ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 414

[EPA–HQ–OW–2020–0582; FRL 10019–06–OW]

RIN 2040–AG10

Clean Water Act Effluent Limitations Guidelines and Standards for the Organic Chemicals, Plastics and Synthetic Fibers Point Source Category

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The U.S. Environmental Protection Agency (EPA or Agency) is initiating further data collection and analysis to support potential future rulemaking, under the Clean Water Act (CWA), relating to the effluent limitations guidelines, pretreatment standards and new source performance standards applicable to the Organic Chemicals, Plastics and Synthetic Fibers (OCPSF) point source category to address discharges from manufacturers of per- and polyfluoroalkyl substances (PFAS) and is considering revising the same for formulators of PFAS. PFAS are a group of man-made organic chemicals. Some PFAS compounds are persistent in the environment and in the human body. Analysis of animal studies and human epidemiological research suggest that exposure above certain levels to some PFAS may be associated with adverse human health effects. The Agency has identified several industries with facilities that are likely to be discharging PFAS in their wastewater, including OCPSF manufacturers and formulators. This advance notice of proposed rulemaking (ANPRM) provides for public review and comment on the information and data regarding PFAS manufacturers and formulators that EPA has collected to date. EPA is requesting public comment on the information and data presented in this ANPRM. EPA is also soliciting additional information and data regarding discharges of PFAS from these facilities to inform future revisions to the wastewater discharge requirements that apply to the OCPSF point source category.

DATES: Comments must be received on or before May 17, 2021.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OW–2020–0582, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Office of Water, Office of Science and Technology Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery or Courier (by scheduled appointment only):* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/* or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Ms. Samantha Lewis, Engineering and Analysis Division, Office of Science and Technology, Office of Water; telephone number: 202–566–1058; email address: *lewis.samantha@epa.gov.*

I. Public Participation

A. Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OW–2020–0582, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. If you wish to submit such information, consult the person listed for additional information in the preceding **FOR FURTHER INFORMATION CONTACT** section. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

EPA is temporarily suspending its Docket Center and Reading Room for public visitors, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/* as there may be a delay in processing mail and faxes. Hand deliveries or couriers will be received by scheduled appointment only. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.*

EPA continues to carefully and continuously monitor information from the Centers for Disease Control and Prevention (CDC), local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID–19.

B. Supporting Information

This notice is supported by documents that are contained in the public docket. EPA has prepared an index of these materials to aid in the public's review and comment. The index can be identified by searching the docket for DCN OCPSF00116.

II. General Information

A. Does this action apply to me?

Entities potentially affected by any rulemaking following this notice include:

Category	Example of regulated entity
Industry	PFAS Manufacturers. PFAS Formulators.

This section is not intended to be exhaustive, but rather provides a guide regarding entities likely to be regulated by any future rulemaking activities following this notice. Other types of entities that are not included in the examples above could also be regulated. PFAS manufacturers are facilities that produce PFAS compounds or precursors through processes including, but not limited to, electrochemical fluorination (ECF) and telomerization. Facilities that manufacture PFAS are currently regulated under EPA's national Effluent Limitations Guidelines and Standards (ELGs) for the OCPSF category (40 CFR part 414). EPA has also gathered more limited information about PFAS formulators. PFAS formulators are facilities that are the primary customers of the PFAS manufacturers, and that use raw PFAS feedstock to (a) produce commercial or consumer goods (*e.g.,* weather-proof caulking), or (b) as intermediary products for use in the manufacture of commercial goods (*e.g.,* a grease-proof coating for a pizza box).

If you still have questions regarding the applicability of any future rulemaking activities following this notice to a particular entity, please consult the person listed for additional information in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. What is the purpose of this notice?

As part of EPA's statutorily required Effluent Guidelines planning process, EPA has reviewed readily available information about PFAS surface water discharges to identify industrial sources that may warrant further study for potential regulation through national ELGs. Based on the limited data available at the time, in February of 2019, EPA published the PFAS Action Plan, in which it identified several industries with facilities that are likely to be discharging PFAS compounds in their wastewater and EPA began a more detailed study to evaluate the potential for PFAS presence in their wastewater discharges. Through the PFAS Multi-Industry Study, described in EPA's Preliminary Effluent Guidelines Program Plan 14, EPA gathered a range of information about PFAS manufacturers and formulators, as well as the potential discharges of PFAS from these facilities (further details on these efforts are provided in Section V below). PFAS manufacturers are facilities that produce PFAS compounds or precursors through processes including, but not limited to, ECF and telomerization. Facilities that manufacture PFAS are currently regulated under EPA's national ELGs for the OCPSF category (40 CFR part 414). EPA has also gathered some information about PFAS formulators. PFAS formulators are facilities that are the primary customers of PFAS manufacturers, and that use raw PFAS feedstock to (a) produce commercial or consumer goods (*e.g.,* weather-proof caulking), or (b) as intermediary products for use in the manufacture of commercial goods (*e.g.,* a grease-proof coating for a pizza box). EPA's data set for formulators is more limited than for manufacturers, as the Agency has identified little publicly available information on these facilities and their potential discharges.

This notice provides for public review and comment on the information that EPA has collected to date on PFAS discharges from both PFAS manufacturers and formulators. In addition, as detailed in Section V below, EPA is soliciting additional information and data regarding PFAS manufacturers and formulators, including wastewater characteristics and treatability. EPA will use any information and data received to inform potential next steps, which could include developing new or revised ELGs for these categories of dischargers. Because formulators may be subject to national ELGs outside of the OCPSF category, future EPA actions to address PFAS discharges from these facilities may include revisions to ELGs other than the ELGs that apply to the OCPSF category or proposal of a new ELG.

III. Background

A. Clean Water Act

Among its core provisions, the Clean Water Act (CWA) prohibits the discharge of pollutants from a point source to waters of the United States, except as authorized under the CWA. Under CWA Section 402, 33 U.S.C. 1342, discharges may be authorized through a National Pollutant Discharge Elimination System (NPDES) permit. The CWA outlines a dual approach for establishing discharge limits for these permits: (1) Technology-based effluent limitations that establish a floor of performance for categories of dischargers, and (2) water quality-based effluent limitations that are established where technology-based effluent limitations are insufficient to meet applicable state water quality standards (WQS) or site specific water quality goals. The CWA authorizes EPA to establish national technology-based ELGs and new source performance standards for discharges to waters of the United States from categories of point sources (such as industrial, commercial, and public sources). These national ELGs are used by state permitting authorities to establish technology-based effluent limitations for NPDES permits.

The CWA also authorizes EPA to promulgate nationally applicable pretreatment standards that control pollutant discharges from sources that discharge wastewater indirectly to waters of the United States through Publicly Owned Treatment Works (POTWs), as outlined in Sections 307(b) and (c) of the CWA, 33 U.S.C. 1317(b) and (c). EPA establishes national pretreatment standards for pollutants in wastewater from such indirect dischargers shown to pass through, to interfere with, or to be otherwise incompatible with POTW operations. Pretreatment standards are designed to ensure that wastewaters from indirect industrial dischargers are subject to similar levels of treatment as direct dischargers in the same industrial category. See CWA Section 301(b), 33 U.S.C. 1311(b).

Technology-based effluent limitations in NPDES permits are derived from effluent limitations guidelines (CWA Sections 301 and 304, 33 U.S.C. 1311 and 1314) and new source performance standards (CWA Section 306, 33 U.S.C. 1316) promulgated by EPA. Where EPA has not promulgated an applicable ELG or new source performance standard, technology-based effluent limitations are based on the best professional judgment (BPJ) of the permitting authority. Additional limitations are also required in a permit where necessary to meet WQS. CWA Section 301(b)(1)(C), 33 U.S.C. 1311(b)(1)(C). The ELGs are established by EPA regulation for categories of industrial dischargers and are based on the degree of control that can be achieved using various levels of pollution control technology, as specified in the CWA (*e.g.,* Best Practicable Control Technology Currently Available (BPT), Best Conventional Pollutant Control Technology (BCT), Best Available Technology Economically Achievable (BAT); see below).

The EPA promulgates national ELGs for industrial categories for three classes of pollutants: (1) Conventional pollutants (total suspended solids (TSS), oil and grease, biochemical oxygen demand (BOD_5), fecal coliform, and pH), as outlined in CWA Section 304(a)(4), 33 U.S.C. 1314(a)(4), and 40 CFR 401.16; (2) toxic pollutants (*e.g.,* toxic metals such as arsenic, mercury, selenium, and

chromium; toxic organic pollutants such as benzene, benzo-a-pyrene, phenol, and naphthalene), as outlined in CWA Section 307(a), 33 U.S.C. 1317(a); 40 CFR 401.15 and 40 CFR part 423, appendix A; and (3) nonconventional pollutants, which are those pollutants that are not categorized as conventional or toxic (*e.g.,* ammonia-N, phosphorus, and total dissolved solids (TDS)). PFAS compounds fall into the category of nonconventional pollutant, as they are not defined as a toxic or conventional pollutant in the CWA or the Code of Federal Regulations (CFR).

B. Effluent Guidelines Program

EPA establishes ELGs based on the performance of well-designed and well-operated control and treatment technologies. EPA is not to base technology-based requirements on their effects on the receiving water. See *Weyerhaeuser Co.* v. *Costle,* 599 F.2d 1011, 1028, 1042 (D.C. Cir. 1978).

There are four levels of technology-based controls applicable to direct dischargers and two levels of controls applicable to indirect dischargers. These are described in detail below as general background information:

1. Best Practicable Control Technology Currently Available (BPT)

Consistent with the CWA, EPA establishes effluent limitations based on BPT by reference to the average of the best performances of facilities within the industry, grouped to reflect various ages, sizes, processes, or other common characteristics. EPA promulgates BPT effluent limitations for conventional, toxic, and nonconventional pollutants. In specifying BPT, EPA looks at a number of factors. EPA first considers the cost of achieving effluent reductions in relation to the effluent reduction benefits. The Agency also considers the age of equipment and facilities, the processes employed, engineering aspects of the control technologies, any required process changes, non-water quality environmental impacts (including energy requirements), and such other factors as the Administrator deems appropriate. See CWA Section 304(b)(1)(B), 33 U.S.C. 1314(b)(1)(B).

2. Best Conventional Pollutant Control Technology (BCT)

The 1977 amendments to the CWA require EPA to identify additional levels of effluent reduction for conventional pollutants associated with Best Conventional Pollutant Control Technology (BCT) for discharges from existing industrial point sources. In addition to other factors specified in Section 304(b)(4)(B), 33 U.S.C. 1314(b)(4)(B), the CWA requires that EPA establish BCT limitations after consideration of a two-part ''cost reasonableness'' test. EPA explained its methodology for the development of BCT limitations on July 9, 1986 (51 FR 24974). Section 304(a)(4) designates the following as conventional pollutants: BOD_5, TSS, fecal coliform, pH, and any additional pollutants defined by the Administrator as conventional. The Administrator designated oil and grease as a conventional pollutant on July 30, 1979 (44 FR 44501; 40 CFR 401.16).

3. Best Available Technology Economically Achievable (BAT)

BAT represents the second level of control for direct discharges of toxic and nonconventional pollutants. As the statutory phrase intends, EPA considers technological availability and the economic achievability in determining what level of control represents BAT. CWA Section 301(b)(2)(A), 33 U.S.C. 1311(b)(2)(A). Other statutory factors that EPA must consider in assessing BAT are the cost of achieving BAT effluent reductions, the age of equipment and facilities involved, the process employed, potential process changes, non-water quality environmental impacts (including energy requirements), and such other factors as the Administrator deems appropriate. CWA Section 304(b)(2)(B), 33 U.S.C. 1314(b)(2)(B); *Texas Oil & Gas Ass'n* v. *EPA,* 161 F.3d 923, 928 (5th Cir. 1998). The Agency retains considerable discretion in assigning the weight to be accorded each of these factors. *Weyerhaeuser Co.,* 590 F.2d at 1045. Generally, EPA determines economic achievability based on the effect of the cost of compliance with BAT limitations on overall industry and subcategory (if applicable) financial conditions. BAT is intended to reflect the highest performance in the industry, and it may reflect a higher level of performance than is currently being achieved based on technology transferred from a different subcategory or category, bench scale or pilot studies, or foreign facilities. *Am. Paper Inst.* v. *Train,* 543 F.2d 328, 353 (D.C. Cir. 1976); *Am. Frozen Food Inst.* v. *Train,* 539 F.2d 107, 132 (D.C. Cir. 1976). BAT may be based upon process changes or internal controls, even when these technologies are not common industry practice. See *Am. Frozen Food Inst.,* 539 F.2d at 132, 140; *Reynolds Metals Co.* v. *EPA,* 760 F.2d 549, 562 (4th Cir. 1985); *Cal. & Hawaiian Sugar Co.* v. *EPA,* 553 F.2d 280, 285–88 (2nd Cir. 1977).

One way that EPA may consider differences within an industry when establishing BAT limitations is through subcategorization. The Supreme Court has recognized that the substantive test for subcategorizing an industry is the same as that which applies to establishing fundamentally different factor variances—*i.e.,* whether the plants are different with respect to relevant statutory factors. See *Chem. Mfrs. Ass'n* v. *EPA,* 870 F.2d 177, 214 n.134 (5th Cir. 1989) (citing *Chem. Mfrs. Ass'n* v. *NRDC,* 470 U.S. 116, 119–22, 129–34 (1985)). Courts have stated that there need only be a rough basis for subcategorization. See *Chem. Mfrs. Ass'n,* 870 F.2d at 215 n.137 (summarizing cases).

4. Best Available Demonstrated Control Technology/New Source Performance Standards (NSPS)

NSPS reflect ''the greatest degree of effluent reduction'' that is achievable based on the ''best available demonstrated control technology'' (BADCT), ''including, where practicable, a standard permitting no discharge of pollutants.'' CWA Section 306(a)(1), 33 U.S.C. 1316(a)(1). Owners of new facilities have the opportunity to install the best and most efficient production processes and wastewater treatment technologies. As a result, NSPS generally represent the most stringent controls attainable through the application of BADCT for all pollutants (that is, conventional, nonconventional, and toxic pollutants). In establishing NSPS, EPA is directed to take into consideration the cost of achieving the effluent reduction and any non-water quality environmental impacts and energy requirements. CWA Section 306(b)(1)(B), 33 U.S.C. 1316(b)(1)(B).

5. Pretreatment Standards for Existing Sources (PSES)

Section 307(b) of the CWA, 33 U.S.C. 1317(b), authorizes EPA to promulgate pretreatment standards for discharges of pollutants to POTWs. PSES are designed to prevent the discharge of pollutants that pass through, interfere with, or otherwise are incompatible with the operation of POTWs. Categorical pretreatment standards are technology-based and are analogous to BPT and BAT effluent limitations guidelines, and thus the Agency typically considers the same factors in promulgating PSES as it considers in promulgating BPT and BAT. The General Pretreatment Regulations, which set forth the framework for the implementation of categorical pretreatment standards, are found at 40 CFR part 403. These regulations establish pretreatment standards that apply to all non-domestic dischargers. See 52 FR 1586 (January 14, 1987).

6. Pretreatment Standards for New Sources (PSNS)

Section 307(c) of the CWA, 33 U.S.C. 1317(c), authorizes EPA to promulgate PSNS at the same time it promulgates NSPS. As is the case for PSES, PSNS are designed to prevent the discharge of any pollutant into a POTW that interferes with, passes through, or otherwise is incompatible with the POTW. In selecting the PSNS technology basis, the Agency generally considers the same factors it considers in establishing NSPS, along with the results of a pass-through analysis. Like new sources of direct discharges, new sources of indirect discharges have the opportunity to incorporate into their operations the best available demonstrated technologies. As a result, EPA promulgates pretreatment standards for new sources based on best available demonstrated control technology for new sources. See *Nat'l Ass'n of Metal Finishers* v. *EPA,* 719 F.2d 624, 634 (3rd Cir. 1983).

C. Summary of the Existing OCPSF ELGs

The OCPSF ELGs (40 CFR part 414) were originally promulgated in 1987, and then amended in 1989, 1990, 1992, and 1993. The OCPSF category includes more than 1,000 chemical facilities producing over 25,000 end products. These include such products as benzene, toluene, polypropylene, polyvinyl chloride, chlorinated solvents, rubber precursors, rayon, nylon, and polyester. The OCPSF industry is large and diverse with complex operations and processes. Some plants produce chemicals in large volumes through continuous chemical processes, while others produce only small volumes of ''specialty'' chemicals through batch chemical processes.

Only a small subset of the facilities that are currently regulated under the OCPSF ELGs manufacture or formulate PFAS. Although the OCPSF ELGs may apply to PFAS manufacturers and formulators, the OCPSF ELGs do not establish effluent limitations or pretreatment standards for any PFAS compounds. Rather, the revision to the OCPSF ELGs would address PFAS discharges from PFAS manufacturers and formulators.

IV. The EPA's PFAS Multi-Industry Study and Identification of PFAS Manufacturers and Formulators for Potential Regulation

As described in the Preliminary Effluent Guidelines Program Plan 14 (Preliminary Plan 14), published in October 2019, EPA conducted an initial examination of readily available public information about PFAS surface water discharges to identify industrial sources that may warrant further study. The Preliminary Plan 14 docket (EPA–HQ–OW–2018–0618) includes a summary of the information EPA reviewed and a report with a more thorough description of our review activities. Based on this initial review, EPA decided to conduct further studies to better understand and document facilities discharging PFAS compounds to surface waters and to POTWs. This was introduced in the Preliminary Plan 14 as the PFAS Multi-Industry Study.

The goals of the PFAS Multi-Industry Study are to identify industries and specific facilities producing or using PFAS compounds; quantify—to the best of EPA's ability—the amounts of PFAS being discharged; identify PFAS control practices and treatment technologies; document PFAS removal efficiency in wastewater; and estimate costs associated with PFAS treatment systems. EPA identified the following industrial point source categories as the primary focus of this study: OCPSF manufacturers; pulp and paper manufacturers; textiles and carpet manufacturers; and commercial airports.[1]

For the OCPSF manufacturers, EPA reviewed numerous data sources and identified six PFAS manufacturers and ten likely PFAS formulators. EPA is not sure that the ten facilities that it identified as ''likely'' PFAS formulators are actually PFAS formulators due to limited data available at this time. We discuss each of these data sources in greater detail below.

EPA reviewed 2019 Discharge Monitoring Reports (DMRs) and obtained PFAS data for six PFAS manufacturers and three likely PFAS formulators (the other seven facilities do not report PFAS compounds in their DMRs or they do not have DMRs because they are indirect dischargers). These nine facilities combined reported a total of 17 PFAS compounds in their discharges. Based on the DMRs, effluent data detected a total of 15 PFAS compounds, and concentrations ranged from non-detect to 777 parts per billion (ppb). The ''2019 Monitoring Period Level DMR PFAS Data'' (DCN OCPSF00030) includes additional information on the compounds that were monitored, and the concentration ranges reported in DMRs.

EPA reviewed NPDES permits for these PFAS manufacturers and formulators to evaluate whether their permits contain effluent limitations or monitoring requirements for PFAS compounds. One current NPDES permit in West Virginia contains effluent limitations for two PFAS compounds (Perfluorooctanoic acid (PFOA) and Hexafluoropropylene oxide dimer acid (HFPODA) that go into effect on September 1, 2021. Another facility in North Carolina is under a consent decree with requirements for no discharge of PFAS process wastewater. See DCN OCPSF00079 for consent decree. The North Carolina facility is currently hauling all PFAS process wastewater off-site for disposal. The consent decree went into effect on February 25, 2019 and ends on January 31, 2023. This North Carolina facility reported detections of PFOA for 9 of 12 reporting periods in 2019 DMRs, including periods after February 2019. Four of the other PFAS manufacturers and formulators have PFAS monitoring requirements, and no effluent limitations, in their NPDES permits. Two Alabama facilities and one Illinois facility are operating under expired, administratively continued NPDES permits. The NPDES permit materials collected and reviewed are available as DCNs OCPSF000008 to OCPSF00025.

EPA also reviewed the Toxics Release Inventory (TRI), which is managed by EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and tracks annual environmental waste management, including releases, of 767 individually listed chemicals and 33 chemical categories from industrial facilities that manufacture, process, or otherwise use these chemicals in amounts above their applicable reporting thresholds. Release of a TRI chemical refers to an emission to air, discharge to water, or placement in some type of land disposal. EPA has not yet received any information or data pertaining to the release of PFAS compounds through TRI reporting. However, the National Defense Authorization Act for Fiscal Year 2020 added 172 PFAS compounds to the TRI. TRI reporting for these PFAS will be due to EPA by July 1, 2021, for calendar year 2020 data. For additional information on the addition of 172 PFAS to TRI, see *https://www.epa.gov/toxics-release-inventory-tri-program/list-pfas-added-tri-ndaa.*

EPA reviewed data from the Toxic Substances Control Act (TSCA) Inventory, which lists chemicals manufactured (including imported) or processed in the United States. The TSCA Inventory, managed by the Office of Pollution Prevention and Toxics (OPPT) within OCSPP, currently lists more than 86,000 chemicals, of which approximately half are currently in

[1] Military bases and airports are not included in the scope of this study.

commerce or ''active.'' For PFAS specifically, the TSCA Inventory lists over one thousand compounds, of which approximately half are known to be commercially active within the last decade. The TSCA Inventory by itself cannot be used to identify dischargers.

EPA also reviewed the Chemical Data Reporting (CDR) database, which compiles information collected under a TSCA Section 8(a) rule that requires chemical manufacturers (including importers) to provide EPA with production, import, and customer use information about chemicals in commerce. Manufacturers and importers must report to the CDR database if they meet certain annual volume thresholds, typically 25,000 pounds, but 2,500 pounds for chemicals subject to certain TSCA actions. EPA matched the chemicals in the 2016 CDR data (the most recent year available) [2] against EPA's Cross-Agency Research List [3] and identified 118 PFAS compounds in the CDR database. See DCN OCPSF00032 for ''2016 nonCBI CDR Data for PFAS Compounds'' and DCN OCPSF00003 for ''EPA's CompTox Cross Agency PFAS List.'' Using this list of CDR PFAS compounds, EPA summed the reported production volumes to calculate a total PFAS production and importation volume of approximately 608 million pounds for 2015. See DCN OCPSF00033 for ''Review of 2015 non-CBI CDR Data for PFAS Compounds.'' The CDR database contains data identifying which facilities produced PFAS compounds, but does not have any information on PFAS discharges. The six PFAS manufacturing facilities that reported 2019 DMR data also appear in the CDR data as domestic manufacturers of 76 separate PFAS compounds. An additional 55 facilities appear in the CDR dataset; however, EPA has no corresponding data on their potential PFAS discharges. The deadline for the CDR data for the 2020 reporting cycle is in January 2021. Additional PFAS-related data submitted by CDR sites can be assessed shortly thereafter.

EPA collected and reviewed 15 treatment technology technical articles from a range of sources including EPA publications, federal, state, and local government publications, PFAS manufacturers, and non-governmental organizations (NGOs). Through these articles, EPA identified eight potential technologies that can remove PFAS from wastewater. These include granular activated carbon, reverse osmosis filtration, and ion exchange. A full list of available technologies that EPA has identified to date is included in DCN OCPSF00096.

EPA began stakeholder outreach in July 2019 by meeting with stakeholders to collect, on a voluntary basis, additional information such as supplementary effluent data, information on PFAS compounds being produced/used and discharged, and any information about treatment technologies being used, along with their effectiveness and costs, to augment the available information EPA reviewed. This information gathering effort was performed under the Multi-Industry Study noted above. The information provided by stakeholders is included in DCN OCPSF00042–OCPSF00078.

EPA met with the FluoroCouncil of the American Chemistry Council,[4] the primary trade association that represents PFAS manufacturers and formulators, and its members. See DCN OCPSF00054 for meeting notes. They provided EPA with technical literature concerning PFAS terminology and classification, a list of short chain fluorotelomers studies, an economic assessment of the U.S. fluoropolymer industry, and the names of contacts at entities that they identified as the sole three PFAS manufacturing companies in the United States. These three manufacturers (with a total of six facilities) mirrored the six facilities for which EPA found DMR data and an additional facility for which EPA received internal monitoring data.

EPA met with representatives of one company that operates multiple facilities that manufacture PFAS in West Virginia, New Jersey and North Carolina. They provided EPA with a copy of the presentation they gave during their meeting with the Agency, a copy of a New Jersey facility's NPDES permit, data for an internal outfall at that facility, a document addressing PFAS concerns at a North Carolina facility, and technical literature on fluoropolymers of low concern. See DCN OCPSF00061 for meeting notes and DCNs OCPSF00062 to OCPSF00064 for materials provided.

EPA met with representatives of one company that operates multiple facilities that manufacture PFAS in Alabama, Illinois and Minnesota. Representatives of this company provided EPA with a PFAS production history in addition to current PFAS product categories, wastewater process flow diagrams, copies of their NPDES permits, documentation for a direct injection analytical method, sampling data for both PFAS manufacturing facilities and a formulating facility, and related published literature. See DCN OCPSF00042 for meeting notes and DCNs OCPSF00043 to OCPSF00052 for materials provided.

EPA met with representatives of another PFAS manufacturing facility in Alabama. See DCN OCPSF00065 for meeting notes.

EPA spoke to a representative of another company who stated that the company does not produce PFAS compounds in the United States. EPA learned that this company imports products from international manufacturing facilities and other manufacturers both inside and outside of the United States. Those materials are further processed at a domestic facility in Pennsylvania. See DCN OCPSF00060 for meeting notes. EPA is not aware of any PFAS discharge data from this facility, but EPA is requesting additional information regarding these and similar operations through this notice.

EPA made attempts to contact the other PFOA/PFOS Stewardship Program *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program*) companies but did not receive any additional information. EPA continues to coordinate with manufacturers to obtain additional information, including a list of PFAS compounds they manufacture, documentation for the analytical methods they use to analyze PFAS in waste streams, and PFAS analytical data collected from source water, process water, and effluent at their facilities.

EPA spoke with representatives of the Michigan Department of Environment, Great Lakes, & Energy (MI EGLE). Michigan EGLE provided EPA with sampling data for 30 direct discharging facilities and 633 indirect discharging facilities across 44 industrial categories, mostly for PFOA and PFOS. See DCN OCPSF00067 for direct discharging data and DCN OCPSF00068 for indirect discharging data provided by MI EGLE.

Four of these facilities were likely PFAS formulators based on the concentrations of PFAS in discharges and the operations of the facilities. EPA also reviewed an investigation report

[2] The information for the CDR is collected every four years from manufacturers (including importers). The 2016 CDR data contains information reported in 2016 and covering 2012 to 2015. *https://www.epa.gov/chemical-data-reporting/basic-information-about-chemical-data-reporting#what.*

[3] EPA's Cross-Agency Research PFAS list, from the CompTox Chemicals Dashboard, is a manually curated listing of mainly straight-chain and branched PFAS compiled from various internal, literature and public sources by EPA researchers and program office representative (*https://comptox.epa.gov/dashboard*).

[4] The FluoroCouncil of the American Chemistry Council has disbanded since EPA last spoke to them.

from EPA's Region 3, looking for potential PFAS sources in Goose Creek, Pennsylvania. From this report, EPA was able to identify another likely PFAS formulator. See DCN OCPSF00038 for report and communications.

V. Request for Further Information on PFAS Manufacturers and Formulators

A. PFAS Manufacturers

EPA has identified six facilities (Alabama, North Carolina, West Virginia, New Jersey, Illinois) in the United States that currently manufacture PFAS compounds and have an associated wastewater discharge.

Throughout the course of EPA's PFAS Multi-Industry Study, the Agency worked collaboratively with stakeholders to obtain information regarding facilities that manufacture and formulate fluorochemicals in the United States. EPA appreciates the information that these entities have provided to the Agency to date.[5] This information has greatly increased the Agency's understanding of current manufacturing facilities, their operations, their production of fluorochemicals, their wastewater generation activities, and their wastewater treatment activities. After reviewing the information received to date, EPA is inviting stakeholders to review this information and provide comment and is seeking additional information and data to inform EPA's next steps.

Specifically, EPA is requesting the following information and data regarding PFAS manufacturers:

1. The identity of or suggestions for how to identify any other facilities in the United States currently manufacturing PFAS.

2. Descriptions of the manufacturing processes being employed at PFAS manufacturing facilities, including process flow diagrams.

3. Information and data on the specific PFAS compounds that are currently being produced (including as byproducts) at these facilities (including the product name, CAS number and class of each compound), the quantities that are being produced, the customers or industries that are purchasing these materials, and the quantities of materials sold to various customers. For sales, EPA is also interested in knowing the quantities of PFAS compounds that are exported outside of the United States.

4. Identification of the wastewater streams at manufacturing facilities that contain PFAS (*e.g.,* process wastewater, cooling water, contaminated stormwater, wastewater from aqueous scrubbers or air pollution control equipment, off-specification products, equipment cleaning wastewater, spills and leaks), their volumes, characteristics, the identity (including CAS Number), and concentrations of PFAS compounds in those individual waste streams.

5. Information and data on the current wastewater treatment and management practices (including pollution prevention and product recovery practices) being utilized at existing PFAS manufacturers. Specific information requested includes descriptions of the treatment technologies, their size and flow rate, process flow diagrams, capital and operation and maintenance costs, treatment chemical utilization, and residuals generation and management. If wastewater storage ponds are used to hold PFAS wastewater, EPA also requests a description of the ponds, including purpose, age, capacity, design, wastewater characteristics, whether they are lined or unlined, and whether they have discharge outfalls.

6. If manufacturers are not treating PFAS containing wastewater onsite, EPA is requesting information on the management or disposal practices being utilized (*e.g.,* zero liquid discharge, disposal wells, transfer to off-site centralized waste treatment facilities or transfer to POTWs), the volumes of wastewaters being managed via different practices, the name and location of the facilities receiving wastewaters, and their associated costs.

7. Information and data on future planned process changes at existing PFAS manufacturing facilities, any plans to change or phase-out manufacture of specific fluorinated compounds or to increase or decrease production of specific compounds, and any planned major upgrades to existing manufacturing facilities or construction of new PFAS manufacturing facilities in the United States. EPA is also requesting information regarding any potential changes in PFAS manufacturing processes, pollution prevention practices or chemicals used as PFAS substitution, or use and cost of specific technologies that can reduce the quantity of PFAS in wastewater from PFAS manufacturing operations.

8. EPA has collected existing publicly available DMR data and monitoring data from known manufacturers, as well as data from TRI and CDR databases, as indicated in the docket. These DMRs contain data on only a subset of the total PFAS that are potentially present in discharges from these facilities. EPA requests additional monitoring data (see DCN OCPSF00115 for suggested data format and fields) on PFAS compounds in wastewater discharges from PFAS manufacturing facilities. Since there is currently no CWA-approved analytical method promulgated for analysis of PFAS compounds in wastewater, EPA requests that monitoring data that is submitted include information on the analytical methods used as well as associated information and data that can be used by EPA to determine the quality of the data. EPA also requests comment on whether additional PFAS compounds or precursors that are not reported in DMRs are found in wastewater discharges from these facilities, and the quantities of such PFAS compounds, precursors, and other organofluoride compounds found in untreated and treated wastewaters from these facilities. In addition to data on individual compounds, EPA is also particularly interested in data that would provide the total quantity of organofluorides present, such as would be provided by a Total Organic Fluorine (TOF) analysis or other assays.

9. In addition to treatment technologies being used at the six known PFAS manufacturing facilities, EPA is requesting additional information and data regarding treatment and destruction technologies for PFAS in industrial wastewater, including data on their performance, costs (both capital and operation and maintenance), and the types, quantities and management practices for any treatment residuals that are generated. Data from laboratory, bench, pilot, and full-scale facilities are requested. EPA also requests comment on the 15 treatment technology articles included in the docket.

10. Analytical methodologies used to monitor wastewater at PFAS manufacturing facilities, including in house SOPs and method performance data, including lists of specific PFAS compounds being monitored, and any aggregate procedures (*e.g.,* adsorbable or extractable organic fluorine by combustion ion chromatography).

11. Any studies that have been conducted concerning environmental or human health impacts (*e.g.,* toxicity, risk, fate and transfer, cross media) of PFAS discharges from PFAS manufacturers.

B. PFAS Formulators

EPA has identified limited publicly available information regarding the universe of PFAS formulators. To date, EPA has identified ten facilities (in Ohio, Virginia, Michigan, Minnesota, Pennsylvania and New Jersey) that are

[5] These data and information are contained in the docket supporting this notice.

potential formulators, but requests additional details regarding formulator facilities.

As with manufacturers, EPA is interested in obtaining additional information and data regarding discharges of PFAS from formulators in order to inform the Agency's decision-making regarding the need for new or revised ELGs for these types of facilities. EPA is requesting the following information and data from PFAS formulators:

1. Identification of all known PFAS formulators in the United States.

2. Descriptions of the manufacturing processes occurring at formulating facilities, including descriptions of how PFAS compounds are utilized at these facilities.

3. The SIC or NAICS codes of formulating facilities.

4. Information and data on the PFAS compounds that are currently being used at these facilities (including the product name, CAS number and class of each compound), the quantities that are being used, the quantities that are being sold or transferred for further processing or as materials for incorporation into finished products, and the customers or industries that are purchasing these materials and products.

5. Information on whether PFAS is being imported by formulators from outside the United States, and if any formulators are exclusively utilizing imported PFAS.

6. The locations and number of formulating facilities, as well as whether process wastewater associated with PFAS formulating is being discharged at these facilities.

7. Whether facilities have current monitoring requirements for PFAS or other fluorocarbons.

8. Information and data on the current wastewater treatment and management practices (including pollution prevention and product recovery practices) being utilized at existing PFAS formulators. Specific information requested includes descriptions of the treatment technologies, their size and flow rate, process flow diagrams, capital and operation and maintenance costs, treatment chemical utilization, and residuals generation and management. If wastewater storage ponds are used to hold PFAS wastewater, provide a description of the ponds including purpose, age, capacity, design, wastewater characteristics, whether they are lined or unlined, and whether they have discharge outfalls.

9. For facilities that discharge process wastewater, whether facilities are subject to national ELGs, and if so, identification of the applicable part(s) and subpart(s) (*e.g.,* 40 CFR 414 Subpart H) and the wastewater discharge permit identification numbers. EPA is also requesting copies of NPDES permits and fact sheets (or statement of basis) for direct discharging facilities, and copies of control agreements for indirect discharging facilities.

10. Process flow diagrams showing where wastewater is generated.

11. Identification of the wastewater streams at formulating facilities that contain PFAS (*e.g.,* process wastewater, cooling water, contaminated stormwater, wastewater from aqueous scrubbers or air pollution control equipment, off-specification products, equipment cleaning wastewater, spills and leaks), their volumes, characteristics, and concentrations of PFAS compounds in those individual waste streams.

12. If formulators are not treating PFAS containing wastewater onsite, EPA is requesting information on the management or disposal practices being utilized (*e.g.,* zero liquid discharge, disposal wells, transfer to off-site centralized waste treatment facilities or transfer to POTWs), the volumes of wastes being managed via different practices, and their associated costs.

13. Information and data on future planned process changes at formulators, any plans to change or phase-out use of specific fluorinated compounds or to increase or decrease production of specific compounds, and any planned major upgrades to existing formulating facilities or construction of new formulating facilities in the United States.

14. EPA has collected existing publicly available DMR data and monitoring data from potential PFAS formulators, as well as data from TRI and CDR databases, as indicated in the docket. These DMRs contain data on only a subset of the total PFAS that are potentially present in discharges from these facilities. EPA requests additional monitoring data (see DCN OCPSF00115 for suggested data format and fields) on PFAS compounds in wastewater discharges from PFAS formulating facilities. Since there is currently no CWA-approved analytical method promulgated for analysis of PFAS compounds in wastewater, EPA requests that monitoring data that is submitted include information on the analytical methods used as well as associated information and data that can be used by EPA to determine the quality of the data. EPA also requests comment on whether additional PFAS compounds or precursors that are not reported in DMRs are found in wastewater discharges from these facilities, and the quantities of such PFAS compounds, precursors and other organofluoride compounds found in untreated and treated wastewaters from these facilities. In addition to data on individual compounds, EPA is also particularly interested in data that would provide the total quantity of organofluorides present, such as would be provided by a Total Organic Fluorine (TOF) analysis or other assays.

15. EPA is interested in information regarding any potential changes in PFAS formulating processes, pollution prevention practices or product substitution, or use and cost of specific technologies that can reduce the quantity of PFAS in wastewater from PFAS formulating operations.

16. Analytical methodologies used to monitor wastewater at PFAS formulating facilities, including in house SOPs and method performance data, including lists of specific PFAS compounds being monitored, and any aggregate procedures (*e.g.,* adsorbable or extractable organic fluorine by combustion ion chromatography).

17. Any studies that have been conducted concerning environmental or human health impacts (*e.g.,* toxicity, risk, fate and transfer, cross media) of PFAS discharges from formulators.

VI. Statutory and Executive Order Reviews

Under Executive Order 12866, titled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), this is a ''significant regulatory action'' ''because the action raises novel legal or policy issues.'' Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Order 12866, and any changes made in response to OMB recommendations have been documented in the docket for this action. Because this action does not propose or impose any requirements, other statutory and Executive Order reviews that apply to rulemaking do not apply. Should EPA subsequently determine to pursue a rulemaking, EPA will address the statutes and Executive Orders that apply to that rulemaking.

EPA welcomes comments and/or information that would help the Agency to assess any of the following: The potential impact of a rule on small entities pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*); potential impacts on federal, state, or local governments pursuant to the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531–1538); federalism implications pursuant to Executive Order 13132, entitled *Federalism* (64 FR 43255, November 2,

1999); availability of voluntary consensus standards pursuant to Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113; tribal implications pursuant to Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000); environmental health or safety effects on children pursuant to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997); energy effects pursuant to Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001); Paperwork burdens pursuant to the Paperwork Reduction Act (PRA) (44 U.S.C. 3501); or human health or environmental effects on minority or low-income populations pursuant to Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). The Agency will consider such comments during the development of any subsequent rulemaking.

List of Subjects in 40 CFR Part 414

Environmental protection, Chemicals, Plastics materials and synthetics, Waste treatment and disposal, Water pollution control.

Jane Nishida,

Acting Administrator.

[FR Doc. 2021–05402 Filed 3–16–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906–AB24

National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of proposed withdrawal; request for comments.

SUMMARY: HHS proposes rescinding the final rule entitled ''National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table,'' published in the **Federal Register** on January 21, 2021. That final rule, if it were to go into effect, would amend our regulations by removing Shoulder Injury Related to Vaccine Administration (SIRVA), vasovagal syncope, and the new vaccines category (Item XVII) from the Vaccine Injury Table (Table). HHS seeks comments on this proposed rescission.

DATES: The final rule published January 21, 2021, at 86 FR 6249, delayed February 23, 2021, at 86 FR 10835, is proposed to be withdrawn. Written comments and related material to this proposed withdrawal must be received on or before April 16, 2021.

ADDRESSES: You may submit written comments electronically by the following method: *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions on the website for submitting comments.

Instructions. Include the HHS Docket No. HRSA–2021–0001 in your comments. All comments received will be posted without change to *http://www.regulations.gov.* Please do not include any personally identifiable or confidential business information you do not want publicly disclosed.

FOR FURTHER INFORMATION CONTACT: Please visit the National Vaccine Injury Compensation Program's website, *https://www.hrsa.gov/vaccinecompensation/,* or contact Tamara Overby, Acting Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, Room 08N146B, 5600 Fishers Lane, Rockville, MD 20857; by email at *vaccinecompensation@hrsa.gov;* or by telephone at (855) 266–2427.

SUPPLEMENTARY INFORMATION: This is a notice of proposed rulemaking by which HHS proposes to rescind the final rule titled ''National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table,'' (final rule), January 21, 2021, 86 FR 6249, delayed February 23, 2021, 86 FR 10835, which, if it were to go into effect, would amend the provisions of 42 CFR 100.3 by removing Shoulder Injury Related to Vaccine Administration (SIRVA), vasovagal syncope, and the new vaccines category (Item XVII) from the Table.

I. Background and Purpose

The National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660 (42 U.S.C. 300aa–10 *et seq.*) (Vaccine Act), established the National Vaccine Injury Compensation Program (VICP) to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines to be compensated. The Vaccine Act has been amended several times since 1986.

Petitions for compensation under this Program are filed in the United States Court of Federal Claims (Court), with a copy served on the Secretary, who is the ''Respondent.'' The Court, acting through judicial officers called Special Masters, makes findings as to eligibility for, and the amount of, compensation. To be found entitled to an award under the VICP, a petitioner must establish a vaccine-related injury or death, either by proving that a vaccine actually caused or significantly aggravated an injury (causation-in-fact) or by demonstrating the occurrence of what has been referred to as a Table injury. That is, a petitioner may show that the vaccine recipient suffered an injury of the type enumerated in the regulations at 42 CFR 100.3—the Vaccine Injury Table—corresponding to the vaccination in question, and that the onset of such injury took place within a time period also specified in the Table. The Table is accompanied by, among other provisions, the Qualifications and Aids to Interpretation (QAI), which defines the injuries and conditions listed on the Table. If these criteria are met, the injury is presumed to have been caused by the vaccination, and the petitioner is entitled to compensation (assuming that other requirements are satisfied), unless the respondent affirmatively shows that the injury was caused by some factor other than the vaccination (*see* 42 U.S.C. 300aa–11(c)(1)(C)(i), 300aa–13(a)(1)(B)), and 300aa–14(a)). Currently, cases are often resolved by negotiated settlements between the parties and approved by the Court. In such situations, HHS and the Court have not concluded, based upon review of the evidence, that the vaccine caused the alleged injury.

Revisions to the Table are authorized under the Vaccine Act (42 U.S.C. 300aa–14(c)–(e)). The Vaccine Act prohibits the Secretary of HHS from proposing a revision to the Table ''unless the Secretary has first provided to the [Advisory] Commission [on Childhood Vaccines] a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations'' (42 U.S.C. 300aa–14(d)). Further, once the proposed revision is published, the Secretary must afford the public at least 180 days of public comment (42 U.S.C. 300aa–14(c)(1)).

HHS added SIRVA and vasovagal syncope to the Table in March 2017, following an extensive, multi-year process that involved nine HHS workgroups, including HRSA and the