their claims to avoid deception. The current state of the science with regard to exposure from PFAS in consumer products is not well developed. In the absence of that kind of research base, consumer product manufacturers that make products containing PFAS may seek to avoid those kinds of claims.

On December 14, 2022, the FTC announced that it sought public comment on potential updates to the Green Guides, given "increasing consumer interest in buying environmentally friendly products."[253] Among other things, the FTC is interested in comments on claims about carbon offsetting and climate change, the terms "recyclable" and "recycled content," the terms "compostable" and "degradable," and other terms like "organic" and "sustainable." As the Green Guides evolve, they will almost certainly create additional limits on representations of products containing PFAS.

B. California Marketing Claim Laws

Some states have begun to regulate PFAS through new or existing product labeling standards for businesses. A prominent example is California. As described above, the state has already begun to integrate PFAS into the warning label regime created by Proposition 65. The state has also adopted a law that creates stringent requirements for the use of environmental marketing or labeling terms such as "environmentally friendly," "ecologically safe," or "green product."[254] The law also regulates the use of the triangular chasing-arrows symbol commonly associated with recycling as well as other recycling symbols.

In California, if a person or corporation wishes to display such terminology or symbology on the labeling or packaging of its consumer products, they must create and maintain records demonstrating the validity of such representations. All information and documentation maintained by individuals and companies pursuant to this regulation must be fully disclosed to the public and available upon request. In general, these records must include the following information:

- The reasons the person believes the representation to be true
- Any significant adverse environmental impacts directly associated with the production, distribution, use, and disposal of the consumer good
- Any measures that are taken by the person to reduce the environmental impacts directly associated with the production, distribution, and disposal of the consumer good
- Violations of any federal, state, or local permits directly associated with the production or distribution of the consumer good[255]

If the product involves any representation regarding recycling, the associated records must also document whether the product conforms with the standards laid out in the FTC Green Guides for the use of the terms "recycled," "recyclable," "biodegradable," "photodegradable," or "ozone friendly."[256] A violation of California's environmental marketing laws constitutes a misdemeanor punishable by imprisonment not to exceed six months, a fine not to exceed $2,500, or both.[257]

Beyond this general law, California has specifically targeted the marketing of PFAS-containing products. A product cannot be represented as recyclable if it is "made from plastic or fiber that contains perfluoroalkyl or polyfluoroalkyl substances or PFAS" that is either intentionally added by a manufacturer or detectable at or above 1,000 ppm, measured in TOF.[258] But California recognizes exceptions to these rules for products that are required by federal or California law to display a chasing-arrows symbol, as well as beverage containers subject to the California Beverage Container Recycling and Litter Reduction Act. As of 2021, PFAS-containing products also may not be marketed in California as "compostable" if they contain more than 100 ppm of TOF.[259] In addition, after January 1, 2023, cookware manufacturers will no longer be allowed to claim that their products are "PFOS-free" unless the products also do not contain any intentionally added substances from a broader list of PFAS designated by the state.[260]

251. *Id.* §260.9(c). "Trace contaminant" and "background level" are imprecise terms, although allowable manufacturing "trace contaminants" may be defined according to the product area concerned. What constitutes a trace amount or background level depends on the substance at issue and requires a case-by-case analysis. *Id.* §260.9(c) n.47.
252. *Id.* §260.10.
253. Guides for the Use of Environmental Marketing Claims, 87 Fed. Reg. 77766 (Dec. 20, 2022); Press Release, FTC, FTC Seeks Public Comment on Potential Updates to Its "Green Guides" for the Use of Environmental Marketing Claims (Dec. 14, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/12/ftc-seeks-public-comment-potential-updates-its-green-guides-use-environmental-marketing-claims.
254. Cal. Bus. & Prof. Code §17580.
255. *Id.* §17580(a).
256. *Id.* §17580.
257. *Id.* §17581.
258. *Id.* §17580(a)(6) (citing Cal. Pub. Res. Code §42355.51).
259. Cal. Pub. Res. Code §42357(g).
260. Cal. Health & Safety Code §109013.

California represents an important state for marketing purposes—but it is only one of many potential regulators that consumer product manufacturers must consider as they make marketing representations. Consumer product manufacturers should continue to monitor the development of state marketing requirements to ensure their representations comply with state and federal law alike.

VI. PFAS Products Litigation

For years, legal commentators have warned that lawsuits over PFAS would develop in the consumer products space. The first lawsuits related to PFAS contamination and exposure began nearly two decades ago. Those lawsuits were largely limited to water contamination linked to industrial PFAS production or use. However, 2022 saw a massive increase in the number of consumer products lawsuits filed related to PFAS.

Plaintiffs, including private class-action plaintiffs and nonprofits, are now targeting consumer product manufacturers and retailers that manufacture or sell products containing PFAS. A major part of this emerging litigation has been a development in the science surrounding PFAS. Advocates and scientists alike have worked in recent years to understand how to test for PFAS in products, and how PFAS in products can affect people and the environment.

New testing methodologies have been central to the recent development of consumer product litigation. Testing for PFAS has historically centered on chemical-by-chemical analysis that makes testing expensive and challenging in the context of a chemical family with thousands of members. Laboratories have started to use new testing methodologies to analyze levels of total fluorine (TF) or TOF as a proxy for PFAS content. These test methods have allowed advocates and consumers alike to approximately test for total PFAS content in consumer products. This relatively cost-effective test method has resulted in reports of fluorine found in food packaging,[261] yoga pants,[262] cosmetics,[263] sports bras,[264] rain jackets,[265] comforters,[266] pet food,[267] and a variety of other products.

Although fluorine can act as an approximation of PFAS content, fluorine identified from a sample may come from a variety of sources, including fluorinated tap water, contamination accrued during sample collection or during the laboratory testing process, as well as cross-contamination from products stored nearby, shared manufacturing equipment with PFAS-integrated products, or even decorations at the manufacturing facility. Fluorine also does not indicate which of the many PFAS chemicals the sample contains. Simply put, fluorine content can signal PFAS contamination, but it does not provide the full story.

Historically, PFAS exposure and attendant health impacts have been connected to ingestion of contaminated water and food, particularly near highly contaminated manufacturing or firefighting sites. New studies suggest potential human exposure pathways through inhalation of airborne PFAS particles, direct dermal transmission from prolonged skin contact, and ingestion of food stored in PFAS-containing food packaging.[268] A 2020 study on firefighter textiles demonstrated that firefighters may be exposed to PFAS due to dermal uptake in high-heat contexts.[269] Other studies show how PFAS-treated products that break down with consumer use can release PFAS into surrounding air, resulting in exposure risk.[270] These findings, however, remain in preliminary stages. There is still a clear need for more research regarding exposure pathways for PFAS, the attendant health effects related to those exposure levels, as well as studies that account for the thousands of members of the PFAS family.

The combination of tests that approximate PFAS content in products and studies that show potential pathways for PFAS exposure have spurred an increase in awareness, reporting, and advocacy around PFAS in products. There has also been a parallel rise in lawsuits against product manufacturers that use PFAS in their products or production processes, covering a diverse range of industries such as apparel, cosmetics, food service, paper products, feminine hygiene products, cleaning supplies, and dental products. In the past year alone, complaints have been filed against Clorox as parent company of Burt's Bees,[271]

261. Kevin Loria, *Dangerous PFAS Chemicals Are in Your Food Packaging*, Consumer Reps. (Mar. 24, 2022), https://www.consumerreports.org/pfas-food-packaging/dangerous-pfas-chemicals-are-in-your-food-packaging-a3786252074/.
262. *Investigation Finds Evidence of PFAS in Workout and Yoga Pants*, Env't Health News (Jan. 20, 2022), https://www.ehn.org/pfas-clothing-2656435785.html.
263. Whitehead et al., *supra* note 113.
264. *Evidence of PFAS Chemicals in Sports Bras*, Env't Health News (Feb. 2, 2022), https://www.ehn.org/pfas-clothing-2656531753.html.
265. Erika Schreder & Matthew Goldberg, Toxic-Free Future, Toxic Convenience: The Hidden Costs of Forever Chemicals in Stain- and Water-Resistant Products (2022), https://toxicfreefuture.org/wp-content/uploads/2022/08/toxic-convenience.pdf.
266. *Id.*
267. News Release, Environmental Working Group, New Tests Find Toxic "Forever Chemicals" in Pet Food Bags and Baby Textiles (Nov. 3, 2022), https://www.ewg.org/news-insights/news-release/2022/11/new-tests-find-toxic-forever-chemicals-pet-food-bags-and-baby.
268. Nicole M. DeLuca et al., *Human Exposure Pathways to Poly- and Perfluoroalkyl Substances (PFAS) From Indoor Media: A Systematic Review*, 162 Env't Int'l 107149 (2022); Amila O. De Silva et al., *PFAS Exposure Pathways for Humans and Wildlife: A Synthesis of Current Knowledge and Key Gaps in Understanding*, 40 Env't Toxicology & Chemistry 631 (2021), *available at* https://setac.onlinelibrary.wiley.com/doi/10.1002/etc.4935; Graham F. Peaslee et al., *Another Pathway for Firefighter Exposure to Per- and Polyfluoroalkyl Substances: Firefighter Textiles*, 7 Env't Sci. & Tech. Letters 594 (2020), *available at* https://pubs.acs.org/doi/abs/10.1021/acs.estlett.0c00410; Danish Environmental Protection Agency, Short-Chain Polyfluoroalkyl Substances (PFAS) (Allan Astrup Jensen et al. eds., 2015), https://www2.mst.dk/Udgiv/publications/2015/05/978-87-93352-15-5.pdf.
269. Peaslee et al., *supra* note 268; Danish Environmental Protection Agency, *supra* note 268.
270. Seung-Kyu Kim et al., *Indoor and Outdoor Poly- and Perfluoroalkyl Substances (PFASs) in Korea Determined by Passive Air Sampler*, 162 Env't Pollution 144 (2012); Bo Zhang et al., *Novel and Legacy Poly- and Perfluoroalkyl Substances (PFASs) in Indoor Dust From Urban, Industrial, and E-Waste Dismantling Areas: The Emergence of PFAS Alternatives in China*, 263 Env't Pollution 114461 (2020); Alicia J. Fraser et al., *Polyfluorinated Compounds in Serum Linked to Indoor Air in Office Environments*, 46 Env't Sci. & Tech. 1209 (2012), *available at* https://pubs.acs.org/doi/abs/10.1021/es2038257.
271. Class Action Complaint, Gruen v. Clorox Co., No. 3:22-cv-935 (N.D. Cal. Feb. 15, 2022) [hereinafter Class Action Complaint, *Gruen v. Clorox*].

Shiseido,[272] CoverGirl,[273] L'Oréal[274] McDonald's,[275] Kroger,[276] REI,[277] Keurig Dr. Pepper,[278] and many other companies. The rapid development of consumer products litigation could preview a true tidal wave to come.

Consumer products litigation so far has centered on two general types of legal claims: claims related to marketing, and claims related to personal injury. These are not entirely distinct categories, of course, but dividing claims this way may be analytically useful.

Marketing claim lawsuits include claims such as deceptive marketing, greenwashing allegations, negligent misrepresentation, unjust enrichment, and claims filed under state consumer protection laws. Claimants in these cases tend to focus on the economic harms related to purchasing those products as well as the impact the products have on the environment. Many lawsuits focus on marketing materials that represent the product as "natural"[279] or "chemical free" or "safe"[280] for particular populations, and then point to evidence of PFAS in the product as contradicting such claims. Others focus on greenwashing: alleged misrepresentations about products being "environmentally friendly" despite their containing fluorine or PFAS.[281] Still others are based on misrepresentation by omission—failing to disclose the presence of PFAS in a product and the risks posed by PFAS to human or animal health.[282] To ward off these kinds of claims, consumer product vendors should review their marketing practices to ensure that they do not create potential liability.

Personal injury claim lawsuits include claims such as failure to warn, design defect, breach of implied or express warranty, negligence, and other torts. Claimants in these cases tend to focus on the potential health and economic harms related to the product and attendant health exposures. On the merits, such claims will depend critically on the science related to PFAS detection, PFAS exposure from the product category, and PFAS health effects. Plaintiffs in these kinds of cases will have to show pathways of exposure and harm that may be difficult given the current status of the science.

Few consumer product lawsuits have gone beyond the complaint stage, but defense patterns have already begun to emerge in both marketing and personal injury cases. First, defendants have tended to argue lack of Article III standing. The common arguments are that plaintiffs lack an injury-in-fact because they have suffered neither an identifiable injury to health (given problems proving causation) nor a cognizable economic injury (given the lack of pleaded facts showing that the products purchased were worth less because of alleged PFAS contamination).[283] Along the same lines, defendants have asserted that alleged injuries, especially those proven by reference to third-party studies, are not sufficiently particularized because plaintiffs had not proven that the specific products *they* purchased were contaminated.[284]

272. Class Action Complaint, Onaka v. Shiseido Ams. Corp., No. 1:21-cv-10665 (S.D.N.Y. Dec. 14, 2021) [hereinafter Class Action Complaint, *Onaka v. Shiseido*].
273. Complaint, GMO Free USA v. CoverGirl Cosmetics, No. 2021 CA 004786B (D.C. Sup. Ct. Dec. 20, 2021).
274. Complaint for Damages, Davenport v. L'Oréal USA, Inc., No. 2:22-cv-1195 (C.D. Cal. Feb. 22, 2022).
275. Class Action Complaint, McDowell v. McDonald's Corp., No. 1:22-cv-01688 (N.D. Ill. Mar. 31, 2022).
276. Class Action Complaint, Ambrose v. Kroger Co., No. 3:20-cv-04009 (N.D. Cal. June 16, 2020) [hereinafter Class Action Complaint, *Ambrose v. Kroger*].
277. Class Action Complaint, Lupia v. Recreational Equip., Inc., No. 3:22-cv-02510 (N.D. Cal. Apr. 25, 2022) [hereinafter Class Action Complaint, *Lupia v. Recreational Equip*.].
278. Class Action Complaint, Walker v. Keurig Dr. Pepper, No. 2:22-cv-05557 (E.D.N.Y. Sept. 16, 2022).
279. *See* Class Action Complaint, Spindel v. Burt's Bees, Inc., No. 3:22-cv-01928 (N.D. Cal. Mar. 25, 2022) (alleging that skincare product company's advertisement of products as "100% natural" misled consumers into thinking products did not contain PFAS); Class Action Complaint, *Gruen v. Clorox*, *supra* note 271 (challenging company's representations: "KIND TO SKIN AND PLANET," "consciously crafted with ingredients from nature," and "[w]e formulate without phthalates, parabens, petrolatum, sodium lauryl sulfate (SLS) and other chemicals of concern"); Class Action Complaint, *Onaka v. Shiseido*, *supra* note 272 (challenging company's descriptions of PFAS-containing beauty products as "free of harsh chemicals and unnecessary additives," "rigorously safety tested," "pure," and "clean, conscious beauty that's good to your skin, good for the community and good for the planet").
280. Class Action Complaint, Clark v. McDonald's Corp., No. 3:22-cv-00628-NJR (S.D. Ill. Mar. 28, 2022) (challenging fast-food restaurant's representation that its food is safe, high-quality, and suitable for consumption); Class Action Complaint, Hussain v. Burger King Corp., No. 4:22-cv-02258-HSG (N.D. Cal. Apr. 11, 2022) (similar); Class Action Complaint, Rivera v. Knix Wear, Inc., No. 5:22-cv-02137-EJD (N.D. Cal. Apr. 4, 2022) (menstrual products marketed as "[f]ree from PFAS and other toxic chemicals," and "designed to be both safe and effective" alleged to contain PFAS); Complaint for Damages, Brown v. CoverGirl Cosmetics, No. 1:22-cv-02696 (S.D.N.Y. Apr. 1, 2022) (similar with respect to beauty products); Class Action Complaint, Galarsa v. Astral Health & Beauty Inc., No. 4-22-cv-07020 (N.D. Cal. Nov. 9, 2022) (similar); Class Action Complaint, Ruiz v. Conagra Brands, Inc., No. 1:22-cv-02421 (N.D. Ill. May 6, 2022) (microwave popcorn allegedly containing PFAS advertised as containing "only real ingredients"); Class Action Complaint, Richburg v. Conagra Brands, Inc., No. 1:22-cv-02421 (N.D. Ill. May 6, 2022) (same).
281. Class Action Complaint, *Lupia v. Recreational Equip*., *supra* note 277 (challenging representations of apparel allegedly containing PFAS as "sustainable" and "Fair Trade Certified"); Class Action Complaint, Nguyen v. Amazon.com, No. 4:20-cv-04042 (N.D. Cal. June 17, 2020) (claiming disposable tableware allegedly containing PFAS was fraudulently advertised as "compostable"); Class Action Complaint, *Ambrose v. Kroger*, *supra* note 276 (similar).
282. Class Action Complaint, Humphrey v. J.M. Smucker Co., No. 1:22-cv-06913 (N.D. Cal. Nov. 4, 2022) (omissions about PFAS in pet food allegedly breached reasonable consumer's expectations).
283. *E.g.*, Motion to Dismiss at 9-12, Onaka v. Shiseido, No. 1:21-cv-10665 (S.D.N.Y. June 2, 2022) [hereinafter Motion to Dismiss, *Onaka v. Shiseido*] ("buyer's remorse does not confer Article III standing"); Motion to Dismiss at 7-9, McDowell v. McDonald's Corp., No. 1:22-cv-01688 (N.D. Ill. Aug. 12, 2022) [hereinafter Motion to Dismiss, *McDowell v. McDonald's*] (arguing plaintiffs' injuries were "hypothetical" because plaintiffs "ate the menu items and allege no physical injury"); Motion to Dismiss at 8-12, Solis v. CoverGirl Cosmetics, No. 3:22-cv-00400 (S.D. Cal. May 25, 2022) [hereinafter Motion to Dismiss, *Solis v. CoverGirl*] ("Plaintiff apparently wishes she had not purchased the Product, but such purchasing remorse does not confer Article III standing."). *But see* Order Granting in Part and Denying in Part Motion to Dismiss First Amended Complaint at 9-10, Kanan v. Thinx Inc., No. 2:20-cv-10341 (C.D. Cal. June 23, 2021) (holding Article III standing was plausibly alleged by economic injury based on buying or overpaying for PFAS-contaminated product).
284. Motion to Dismiss at 12-14, Brown v. CoverGirl Cosmetics, No. 1:22-cv-02696 (S.D.N.Y. July 26, 2022) [hereinafter Motion to Dismiss, *Brown v. CoverGirl*]; Motion to Dismiss at 10-12, Clark v. McDonald's Corp., No. 3:22-cv-00628-NJR (S.D. Ill. June 1, 2022) [hereinafter Motion to Dismiss, *Clark v. McDonald's*].

Second, defendants that are regulated by FDA have consistently argued that FDA should take the primary role in regulating PFAS. Such an argument can be framed through preemption,[285] primary-jurisdiction,[286] or safe-harbor[287] defenses. Although they arise under different legal theories, these arguments all urge dismissal of the complaint because FDA has been tasked with the primary duty of regulating food, drugs, and cosmetics and because the defendants have purportedly complied with all extant FDA regulations.

Third, product manufacturers have attacked the methodologies plaintiffs use to attempt to prove PFAS contamination. Such attacks often go to both Article III standing and the merits of causation and damages. Some defendants have contested allegations of PFAS content that rely on the product's TF or TOF content as a proxy for PFAS.[288] As described above, TF and TOF provide an indication of fluorine content within a given sample, no matter the source. Those measurements also cannot provide plaintiffs with a look at what *particular* PFAS are in a given sample. And even when a plaintiff identifies a particular PFAS beyond general allegations of fluorine content, manufacturers may contest whether any research has been conducted on the particular PFAS at issue, and whether that PFAS has been shown to be harmful. Because only certain PFAS have been proven to be toxic to humans, plaintiffs may have an uphill battle obtaining evidence of causation or harm.[289]

Relatedly, manufacturers have emphasized the lack of research regarding both the exposure pathways that could be argued for the manufacturer's product and the attendant health effects of that level of exposure.[290] Exposure research remains in its early stages outside the drinking water arena. As a result, it may be difficult for plaintiffs to show how much PFAS people can uptake from a given product.

Marketing and personal injury claims also each present unique challenges to plaintiffs. Marketing claims are generally subject to a heightened pleading standard, as claims "sounding in fraud" must be stated with particularity under Federal Rule of Civil Procedure 9(b).[291] In conjunction with the aforementioned difficulties in proving causation or harm, this heightened pleading standard could be quite difficult to overcome.[292] Another common refrain by defendants is that their marketing statements were too general to mislead a reasonable consumer about their products' PFAS content.[293]

In the personal injury realm, defendants have responded to failure-to-warn claims with resort to three major arguments: that the defendant had no duty to disclose the presence of PFAS in its products; that there was no danger to disclose, in any event; and that purely economic losses are not actionable in tort.[294] Defendants have responded to the rarer breach-of-warranty claims by pointing out that the products at issue were fit for ordinary use, that no express promises were unfulfilled, and that any promises were mere puffery.[295]

Consumer product litigation remains in the relatively early stages. As these cases continue to develop, it will become more clear what kinds of liabilities companies that manufacture products with PFAS will face. It may depend on the particular circumstances of the lawsuit: the product at issue, the scientific research, the PFAS at issue, and the company's representations of their product. Considering the ubiquity of PFAS in consumer products, there is a potentially expansive set of manufacturers and retailers to test such claims.

VII. AFFF

AFFF is one of the most well-understood sources of PFAS contamination in the United States. AFFF utilizes PFAS as a key ingredient to effectively smother the surface of fuel fires with a thin layer of foam. The foam layer also prevents the release of vapor that would otherwise ignite.[296] It is a unique PFAS product that deserves its own special attention here.

AFFF is a recurring and pervasive source of groundwater contamination at military, airport, and industrial sites,

285. Motion to Dismiss at 11-14, Hicks v. L'Oréal USA, Inc., No. 1:22-cv-01989 (S.D.N.Y. June 24, 2022) (arguing FDCA preempts any state-law claim that would impose a labeling requirement on cosmetics not present in federal law).
286. *Id.* at 14-17; *see also* Syntek Semiconductor Co. v. Microchip Tech. Inc., 307 F.3d 775, 780 (9th Cir. 2002) (explaining prudential doctrine of primary jurisdiction).
287. Motion to Dismiss, *McDowell v. McDonald's*, *supra* note 283, at 25-26 (arguing that under safe-harbor doctrine fast-food company could not be liable when substances used in packaging were permitted under state and federal law); *see also* Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co., 973 P.2d 527, 541 (Cal. 1999) (under California safe-harbor doctrine, "[i]f the Legislature has permitted certain conduct or considered a situation and concluded no action should lie, courts may not override that determination").
288. Motion to Dismiss, Andrews v. Procter & Gamble Co., No. 5:19-cv-00075 (C.D. Cal. Apr. 18, 2019) [hereinafter Motion to Dismiss, *Andrews v. Procter & Gamble*]; Motion to Dismiss at 11-15, Rivera v. Knix Wear, Inc., No. 5:22-cv-02137 (N.D. Cal. June 10, 2022) (faulting plaintiffs for basing standing and claims on third-party study that merely found fluorine in company's menstrual products).
289. Motion to Dismiss, *Brown v. CoverGirl*, *supra* note 284, at 20; Motion to Dismiss at 15, Hamman v. Cava Grp. Inc., No. 5:19-cv-00075 (C.D. Cal. July 14, 2022) [hereinafter Motion to Dismiss, *Hamman v. Cava*]; Motion to Dismiss, *Onaka v. Shiseido*, *supra* note 283, at 11-12; Order Granting Motion to Dismiss, GMO Free USA v. Coty Inc., No. 2021 CA 004786 B (D.C. Sup. Ct. June 1, 2022) [hereinafter Order Granting Motion to Dismiss, *GMO Free USA v. Coty*].
290. Motion to Dismiss, *Andrews v. Procter & Gamble*, *supra* note 288, at 7-8 (faulting plaintiff for failing to show exposure pathway for alleged PFAS in floss).
291. *See* Ackerman v. Northwestern Mut. Life Ins. Co., 172 F.3d 467, 469 (7th Cir. 1999) (Rule 9(b) requires a "plaintiff to allege the who, what, where, and when of the alleged fraud," and the plaintiff must "conduct a pre-complaint investigation in sufficient depth.").
292. *See*, *e.g.*, Motion to Dismiss, *Clark v. McDonald's*, *supra* note 283, at 17-21 (asserting complaint did not meet Rule 9(b) requirements because it did not name any specific PFAS compound or allege specific reliance on any representation).
293. Order Granting Motion to Dismiss, *GMO Free USA v. Coty*, *supra* note 289, at 6 (holding defendants' generic statements about "philosophy and aspirations" could not "plausibly be interpreted as a representation that none of their products contains any PFAS chemical").
294. Motion to Dismiss, *Solis v. CoverGirl*, *supra* note 283, at 21.
295. Motion to Dismiss, *Hamman v. Cava*, *supra* note 289, at 20; Motion to Dismiss, *Solis v. CoverGirl*, *supra* note 283, at 22-23.
296. Sharon Lerner, *The U.S. Military Is Spending Millions to Replace Toxic Firefighting Foam With Toxic Firefighting Foam*, Intercept (Feb. 10, 2018), https://theintercept.com/2018/02/10/firefighting-foam-afff-pfos-pfoa-epa/.

and in adjacent communities. As a result, it has spawned its own set of statutes, regulations, and litigation unique to the product. For now, airports and military bases have been the primary focus of Congress' and agencies' AFFF regulations, as drinking water wells and groundwater supplies on and around these locations are at particular risk for PFAS contamination. Other industries impacted by historical AFFF use include the oil and gas sector, marine facilities, mining properties, and other industrial sectors with special firefighting needs. States have begun to regulate the use and disposal of AFFF. This section provides an overview of federal law and regulations, state regulations, and litigation surrounding AFFF.

A. *Federal Law and Regulations*

Congress has sought to reduce the use of AFFF by the military in several ways—largely through the annual defense funding bills. The FY20 NDAA mandates the phaseout of fluorinated AFFF at all military sites as soon as the Secretary of Defense deems it possible, but no later than October 1, 2024.[297] There is an exception to this prohibition for ocean-going vessels, and the Secretary of Defense may seek a time-limited waiver of the prohibition after informing Congress and notifying the public. Moreover, the law prohibits uncontrolled releases of fluorinated AFFF at military installations except in emergencies, and fluorinated AFFF may not be used for training exercises.[298]

By their terms, these provisions apply only to military facilities on property owned by the federal government—civilian facilities are not included. But more recent congressional actions have grown beyond the phaseouts in military use, with several implications for non-military entities.[299] Through the FY20 NDAA, Congress has funded the identification and development of PFAS-free firefighting alternatives, as well as studies on the impacts of the military's AFFF use on human health in surrounding communities. The law also mandated that DOD test for PFAS at military sites across the country, providing $500 million for the project. And the Act established a temporary moratorium on the incineration of AFFF and other materials containing PFAS until EPA promulgates guidance or a rule on proper PFAS disposal methods—this moratorium covers any incinerator receiving AFFF waste originating from DOD, whether directly or indirectly.

Beyond congressional directives, DOD and individual branches of the military have regulated AFFF and PFAS through department- and branch-specific internal policies. In 2020, DOD created departmentwide reporting requirements for AFFF usage and spills.[300] The U.S. Air Force has instructed its bases since 2016 to "halt routine, daily operational checks and testing of the foam discharge systems on Air Force firefighting vehicles, unless the resulting effluent can be contained and managed in a safe, environmentally-protective manner."[301] And the U.S. Army has issued guidance on removing and disposing of AFFF.[302]

The historical use of AFFF at military facilities and the affirmative responsibility to search for PFAS contamination will almost certainly create a data set of contaminated military sites. Significant federal liability for historical releases of AFFF into the environment will likely arise soon at those sites. When EPA finalizes its proposed rule designating PFOA and PFOS as hazardous substances under CERCLA,[303] the United States will be on the hook—through affected communities' cost-recovery actions—for PFOS and PFOA contamination resulting from military installations' discharges of AFFF.

B. *State Regulations*

Given the federal government's relatively limited response to AFFF contamination, a significant number of states have attempted to fill the gap with their own regulations. As of January 2022, 33 states have either issued or proposed regulations of PFAS in firefighting foams, firefighting clothing, and firefighting equipment.[304] At least 12 states have limited or banned AFFF use in some way.

Washington, where firefighting foam is the suspected source of all PFAS contamination in the state's drinking water,[305] was one of the first states to restrict the use of AFFF in 2018.[306] Colorado, Georgia, Kentucky, New Hampshire, and Virginia all followed suit in 2019.[307] The most common type of state regulation simply prohibits the use of AFFF that contains intentionally added PFAS for testing or training. However, many of these laws allow continued use of AFFF in emergency firefighting situations or if the facility has proper containment methods in place. There are varied approaches to regulating the manufacture, sale, or distribution of foam. While some states have included a phaseout for such practices along with AFFF usage in general, others do not currently prohibit AFFF manufacture or distribution even if they have passed bans on usage.

297. Pub. L. No. 116-92, §322, 133 Stat. 1307-09.
298. *Id.* §§323-324, 133 Stat. at 1309-10.
299. *Id.* §§341-349, 135 Stat. at 1640-50.
300. Memorandum From Peter J. Potochney, Acting Assistant Secretary of Defense, DOD, to Assistant Secretary of the Army (Installations, Energy, and Environment) et al., Re: Aqueous Film Forming Form Usage and Spill Reporting (Jan. 13, 2020), https://www.navfac.navy.mil/Portals/68/Documents/Business-Lines/Environmental/Environmental-Restoration/NAVFAC-Southeast/Whiting-Field-NAS/AQUEOUS-FILM-FORMING-FOAM-USAGE-AND-SPILL-REPORTING.PDF.
301. Memorandum From Miranda A.A. Ballentine, Assistant Secretary, U.S. Air Force, Re: SAF/IE Policy on Perfluorinated Compounds (PFCs) of Concern (Aug. 11, 2016).
302. Memorandum From Mary Williams-Lynch, Chief of Environmental Programs, U.S. Army, Re: Aqueous Film Forming Foam (AFFF), Removal, and Disposal—Corrected (Mar. 25, 2019).
303. U.S. EPA, *Proposed Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances*, https://www.epa.gov/superfund/proposed-designation-perfluorooctanoic-acid-pfoa-and-perfluorooctanesulfonic-acid-pfos (last updated Nov. 2, 2022).
304. For a comprehensive list, see Appendix A in the *PFAS Deskbook*.
305. Washington Department of Ecology, *Per- and Polyfluoroalkyl Substances (PFAS)*, https://ecology.wa.gov/Waste-Toxics/Reducing-toxic-chemicals/Addressing-priority-toxic-chemicals/PFAS (last visited Jan. 31, 2023).
306. Wash. Rev. Code Ann. §§70A.400.010, 70A.400.020.
307. Colo. Rev. Stat. §§24-33.5-1234, 25-5-1303; Ga. Code Ann. §25-2-41; Ky. Rev. Stat. Ann. §227.395; N.H. Rev. Stat. §154:8-b; Va. Code Ann. §9.1-207.1.

Many states have implemented reporting regimes for the use or discharge of AFFF. States that have implemented those requirements include California, Colorado, Illinois, Maine, Michigan, Minnesota, Nevada, and New Hampshire.[308] But only a few states have adopted regulations to govern the proper disposal of AFFF. For example, Illinois specifies that disposal is improper if done by flushing, draining, or otherwise discharging into ditches, waterways, storm drains, or sanitary sewers.[309] Maryland prohibits disposal by incineration.[310]

Some states have implemented collection or recall programs for AFFF. Colorado, Connecticut, Indiana, Michigan, New Hampshire, New York, and Vermont have collection or take-back programs.[311] Hawaii, Maine, New York, Vermont, and Washington require manufacturers to recall prohibited AFFF products and reimburse the retailer or purchaser.[312]

PPE such as turnout gear worn by firefighters frequently includes PFAS for heat and fire resistance. Although separate from AFFF, regulation of PPE has been implemented in tandem with AFFF regulation. Many states require PPE sellers to provide the purchaser with written notice that the equipment contains intentionally added PFAS. These types of regulations can be found in California, Colorado, New Hampshire, New York, Vermont, and Washington.[313]

Civil penalties are a frequent feature of states' AFFF regulations. Most regulations with penalties impose no more than a $5,000 fine for the first violation and no more than $10,000 for subsequent violations. California, Colorado, Hawaii, Illinois, New Hampshire, New York, and Washington all adopted this civil penalty structure.[314] Maryland has a more lenient penalty of only $500 for the first violation and no more than $1,000 for subsequent violations.[315] A person in Nevada is guilty of a misdemeanor for a violation.[316] In some other states, like Vermont, a violation of the AFFF regulations constitutes a violation of the state's consumer protection law.[317]

Appendix A in the *PFAS Deskbook* contains a table that provides a comprehensive summary of the various state regulations, up to date as of May 2023. The fast growth of state regulations highlights the widespread impacts and growing concern over drinking water contamination from AFFF throughout the United States.

C. *AFFF Lawsuits*

AFFF has been a focal point for ongoing PFAS products litigation. Litigation has so far targeted mainly manufacturers of PFAS chemicals, but plaintiffs have also targeted users of AFFF like the U.S. military. Any entity that has dealt with AFFF—ranging from use to storage, discharge, and disposal—may be at risk for future legal liability.

1. AFFF Manufacturers

Perhaps the most prominent litigation involving AFFF are the thousands of cases arising from AFFF-contaminated groundwater. In 2018, these cases were consolidated with the multidistrict litigation (MDL) mechanism. MDLs are designed to "promote the just and efficient conduct" of pretrial proceedings through economies of scale.[318] The MDL's presiding judge can manage common discovery, prevent wasteful duplication of effort, and create general conditions and opportunities for advancing information exchange to facilitate parties' assessments of the strengths and weaknesses of their cases. Moreover, the MDL court can conduct bellwether trials that create data points based on real jury results, which may help inform settlement negotiations.[319]

Plaintiffs began filing groundwater contamination cases against PFAS and AFFF manufacturers by September 2016. In one of the earliest filed cases, three residents living near Peterson Air Force Base just east of Colorado Springs, Colorado, brought a federal suit against 3M, Ansul Company, and National Foam, Inc.[320] The plaintiffs alleged that the defendants had for decades manufactured and sold AFFF to the Air Force, including Peterson Air Force Base, causing PFAS contamination of drinking water in the area. The plaintiffs further alleged that the defendants "knew or should have known that the inclusion of [PFAS chemicals] in AFFF presented an unreasonable risk"; that PFAS "are highly soluble in water, and highly mobile and highly persistent in the environment, and highly likely to contaminate water supplies if released to the environment"; and that the defendants "marketed and sold their products with knowledge that large quantities of toxic AFFF

308. Cal. Health & Safety Code §13061(b)(7); Colo. Rev. Stat. Ann. §25-5-1303.5; 415 Ill. Comp. Stat. 170/15; Me. Rev. Stat. Ann. tit. 38, §424-C(3); Mich. Comp. Laws §324.14703; Minn. Stat. §325F.072(2); Nev. Rev. Stat. §459.684; N.H. Rev. Stat. §154:8-b(XI).

309. 415 Ill. Comp. Stat. 170/30.

310. Md. Code Ann., Env't §6-1604.

311. Colo. Rev. Stat. Ann. §25-5-1311; Conn. Gen. Stat. Ann. §22a-903a(c); Indiana Department of Homeland Security, *Foam Collection Program: Indiana Class B PFAS Foam Collection Initiative*, https://www.in.gov/dhs/fire-and-building-safety/division-of-fire-and-building-safety-overview/foam-program/ (last visited Jan. 31, 2023); Mich. Comp. Laws §324.14705; N.H. Rev. Stat. §154:8-b(VIII); New York Department of Environmental Conservation, *Per- and Polyfluoroalkyl Substances (PFAS)*, https://www.dec.ny.gov/chemical/108831.html (last visited Jan. 31, 2023); Vermont Agency of Natural Resources, *State Partners With Local Fire Departments to Safely Get Rid of Toxic Fire-Fighting Foam*, https://anr.vermont.gov/node/1276 (last visited Jan. 31, 2023).

312. Haw. Rev. Stat. §321-604(b); Me. Rev. Stat. Ann. tit. 38, §424-C(5); N.Y. Gen. Bus. Law §391-u(4)(b); Vt. Stat. Ann. tit. 18, §1665; Wash. Rev. Code Ann. §70A.400.040(2).

313. Cal. Health & Safety Code §13029; Colo. Rev. Stat. Ann. §25-5-1305; N.H. Rev. Stat. §154:8-c; N.Y. Gen. Bus. Law §391-u(5); Vt. Stat. Ann. tit. 18, §1664; Wash. Rev. Code Ann. §70A.400.030.

314. Cal. Health & Safety Code §13029; Colo. Rev. Stat. Ann. §25-5-1307; Haw. Rev. Stat. §321-604(d); 415 Ill. Comp. Stat. 170/35; N.H. Rev. Stat. §154:8-b(V); N.Y. Gen. Bus. Law §391-u(7); Wash. Rev. Code Ann. §70A.400.060.

315. Md. Code Ann., Env't §6-1605.

316. Nev. Rev. Stat. §459.682.

317. Vt. Stat. Ann. tit. 18, §1667.

318. 28 U.S.C. §1407(a).

319. Manual for Complex Litigation (Fourth) §22.315 (2004).

320. Jakob Rodgers & Tom Roeder, *McDivitt Files for Class Action on Second Drinking-Water Lawsuit*, Gazette (Mar. 4, 2019), https://gazette.com/news/mcdivitt-files-for-class-action-on-second-drinking-water-lawsuit/article_bd2aa021-02ea-5533-ae6c-faeaf62cc7d2.html.

would be used in training exercises and in emergency situations at Air Force bases in such a manner that dangerous chemicals would be released into the environment."[321] The claims included negligence, product defect (including failure to warn and design defect), and unjust enrichment, with compensatory damages sought for loss of property value, cost of property remediation, provision of alternative water supplies, and loss of enjoyment. Dozens more similar cases—including many brought by water utilities and local governments—were filed over the next two years.

In December 2018, the U.S. Judicial Panel on Multidistrict Litigation, at the request of foam manufacturers Tyco Fire Products and Chemguard, Inc., consolidated 75 actions, including the Colorado suit discussed above, in an MDL.[322] Although these cases differed based on plaintiff identity, class-action posture, and type of claim, the panel noted that "[i]n each of these actions, plaintiffs allege that AFFF products used at airports, military bases, or certain industrial locations caused the release of PFOA or PFOS into local groundwater and contaminated drinking water supplies."[323] Furthermore, "[w]ith some minor variations, the same group of AFFF manufacturer defendants is named in each action" and many "likely will assert identical government contractor defenses."[324] At bottom, each case "involve[d] the same mode of groundwater contamination caused by the same product," so centralization was proper. Notably, the panel declined to include in the MDL several cases that concerned PFAS-contamination pathways other than the AFFF-groundwater pathway.

The panel consolidated the cases in the District of South Carolina, in MDL No. 2873, under presiding Judge Richard M. Gergel. As of January 12, 2023, the MDL comprises almost 3,474 cases, making it the 12th largest MDL in the United States.[325] Those cases involve nearly 15,000 plaintiffs, including individuals, local governments, states, tribes, water districts, airports, companies, and colleges. The approximately 200 defendants include suppliers of precursor chemicals, manufacturers, distributors, and government actors such as the Air Force, Army, and U.S. Navy.

The plaintiffs in the MDL cleared some important pretrial hurdles. In November 2021, the defendants moved for partial summary judgment on the government contractor defense. That defense confers immunity on a federal contractor when the contractor's provision of military equipment conforms with the United States' reasonably precise specifications, and the contractor otherwise warned the United States of any known dangers associated with the equipment.[326] In their motion, the defendants claimed that the federal government issued precise specifications for a specific type of AFFF (MilSpec AFFF) and that defendants manufacturing this AFFF should be protected from state tort liability. In September 2022, Judge Gergel rejected their assertion of the government contractor defense.[327] The court observed that the MilSpec AFFF was not so precise that it dictated that PFOS or PFOA be used as ingredients in the foam, and that defendants had withheld information from the federal government about AFFF's health risks.

The first bellwether case, a suit brought by the city of Stuart, Florida, against 3M, was selected in October 2022; the trial was set for June 2023.[328] On the eve of trial, both 3M and DuPont announced proposed settlements with drinking water plaintiffs.[329] The combined settlements reach nearly $12 billion—one of the largest environmental settlements in history.[330] As of this writing, the settlements are pending resolution with the MDL judge.

Few cases from the MDL have fully settled to date. In August 2021, a final order settled the suit brought by several hundred residents of Peshtigo, Wisconsin, against Tyco Fire Products and two other affiliated AFFF manufacturers.[331] Plaintiffs claimed they were exposed to PFAS through drinking water wells near a Tyco Fire Technology Center that routinely used firefighting foam. The settlement agreement provided for a total settlement amount of $15 million, $11 million for property value diminution and $4 million for drinking water exposure to PFAS; the final settlement approved by the court did not resolve personal injury claims for individuals suffering from diseases traceable to PFAS in the drinking water.[332] The settlement administrator received 499 property and 1,109 exposure claims prior to the claim deadline. Estimated payments range from $1,000, for a former resident exposed to PFAS in drinking water, to $65,000, for a current property owner with total PFAS concentration in drinking water of more than 70 ppt.[333]

2. DOD

A separate set of lawsuits in the MDL implicates the U.S. military as a defendant along with AFFF or PFAS manu-

321. Fifth Amended Class Action Complaint, Bell v. 3M Co., No. 18-3366 (D.S.C. Sept. 25, 2020).
322. Transfer Order, In re Aqueous Film-forming Foams Prods. Liab. Litig., MDL No. 2873 (J.P.M.L. Dec. 7, 2018), https://www.jpml.uscourts.gov/sites/jpml/files/MDL-2873_Initial_Transfer%2011-18.pdf.
323. *Id.* at 3.
324. *Id.*
325. U.S. Judicial Panel on Multidistrict Litigation, Joint Status Report for December 22, 2022, Case Management Conference (2022).
326. *See generally* Boyle v. United Techs. Corp., 487 U.S. 500 (1988).
327. Order and Opinion, In re Aqueous Film-Forming Foams Prods. Liab. Litig., MDL No. 2:18-mn-2873-RMG (D.S.C. Sept. 16, 2022).
328. Sixth Amended Scheduling Order Governing First Water Provider Bellwether Trial, In re Aqueous Film-Forming Foams Prods. Liab. Litig., MDL No. 2:18-mn-2873-RMG (D.S.C. Oct. 24, 2022).
329. *See* Lisa Friedman & Vivian Giang, *3M Reaches $10.3 Billion Settlement in 'Forever Chemicals' Suits*, N.Y. Times (June 22, 2023), https://www.nytimes.com/2023/06/22/business/3m-settlement-forever-chemicals-lawsuit.html.
330. *See id.*
331. Final Order and Judgment of Dismissal With Prejudice, In re Aqueous Film-Forming Foams Prods. Liab. Litig., MDL No. 2:18-mn-2873-RMG (D.S.C. Aug. 4, 2021), https://www.firefightingfoamsettlement.com/wp-content/uploads/2021/08/Campbell-Final-Order-and-Judgment.pdf.
332. *Id.*; Fourth Amended Class Settlement and Release Agreement, In re Aqueous Film-Forming Foams Prods. Liab. Litig., MDL No. 2:18-mn-2873-RMG (D.S.C. July 26, 2021), https://www.firefightingfoamsettlement.com/wp-content/uploads/2021/08/2021.07.26-FINAL-FOURTH-AMENDED-Campbell-Settlement-Agreement.pdf.
333. Status Report From the Settlement Administrator at 8, In re Aqueous Film-Forming Foams Prods. Liab. Litig., MDL No. 2:18-mn-2873-RMG (D.S.C. Mar. 31, 2022), https://www.firefightingfoamsettlement.com/wp-content/uploads/2022/04/Campbell-Class-Status-Report.pdf.

facturers. Military installations started using AFFF in the 1970s as a firefighting agent to extinguish chemical fires or spills in emergency situations, training exercises, and hangar system operations. Despite ongoing efforts to replace PFAS-based AFFF with nonfluorinated alternatives, DOD continues to use AFFF in emergency response situations because "[n]o fluorine-free foam has proved it can meet military specifications to protect DOD Service members by rapidly extinguishing dangerous fuel fires."[334] But DOD represents it is "actively seeking an alternative that can meet this critical safety need."[335]

The majority of lawsuits in the AFFF MDL target manufacturers and distributors of PFAS and AFFF. As a result of its past and present use of AFFF, DOD now faces lawsuits from private individuals, states, and water utilities for alleged PFAS contamination stemming from AFFF use, storage, and disposal. As of January 2023, 27 of the suits in the MDL name a federal entity as a defendant.[336] These suits began as early as 2016, when residents living near the Willow Grove Naval Air Station Joint Reserve Base and former Naval Air Warfare Center, close to Philadelphia, filed two state lawsuits against the Navy, asserting that disposal of AFFF at the facilities violated Pennsylvania's hazardous site cleanup law.[337] The cases were removed to federal court and consolidated. The Navy invoked CERCLA §113(h), which strips federal courts of jurisdiction to hear a "challenge" to a "removal or remedial action."[338]

The U.S. Court of Appeals for the Third Circuit held that the plaintiffs' requested health assessments and community-health studies were barred because they would interfere with ongoing CERCLA cleanups, but the court held that the plaintiffs' requests for medical monitoring costs could proceed. In so holding, the court determined that sovereign immunity did not bar the plaintiffs from seeking medical monitoring costs because an order for such costs amounted to equitable relief, for which the federal government has waived immunity under RCRA.[339] On remand, the district court ultimately dismissed the case, finding that because PFAS were not designated hazardous substances under state law, there was no release of hazardous substances under the state cleanup law.[340]

Later cases against DOD have been added into the above-mentioned AFFF MDL. For instance, in March 2019, New Mexico filed a lawsuit against the United States in the District of New Mexico concerning PFAS contamination at Cannon Air Force Base and Holloman Air Force Base.[341] The state alleged that the Air Force violated New Mexico's hazardous waste law through its "past and present handling, storage, treatment, transportation, and/or disposal of solid or hazardous waste which has or may present an imminent and substantial endangerment to health and/or the environment."[342] New Mexico's complaint seeks, among other things, injunctive relief to abate and remediate the PFAS contamination, civil penalties, and payment of the state's oversight costs at the cleanup sites. In June 2020, the case was transferred to the AFFF MDL over New Mexico's objections; the state unsuccessfully tried to distinguish its case on the grounds that it had neither asserted claims against manufacturers nor made allegations implicating the government contractor defense.[343]

Suits against DOD over AFFF may face unique obstacles. The Federal Tort Claims Act (FTCA) waives federal sovereign immunity for tort claims against the federal government that allege personal injury or property damages caused by the negligent acts or omissions of federal employees and officers.[344] But the FTCA's waiver of the United States' immunity is limited; for one, the law bars recovery for injuries resulting from the government's exercise of a "discretionary function."[345] The types of damages a plaintiff can recover may also be restricted in an FTCA suit.[346] Moreover, a plaintiff must comply with a series of procedural requirements before initiating an FTCA suit, such as giving the government an initial opportunity to evaluate the plaintiff's claim and to decide whether to settle before the case proceeds to federal court.[347] And as to claims other than FTCA claims, a variety of complex jurisdictional and immunity-based defenses may arise when federal defendants are involved—for example, as mentioned, CERCLA §113(h) and federal sovereign immunity.[348] If cases are not dismissed on summary judgment in the MDL, it may be many years before these cases complete their journey through the court system.

VIII. Conclusion

PFAS pose a unique challenge in consumer products. Emerging contaminants tend to be concentrated in particular product classes or categories to achieve a limited range of functions. As a result, they can be replaced through a more limited phaseout. PFAS, in comparison, have been

334. Military Health System and Defense Health Agency, *Perfluoroalkyl and Polyfluoroalkyl Substances*, https://www.health.mil/Military-Health-Topics/Health-Readiness/Public-Health/PFAS (last updated Nov. 28, 2022).
335. *Id.*
336. Letter to Court From Plaintiffs' Executive Committee at Exhibit A, In re Aqueous Film-Forming Foams Prods. Liab. Litig., MDL No. 2:18-mn-2873-RMG (D.S.C. Dec. 12, 2022).
337. Giovanni v. U.S. Dep't of Navy, 906 F.3d 94 (3d Cir. 2018).
338. 42 U.S.C. §9613(h).
339. *Giovanni*, 906 F.3d at 120-21.
340. Giovanni v. U.S. Dep't of Navy, 433 F. Supp. 3d 736 (E.D. Pa. 2020).
341. Complaint, New Mexico v. United States, No. 6:19-cv-00178 (D.N.M. Mar. 5, 2019), https://www.env.nm.gov/wp-content/uploads/sites/21/2016/05/2019-3-5-Complaint.pdf.
342. *Id.* at 23-24.
343. Transfer Order, In re Aqueous Film-Forming Foams Prods. Liab. Litig, MDL No. 2873 (J.P.M.L. June 2, 2020), https://www.env.nm.gov/wp-content/uploads/sites/21/2019/10/Doc-650-Order-Transfering-NM-v-US-to-MDL-2020-06-02.pdf.
344. 28 U.S.C. §§2671-2680.
345. *Id.* §2680(a).
346. *Id.* §2674.
347. *See generally* Jonathan M. Gaffney, Congressional Research Service, R45732, The Federal Tort Claims Act (FTCA): A Legal Overview (2019), https://crsreports.congress.gov/product/pdf/R/R45732.
348. Giovanni v. U.S. Dep't of Navy, 906 F.3d 94 (3d Cir. 2018).

used in a wide range of consumer products to achieve a wide range of characteristics. The chemicals are in many ways uniquely suited to achieve so many qualities at the same time. That same ubiquity and usefulness make PFAS chemicals challenging to phase out.

The wave of regulation and lawsuits involving PFAS-containing products is now top of mind for many companies—that will continue to be the case. With some product bans coming into effect now, PFAS can pose a number of challenges for consumer product manufacturers, including supply chain, reputational, and legal issues. The developing PFAS regulatory and litigation landscape will continue to be important for consumer product manufacturers for years to come.