MAN-MADE CHEMICALS AND POTENTIAL HEALTH RISKS

EPA Has Completed Some Regulatory-Related Actions for PFAS
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Why GAO Did This Study

Beginning in the 1940s, scientists developed a class of heat- and stain-resistant chemicals—PFAS—that are used in a wide range of products, including nonstick cookware, waterproof clothing, and some firefighting foams. PFAS can persist in the environment for decades or longer. The Centers for Disease Control and Prevention has found that most people in the U.S. have been exposed to two of the most widely studied PFAS, likely from consuming contaminated water or food. According to EPA, there is evidence that continued exposure above certain levels to some PFAS may lead to adverse health effects. In February 2019, EPA issued its PFAS Action Plan, which outlined 23 planned actions to better understand PFAS and reduce their risks to the public.

GAO was asked to examine the status of regulatory-related actions in EPA’s plan. For six regulatory-related actions GAO selected in EPA’s PFAS Action Plan, this report examines (1) the number of actions that are complete and the steps EPA took to complete them and (2) the number of actions that are ongoing and EPA’s progress toward completing them. GAO first identified those actions in the PFAS Action Plan that may lead to the issuance of federal regulations or could affect compliance with existing regulations. GAO then assessed the status of the actions by reviewing EPA documents and examining EPA’s response to related FY20 NDAA requirements.

What GAO Found

The Environmental Protection Agency (EPA) has completed three of six selected regulatory-related actions for addressing per- and polyfluoroalkyl substances (PFAS) outlined in EPA’s PFAS Action Plan. (See fig.) For two of the three completed actions, the steps EPA took were also in response to the National Defense Authorization Act for Fiscal Year 2020 (FY20 NDAA):

- After proposing a supplemental significant new use rule in February 2020, EPA met a June 2020 deadline set in the FY20 NDAA when the EPA Administrator signed the final rule. Among other things, under the final rule, articles containing certain PFAS as a surface coating, and carpet containing certain PFAS, can no longer be imported into the U.S. without EPA review.
- EPA incorporated 172 PFAS into the Toxics Release Inventory in June 2020. The FY20 NDAA directed EPA to take this action, extending EPA’s original planned action to explore data for listing PFAS chemicals to the inventory.

Finally, in March 2020, EPA completed a third regulatory-related action, not required under the FY20 NDAA, when the agency proposed a preliminary drinking water regulatory determination for two PFAS—an initial step toward regulating these chemicals in drinking water.

Status of Six Selected Regulatory-Related Actions in the Environmental Protection Agency’s (EPA) Per- and Polyfluoroalkyl Substances (PFAS) Action Plan

<table>
<thead>
<tr>
<th>Planned action</th>
<th>Status</th>
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<tbody>
<tr>
<td>Propose a supplemental significant new use rule.</td>
<td>Complete</td>
</tr>
<tr>
<td>Explore data for listing PFAS chemicals to the Toxics Release Inventory.</td>
<td>Complete</td>
</tr>
<tr>
<td>Propose a drinking water regulatory determination.</td>
<td>Complete</td>
</tr>
<tr>
<td>Monitor PFAS in drinking water.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Explore industrial sources of PFAS that may warrant potential regulation.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Continue the regulatory process for a hazardous substances designation.</td>
<td>Ongoing</td>
</tr>
</tbody>
</table>


Three of the six selected regulatory-related actions are ongoing, and EPA’s progress on these actions varies. For example:

- As of August 2020, EPA was developing a proposed rulemaking for a nationwide drinking water monitoring rule that includes PFAS, which EPA officials said the agency intends to finalize by December 2021.
- EPA planned to continue the regulatory process for designating two PFAS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act, would allow the agency to require responsible parties to conduct or pay for cleanup. On January 14, 2021, EPA issued an advance notice of proposed rulemaking for the hazardous substances designation to get public comment and data to inform the agency’s ongoing evaluation of the two PFAS.

View GAO-21-37. For more information, contact J. Alfredo Gómez at (202) 512-3841 or gomezj@gao.gov.
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CCL       Contaminant Candidate List
CDC       Centers for Disease Control and Prevention
CERCLA    Comprehensive Environmental Response, Compensation, and Liability Act
DOD       Department of Defense
EPA       Environmental Protection Agency
FY20 NDAA National Defense Authorization Act for Fiscal Year 2020
OMB       Office of Management and Budget
PFAS      per- and polyfluoroalkyl substances
PFOA      perfluorooctanoic acid
PFOS      perfluorooctane sulfonate
ppt       parts per trillion
SNUR      significant new use rule
TRI       Toxics Release Inventory
TSCA      Toxic Substances Control Act
UCMR      Unregulated Contaminant Monitoring Rule

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January 27, 2021

The Honorable Tom Carper
United States Senate

The Honorable Ron Johnson
United States Senate

The Honorable Gary C. Peters
United States Senate

Beginning in the 1940s, scientists developed a class of heat- and stain-resistant chemicals that are used in a wide range of commercial and consumer products, including carpet, food packaging, nonstick cookware, waterproof clothing, and firefighting foams that suppress petrochemical fires typically used at airports and on military bases.¹ These chemicals are per- and polyfluoroalkyl substances (PFAS) and have a carbon-fluorine bond that is one of the strongest organic bonds in existence. Some have characterized PFAS as “forever chemicals,” but persistence varies among different types of PFAS; some PFAS can persist in the environment for years, decades, or longer.² Little is known about most PFAS, but some have been shown to be pervasive and to pose potential risks to human health.³ According to the Environmental Protection Agency (EPA), some PFAS are no longer produced in the U.S., but legacy uses and a lack of commercially viable alternatives for certain


²PFAS are a class of fluorinated organic compounds. According to EPA documentation, over 4,000 PFAS may have been manufactured and used in a variety of industries worldwide since the 1940s; of these, fewer than 1,500 are known to have ever been in commerce in the U.S. and around 500 are known to have been commercially active within the last decade.

³According to EPA documents, health and occurrence data and validated analytical methods are available for only a few PFAS. For most PFAS, there is limited or no toxicity information.
safety products (e.g., firefighting foams) have resulted in PFAS contamination across the country.

Since 1999, the Centers for Disease Control and Prevention’s (CDC) National Health and Nutrition Examination Survey has measured some PFAS in the blood of a representative sample of Americans. The survey has found that most people in the U.S. have been exposed to two of the most widely studied PFAS—perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). According to the CDC, people are most likely exposed to PFAS by consuming water or food that contains PFAS. Water may become contaminated by PFAS as the result of chemical releases into surface or ground water from locations such as manufacturing sites, landfills, aviation fire training areas, or wastewater treatment facilities. In 2017, EPA reported that data collected from nearly 5,000 public water systems across the country demonstrated that PFOA, PFOS, or both were present for at least one public water system for 25 states, tribes, or territories. Certain PFAS have been shown to pose hazards to human health. For example, according to EPA, exposure to

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4The National Health and Nutrition Examination Survey assesses the health and nutritional status of adults and children in the U.S. The survey, which began in the 1960s, combines interviews and physical examinations and determines the prevalence of major diseases and risk factors for diseases. Results are shared online, and in scientific and technical journals, and the data are made available to researchers, risk assessors and regulators around the world.


7According to EPA officials, these data were compiled from all large water systems serving populations over 10,000 and a representative sample of small water systems. According to EPA documents, PFOA, PFOS, or both were present in public water systems for 25 states, tribes, or territories and in 1.3 percent of the sampled water systems at a concentration above the lifetime health advisory of 70 parts per trillion (ppt) that EPA established in May 2016. (See footnote 8 for additional information about the lifetime health advisory.) At the time the data were collected, analytical methods for detecting PFOA and PFOS were only reliable at levels at or above 20 and 40 ppt, respectively. According to EPA officials, EPA plans to collect additional occurrence data in drinking water beginning in 2023, using newer analytical methods that can detect 29 different PFAS at levels as low as 1 ppt.
PFOA and PFOS over certain levels may have a variety of adverse effects on human health, including effects on fetal development, the immune system, and thyroid, as well as cause liver damage and cancer.

EPA does not currently regulate PFAS in drinking water but has issued a nonenforceable drinking water lifetime health advisory. EPA, Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS) (May 2016); and Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA) (May 2016). EPA health advisories provide information on contaminants not subject to drinking water regulations, including those that can cause human health effects and are known or anticipated to occur in drinking water. The advisories are nonenforceable and nonregulatory and provide technical information on the health risk of identified but unregulated chemicals to drinking water system managers and others with primary responsibility for overseeing water systems.

According to EPA documents, even when there is a promulgated federal standard, states may choose to adopt standards that are more stringent. Further, according to EPA officials, states have taken approaches to deriving standards for various PFAS that may be different from EPA’s process to develop EPA’s health advisory levels for PFOA and PFOS.

One ppt is comparable to one drop in a swimming pool covering the area of a football field 43 feet deep.

N.J. Admin. Code §7:9C.

In February 2019, EPA released its *PFAS Action Plan*, which identified the need to expand the body of scientific knowledge to understand and effectively manage the risks PFAS pose to human health and the environment. The plan outlined 23 actions EPA planned to implement, including identifying both human health effects and environmental risks of PFAS exposure, as well as methods to remediate contamination. The majority of the actions outlined in the plan consist of projects, studies, or steps to complete. The plan also included a number of regulatory-related actions—actions that may lead to the issuance of federal regulations or could influence or affect compliance. In addition to EPA’s actions, more than 40 bills were introduced in the 116th Congress to address PFAS through various agencies and authorities. For example, the National Defense Authorization Act for Fiscal Year 2020 (FY20 NDAA), enacted in December 2019, included language requiring that DOD take action to address contamination from firefighting foam containing PFAS. The FY20 NDAA also required EPA to take specific steps on three of the regulatory-related actions outlined in its *PFAS Action Plan*, such as monitoring for certain PFAS in drinking water. In February 2020, EPA

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issued an update to the PFAS Action Plan, which provided an overview of the status of some, but not all, actions in the plan.17

You asked us to provide information on the status of the regulatory-related actions in EPA’s plan. For six selected regulatory-related actions we identified in EPA’s February 2019 PFAS Action Plan, this report examines (1) the number of actions that are complete and the steps EPA took to complete them and (2) the number of actions that are ongoing and EPA’s progress toward completing them.

To address both objectives, we reviewed the 23 actions outlined in EPA’s February 2019 PFAS Action Plan. The actions can be described as regulatory-related, research-related, or related to risk-based communication.18 We selected the six regulatory-related actions to review because they may lead to the issuance of federal regulations or could influence or affect compliance with existing regulations, such as permitting decisions. However, according to EPA officials, the actions in the PFAS Action Plan are interrelated; for example, some research initiatives could be used to support potential regulatory actions and to improve risk communications.19 EPA also indicated that the agency has taken steps on many of its non-regulatory-related PFAS actions, which are not described in our report, such as compiling and assessing human

18We developed these three categories to describe the general types of actions outlined in the PFAS Action Plan. When we asked EPA for input on the categories, an EPA official stated that the agency does not categorize the actions. In EPA’s PFAS Action Plan, EPA organized the actions as either short-term, long-term, or priority actions. According to the plan, short-term actions are generally expected to be completed within 2 years. Actions classified as long-term, such as multistep research initiatives or regulatory actions, are generally expected to take more than 2 years. Although EPA did not define “priority action” in its action plan, the agency listed five actions as priority actions. For example, one priority action was to continue the regulatory development process to designate certain PFAS as hazardous substances.
19For example, we did not review actions, such as the development of toxicity values, that could eventually be used in future regulatory-related activities by EPA. However, as noted by EPA officials, EPA’s regulatory-related actions are supported by scientific data and technical research, and research is required to improve understanding about the risks associated with PFAS and to support EPA in making informed decisions to protect public health. For more information about EPA’s Integrated Risk Information System Program—which identifies and characterizes the health hazards of chemicals found in the environment—see GAO, Chemical Assessments: Status of EPA’s Efforts to Produce Assessments and Implement the Toxic Substances Control Act, GAO-19-270 (Washington, D.C.: Mar. 4, 2019) and GAO, Chemical Assessments: Annual EPA Survey Inconsistent with Leading Practices in Program Management, GAO-21-156 (Washington, D.C.: Dec. 18, 2020).
and ecological toxicity information on PFAS to support decision-making. Three of the selected six regulatory-related actions in the PFAS Action Plan address PFAS in water and are associated with federal statutes primarily addressing drinking water and surface water. The remaining three regulatory-related actions address industrial releases of PFAS to the environment, the use of certain PFAS in manufacturing or in imported goods, and the designation of certain PFAS as hazardous substances. These actions are associated with federal statutes primarily addressing risk communication, chemical management, and cleanup. For each of the selected regulatory-related actions, we assessed EPA’s progress in implementing the action by collecting and reviewing documents from EPA and public sources that identified steps the agency had taken. We also asked EPA officials to identify which actions they thought were complete for the purposes of the PFAS Action Plan.

We then conducted an independent assessment to determine whether the selected actions were complete. During our assessment, two analysts first agreed upon three categories—completed, ongoing, and not started—to describe the status of the actions. Each analyst then independently reviewed information previously collected on the steps EPA had taken to address the six regulatory-related actions and compared the steps taken against what EPA officials had identified as the endpoint for the action. Based on the information, each analyst made their own assessment of whether the action was complete, ongoing, or not started. The analysts then compared their assessments against one another’s and against EPA’s. In all six cases, the analysts agreed with one another as well as EPA regarding the status of the six selected regulatory-related actions. Additionally, we collected supporting documentary evidence, interviewed EPA officials, and reviewed written answers provided by EPA in response to our questions. Finally, we assessed EPA’s response to provisions of the FY20 NDAA that were relevant to three of the six selected regulatory-related actions.

We conducted this performance audit from December 2019 to January 2021, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.
Background

PFAS Pathways into the Environment

PFAS are used in consumer and industrial products and at manufacturing and processing facilities, airports, and military installations. According to scientific literature, some PFAS chemicals are pervasive in the environment and bioaccumulate\(^{20}\) in humans and animals.\(^{21}\) PFAS can enter the environment in a number of ways, including when sludge byproducts from wastewater treatment plants—called biosolids—are deposited on agricultural lands as fertilizer.\(^{22}\) The PFAS in biosolids can then run off into surface waters or seep underground and contaminate groundwater.\(^{23}\) PFAS can also enter source waters from the discharge of wastewater effluent or from rain contaminated by industrial facilities' air emissions.\(^{24}\) Additionally, PFAS can enter groundwater from areas where firefighting foam was used or from landfill leachate when materials with high levels of PFAS are disposed (see fig. 1).\(^{25}\)

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\(^{20}\)Bioaccumulation is defined as the accumulation of a substance and especially a contaminant (such as a pesticide or heavy metal) in a living organism.


**Figure 1: Examples of How Per- and Polyfluoroalkyl Substances (PFAS) Enter the Environment and Water**

- **Sludge byproducts (biosolids) from wastewater treatment plants are spread on agricultural land as fertilizer and can contain PFAS and lead to water contamination.**

- **Food products, such as milk, can become contaminated if livestock consume PFAS in food or water.**

- **Groundwater and source water can be contaminated when firefighting foam is used at civilian and military airports or PFAS-containing products are disposed of in landfills.**

- **Wastewater treatment plants can discharge PFAS into source waters used by drinking water systems.**

- **Manufacturing sites can contaminate ground or surface waters with PFAS.**

- **Consumer products may contain PFAS (e.g., carpet, food packaging, and nonstick cookware).**

- **Private wells can be contaminated with groundwater containing PFAS.**

Source: GAO | GAO-21-37
Human Exposure to PFAS

According to epidemiological research by CDC scientists and others, human exposure to PFAS occurs primarily by ingesting contaminated drinking water and food, and also by inhaling indoor air, using products that contain PFAS, and coming into contact with other contaminated media.\(^{26}\) According to EPA and scientific studies, people can also be exposed to PFAS in their workplaces and homes. Workers can be exposed to PFAS at a workplace that produces or uses PFAS. While some companies in the U.S. have voluntarily phased out certain PFAS from their production processes and replaced them with chemicals that are generally less bioaccumulative and potentially less toxic, legacy uses and a lack of commercially viable alternatives for certain safety products, such as firefighting foams, have resulted in PFAS contamination in numerous locations in the U.S., according to EPA’s PFAS Action Plan: Program Update. Further, the public can be exposed to PFAS by consuming meat, fish, or dairy from animals that have been exposed to PFAS. According to EPA’s PFAS Action Plan, fetuses can be exposed to PFAS in utero, and nursing mothers can expose their children to PFAS through breastmilk.

EPA’s PFAS Action Plan

Acknowledging PFAS’s widespread use and persistence in the environment, and evidence that continued exposure to specific PFAS above certain levels may have adverse effects on human health, EPA released a PFAS Action Plan in February 2019. The plan responded to public input the agency received in 2018, during the PFAS National Leadership Summit, multiple community engagements, and through the public docket.\(^{27}\) According to a February 2020 letter included in a PFAS Action Plan: Program Update from EPA’s Administrator, the plan marked the first time that EPA had engaged all of its program offices to deal with emerging chemicals of concern and develop a multimedia, multiprogram, and multiagency approach.


\(^{27}\) According to EPA documents, the PFAS National Leadership Summit included representatives from 13 federal agencies and over 40 states, tribes, and territories, as well as congressional staff, associations, industry groups, and nongovernmental organizations. These groups engaged in discussions about PFAS monitoring, risk characterization, near-term actions, and risk communication strategies.
The plan outlined 23 actions—identified as either priority, short-term, or long-term—that EPA intended to take to reduce exposure to and risk from PFAS and detailed EPA’s commitment to understanding the potential impacts from a broad suite of PFAS. For example, the plan outlined actions EPA intends to take in the near term to address current contamination by PFAS—such as identifying new treatment and remediation options—and steps the agency plans to take in the long term to prevent future contamination, including identifying sources of industrial discharges of PFAS into waterbodies.

Federal Statutes Relevant to the Six Selected EPA Regulatory-Related PFAS Actions

There are five primary federal statutes relevant to our review of six selected regulatory-related actions outlined in EPA’s *PFAS Action Plan*: (1) Toxic Substances Control Act (TSCA); (2) Emergency Planning and Community Right-to-Know Act; (3) Safe Drinking Water Act; (4) Clean Water Act; and (5) Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (see table 1). In addition, the FY20 NDAA also contains provisions related to these actions.

<table>
<thead>
<tr>
<th>Planned action</th>
<th>Description</th>
<th>Relevant statute(s)</th>
</tr>
</thead>
</table>
| Significant new use rule (SNUR) | Issue a supplemental proposed SNUR under the Toxic Substances Control Act. | Toxic Substances Control Act
  - National Defense Authorization Act for Fiscal Year 2020 (FY20 NDAA)<sup>a</sup> |
| Toxics Release Inventory (TRI) | Explore available data for listing PFAS chemicals to the TRI. | Emergency Planning and Community Right-to-Know Act
  - FY20 NDAA |
| Drinking water regulatory determination | Propose a drinking water regulatory determination for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). | Safe Drinking Water Act |
| Monitor PFAS in drinking water | Propose a nationwide drinking water monitoring rule for additional PFAS under EPA’s Unregulated Contaminant Monitoring Rule 5. | Safe Drinking Water Act
  - FY20 NDAA<sup>a</sup> |
| National Effluent Limitations Guidelines | Explore industrial sources of PFAS that may warrant potential regulation through EPA’s National Effluent Limitations Guidelines to include in EPA’s *Effluent Guidelines Program Plan* 14. | Clean Water Act |

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<sup>b</sup>According to the plan, short-term actions are generally expected to be completed within 2 years. Actions classified as long-term, such as multistep research initiatives or regulatory actions, are generally expected to take more than 2 years.
<table>
<thead>
<tr>
<th>Planned action</th>
<th>Description</th>
<th>Relevant statute(s)</th>
</tr>
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<tbody>
<tr>
<td>Hazardous substances</td>
<td>Continue the regulatory process for listing PFOA and PFOS as hazardous</td>
<td>CERCLA</td>
</tr>
<tr>
<td>designation</td>
<td>substances under the Comprehensive Environmental Response, Compensation,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>and Liability Act (CERCLA).</td>
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While not the primary statute governing this EPA action, the FY20 NDAA also contains provisions related to this action.

**Toxic Substances Control Act**

The Toxic Substances Control Act of 1976 (TSCA), as amended, authorizes EPA to review chemicals already in commerce (existing chemicals) and chemicals yet to enter commerce (new chemicals), obtain more information on the effects of chemicals on human health and the environment, and regulate those that EPA determines pose unreasonable risks to human health or the environment.\(^{30}\) For existing chemicals, Section 5 of TSCA allows EPA to issue significant new use rules (SNUR) that require companies to provide notice to EPA before chemical substances and mixtures are manufactured (including imported) or processed for significant new uses. Once notified, EPA must make a determination within 90 days and take any required actions in connection with that determination before the submitter may commence manufacturing (including importing) or processing for a significant new use.

**Emergency Planning and Community Right-to-Know Act**

Under Section 313 of the Emergency Planning and Community Right-to-Know Act, U.S. facilities in certain industry sectors are required to report annually to EPA’s Toxics Release Inventory (TRI) program about the release and other waste management of specific chemicals into the environment.\(^{31}\) The TRI program’s mission is to provide the public with information about TRI chemicals from TRI-reporting facilities and offers multiple online tools to make these data available. The TRI program can also help EPA understand how industrial and federal facilities dispose of PFAS through releases or other waste management practices. TRI data

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\(^{31}\)The term “release” means any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment (including the abandonment or discarding of barrels, containers, and other closed receptacles) of any hazardous chemical, extremely hazardous substance, or toxic chemical. 42 U.S.C. § 11049(8).
do not reveal whether or to what degree the public is exposed to listed chemicals, but the data can be used in conjunction with other information to evaluate the risks posed by exposure. According to the *PFAS Action Plan*, TRI helps support informed decision-making by companies, government agencies, nongovernmental organizations, and the public.\(^\text{32}\)

**Safe Drinking Water Act**

The Safe Drinking Water Act includes a requirement that EPA establish legally enforceable standards for public water systems—called National Primary Drinking Water Regulations—that generally limit the levels of specific contaminants in drinking water based on three criteria, including that the contaminant can adversely affect public health.\(^\text{33}\) EPA has issued primary standards addressing over 90 contaminants. States typically have the lead role in implementing and enforcing these federal drinking water regulations.

EPA established its Unregulated Contaminant Monitoring Rule (UCMR) program under the Safe Drinking Water Act to monitor drinking water for unregulated contaminants.\(^\text{34}\) As part of the UCMR, the act requires EPA to publish a rule every 5 years, listing no more than 30 contaminants to be monitored by public water systems. The Safe Drinking Water Act also requires EPA to issue a list every 5 years—known as the Contaminant Candidate List (CCL)—which identifies unregulated contaminants that are

\(^{32}\) TRI release forms are intended to provide information to federal, state, and local governments and the public, including citizens of communities surrounding covered facilities. The release form shall be available to inform persons about releases of toxic chemicals to the environment; to assist governmental agencies, researchers, and other persons in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes. 42 U.S.C. § 11023(h).

\(^{33}\) Specifically, EPA makes regulatory determinations based on the following, all of which must be met for EPA to decide that a drinking water regulation is warranted: (1) a contaminant may have an adverse health effect; (2) it is known to occur or there is a substantial likelihood that it will occur in public water systems with a frequency and level of public health concern; and (3) in the sole judgment of the EPA Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems. 42 U.S.C. § 300g-1(b)(1)(A).

\(^{34}\) Unregulated drinking water contaminants include chemical and microbial substances that are not currently subject to National Primary Drinking Water Regulations under the Safe Drinking Water Act. States may regulate some of these contaminants. Under state laws, some state environmental agencies have the authority to regulate additional contaminants or establish more stringent standards than federal regulations, while others do not have such authorities.
The Safe Drinking Water Act, as amended in 1996, requires the Environmental Protection Agency (EPA) to make regulatory determinations every 5 years for at least five unregulated contaminants. EPA has issued regulatory determinations for 34 contaminants—24 were negative, six were preliminary negative, three were preliminary positive, and one was a final positive regulatory determination.

Specifically, EPA made preliminary positive regulatory determinations for strontium in 2014 and for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) in March 2020. As of December 2020, the agency had not issued final determinations for PFOA, PFOS, or strontium.

EPA published a final positive regulatory determination to regulate perchlorate in 2011, but did not propose a maximum contaminant level within the 24-month statutory deadline. This resulted in a lawsuit that led to a consent decree requiring EPA to do so by 2019; in June 2019, EPA issued the proposed rule. However, in a July 2020 Federal Register notice, EPA announced the decision not to regulate perchlorate based on data and analysis obtained since the issuance of the 2011 determination. Specifically, EPA determined that the occurrence of perchlorate in public water systems was not at a frequency or level of public health concern. As such, perchlorate no longer met the statutory criteria for regulation and EPA did not have authority to regulate. EPA now seeks to terminate the consent decree, but environmental group plaintiffs argue that the Safe Drinking Water Act prohibits EPA from revoking a positive regulatory determination.

Sources: GAO analysis of EPA documents; GAO (photo).

Contaminants That Have Received Positive Regulatory Determinations under the Safe Drinking Water Act

Known or anticipated to occur in public water systems that may require regulation, and make regulatory determinations for at least five of the contaminants on the list every 5 years. The Safe Drinking Water Act directs EPA to select contaminants that pose the greatest public health
concern for consideration for the CCL and regulatory determinations. EPA is currently preparing for its fifth CCL and UCMR cycle (UCMR5).\(^{35}\)

If EPA makes a positive determination to regulate a contaminant, the Safe Drinking Water Act requires EPA to propose a National Primary Drinking Water Regulation rule within 24 months and to finalize that proposed rule within 18 months (see app. I for an overview of EPA’s process for regulating new drinking water contaminants under the Safe Drinking Water Act). When proposing an initial drinking water regulation, EPA proposes a nonenforceable maximum contaminant level goal at which no known or anticipated adverse health effects are expected to occur. The final rule generally includes an enforceable maximum contaminant level, which EPA sets as close as is feasible to the maximum contaminant level goal or a treatment technique requirement that prevents adverse health effects to the extent feasible.\(^{36}\)

Regulations generally take effect 3 years after promulgation, but EPA may allow up to 2 additional years for the rule to take effect if the agency determines that more time is needed for public water systems to make the necessary capital improvements. EPA is required to review these regulations every 6 years.\(^{37}\) EPA has not regulated any new contaminants through the regulatory determination process since 1996, when the Safe Drinking Water Act was amended to establish the current process (see app. II for additional information on EPA’s regulatory determinations, including the number of contaminants that have been monitored and regulated under the Safe Drinking Water Act).\(^{38}\) According to an EPA official from EPA’s Office of Water, since 1996, the agency has issued a

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\(^{35}\)UCMR 5 will run from 2022 to 2026 and will collect data from public water systems from 2023 to 2025.

\(^{36}\)42 U.S.C. § 300g-1(b)(4)(B), (b)(7). EPA must set maximum contaminant-level goals at levels at which no known or anticipated adverse effects on the health of persons occur, including adequate margins of safety. 42 U.S.C. § 300g-1(b)(4)(A).

\(^{37}\)42 U.S.C. § 300g-1(b)(9). For example, in November 2019, the agency proposed extensive changes to its regulation of lead in drinking water supplies. 84 Fed. Reg. 61684 (Nov. 13, 2019).

\(^{38}\)We previously reported on EPA’s process for regulating drinking water contaminants in GAO, Drinking Water: EPA Has Improved Its Unregulated Contaminant Monitoring Program, but Additional Action Is Needed, GAO-14-103 (Washington, D.C.: Jan. 9, 2014). Since 1999, EPA has monitored 111 contaminants under its UCMR program and has issued 24 negative determinations for contaminants, six preliminary negative determinations, three preliminary positive determinations, and one positive determination; however, EPA has not finalized the process to regulate any new contaminants.
The Clean Water Act aims to "restore and maintain the chemical, physical, and biological integrity of the nation’s waters." One of EPA’s main responsibilities under the act is to regulate point source pollution—that is, pollution such as effluent or wastewater coming from a discrete point, such as a pipe from an industrial facility. EPA’s actions to reduce point source pollution have included establishing national technology-based regulations—or effluent guidelines—for various industrial categories, such as petroleum refining, fertilizer manufacturing, coal mining, and metal finishing. EPA issued the vast majority of these regulations in the 1970s and 1980s and has subsequently revised some of them. The revisions to the regulations have ranged from changes in testing methods to the establishment of more stringent standards. In EPA’s 2016 Effluent Guidelines Program Plan, EPA identified PFAS as a

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41 Technology-based effluent limitations require a minimum level of treatment of pollutants for point source discharges based on available treatment technologies, while allowing the discharger to use any available control technique to meet limits.
topic for future investigation. The plan stated that EPA’s reviews of PFAS will include examination of surface water discharges from industrial categories that still may be using existing supplies of long-chain PFAS, as well as assessment of industrial categories that may be producing or using short-chain PFAS.

Under the Clean Water Act, all facilities that discharge pollutants from any point source to a water of the U.S. must obtain a permit under the National Pollutant Discharge Elimination System program, which sets limits on pollutant discharges. Under the Clean Water Act, EPA can authorize state, tribal, and territorial governments to implement the National Pollutant Discharge Elimination System program, enabling them to develop permits and enact other administrative and enforcement aspects of the program. According to EPA’s PFAS Action Plan, PFAS can be considered pollutants under the Clean Water Act and, therefore, states can use pollutant discharge permits to control discharges containing PFAS from point sources into receiving waters, including sources of drinking water. However, in part because National Effluent Limitations Guidelines currently do not regulate PFAS, relatively few

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42Environmental Protection Agency, Final 2016 Effluent Guidelines Program Plan, EPA-821-R-18-001 (Washington, D.C.: April 2018). Under the Clean Water Act, EPA is required to publish an Effluent Guidelines Program Plan every 2 years. According to EPA, the plan summarizes the agency’s review of effluent guidelines. In establishing and revising effluent guidelines, EPA is to assess (1) the performance and availability of the best pollution control technologies or pollution prevention practices for an industrial category; (2) the economic achievability of those technologies; (3) non-water-quality environmental impacts, such as the energy required to reduce pollutants; and (4) other factors that the EPA Administrator deems appropriate, such as the risk posed by discharges. The legislative history of relevant provisions in the Clean Water Act suggests that effluent guidelines were expected to be revised and made more stringent over time to reflect technological advances.

43Long-chain PFAS are perfluoroalkyl carboxylic acids with eight or more perfluorinated carbons or perfluoroalkyl sulfonic acids with six or more perfluorinated carbons. Short-chain PFAS are perfluoroalkyl carboxylic acids with fewer than eight carbon molecules or perfluoroalkyl sulfonic acids with fewer than six carbon molecules.

44According to EPA’s Preliminary Effluent Guidelines Program Plan 14, over 35,000 industrial facilities directly discharge wastewater into the waters of the U.S. Direct dischargers are subject to National Pollutant Discharge Elimination System permit limits on their discharges. Indirect dischargers, which discharge to sewer systems and not surface waters, do not require a permit. Instead, an indirect discharger must meet EPA’s national pretreatment standards and may have to meet additional pretreatment conditions imposed by its local wastewater treatment plant. Under the national pretreatment standards and conditions, an indirect discharger is required to remove pollutants that may harm wastewater treatment plant operations or workers or, after treatment and discharge, cause violations of the wastewater treatment plant’s permits.
facilities have permit limits or monitoring requirements for PFAS, according to EPA documents we reviewed.\(^{45}\)

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) authorizes EPA and federal agencies to respond to releases or threatened releases of hazardous substances and created a trust fund to provide for certain cleanup activities.\(^{46}\) CERCLA defines hazardous substances to include chemicals and wastes listed as hazardous under any one of several environmental laws, including the Clean Water Act and TSCA. CERCLA also allows EPA to designate additional chemicals as hazardous substances.\(^{47}\) No PFAS are currently designated as hazardous substances under CERCLA.

Three of the six selected regulatory-related actions outlined in EPA’s February 2019 PFAS Action Plan are complete (see table 2). Specifically, the EPA Administrator signed a final SNUR for PFAS, as required by the FY20 NDAA. In addition, in response to the FY20 NDAA, EPA incorporated 172 PFAS into the Code of Federal Regulations for the TRI, which, according to EPA, will require for the first time that the public be provided information about industrial releases of PFAS chemicals. EPA also published a notice in the Federal Register proposing a preliminary drinking water regulatory determination for two PFAS: PFOA and PFOS.

\(^{45}\)To begin addressing PFAS discharges through EPA-issued National Pollutant Discharge Elimination System permits, EPA’s Assistant Administrator for Water sent a November 2020 memo to all 10 EPA regions containing recommendations from an intra-agency workgroup. The memo provides an interim approach for including PFAS-related conditions in EPA-issued permits. See https://www.epa.gov/pfas/interim-strategy-and-polyfluoroalkyl-substances-federally-issued-national-pollutant-discharge.

\(^{46}\)According to EPA’s PFAS Action Plan, PFOA and PFOS are considered CERCLA pollutants or contaminants, not hazardous substances. Thus, federal response and cleanup authority exists where the federal agency with CERCLA authority has made a determination that the PFOA or PFOS release may present an imminent and substantial danger to public health or welfare. Under CERCLA, responsible parties are liable for the cleanup of releases of substances that have been designated as hazardous, but not for pollutants and contaminants, such as PFOA and PFOS. See 42 U.S.C. § 9607(a).

\(^{47}\)EPA’s PFAS Action Plan states that, consistent with CERCLA, the Agency for Toxic Substances and Disease Registry recently released draft toxicological profiles for multiple PFAS, which included minimal risk levels for four PFAS, including PFOA and PFOS. When finalized, these minimal risk levels will serve as screening tools to help public health professionals determine areas and populations potentially at risk for exposure, and the levels can be used as a mechanism to identify hazardous waste sites that are not expected to cause adverse health effects.
Table 2: Selected Regulatory-Related Actions from the Environmental Protection Agency’s (EPA) Per- and Polyfluoroalkyl Substances (PFAS) Action Plan That Are Complete

<table>
<thead>
<tr>
<th>Planned action</th>
<th>Description</th>
<th>Relevant statute(s)</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant new use rule (SNUR)</td>
<td>Issue a supplemental proposed SNUR under the Toxic Substances Control Act.</td>
<td>Toxic Substances Control Act</td>
<td>Complete</td>
</tr>
<tr>
<td></td>
<td></td>
<td>National Defense Authorization Act for Fiscal Year 2020 (FY20 NDAA)^a</td>
<td></td>
</tr>
<tr>
<td>Toxics Release Inventory (TRI)</td>
<td>Explore available data for listing PFAS chemicals to the TRI.</td>
<td>Emergency Planning and Community Right-to-Know Act</td>
<td>Complete</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FY20 NDAA^a</td>
<td></td>
</tr>
<tr>
<td>Drinking water regulatory determination</td>
<td>Propose a drinking water regulatory determination for perfluorooctanoic acid and perfluorooctane sulfonate.</td>
<td>Safe Drinking Water Act</td>
<td>Complete</td>
</tr>
</tbody>
</table>


^aWhile not the primary statute governing this EPA action, the FY20 NDAA also contains provisions related to this action.
EPA’s 2019 PFAS Action Plan identified, as a priority action for the agency, issuing a supplemental proposed SNUR for PFAS after considering the new statutory requirements added to TSCA by the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act. SNURs require that companies notify EPA before chemical substances and mixtures are manufactured (including imported) or processed for significant new uses. On February 20, 2020, EPA issued a supplemental proposed SNUR. On June 22, 2020, EPA finalized the SNUR, a draft of which had been proposed in 2015, authorizing the agency to review new uses of certain PFAS in products before they could be manufactured, imported, or sold in the U.S. The final SNUR was signed by the EPA Administrator on the June 22 deadline set by the FY20 NDAA, which required EPA to take final action on the 2015 proposed rule. The final rule regulates PFAS by requiring notice and EPA review before long-chain PFAS chemicals that had been previously phased out in the U.S. can be used again. Additionally, under the final rule, articles containing certain long-chain PFAS as a surface coating, and carpet containing perfluoroalkyl sulfonate chemical substances, can no longer be imported into the U.S. without EPA review.


49 Under EPA’s 2010/2015 PFOA Stewardship Program, eight major U.S. chemical manufacturers and processors voluntarily phased out the use of PFOA and PFOA-related chemicals in products and emissions from their facilities.

50 Long-chain perfluoroalkyl carboxylates are chemical substances with perfluorinated carbon chain lengths equal to or greater than seven carbons and less than or equal to 20 carbons. Examples of articles that could contain these chemical substances as part of a surface coating include, but are not limited to, apparel, outdoor equipment, automotive parts, carpets, furniture, and electronic components. The Federal Register notice stated that EPA did not intend to finalize a definition of surface coating in the rule but that EPA would issue guidance within a reasonable time frame. The notice further stated that EPA believed this approach would ensure an opportunity to conduct a detailed consideration of potential exposures related to these uses when there is a specific condition of use to review. 85 Fed. Reg. 45,114. According to EPA officials, as of December 2020, EPA has developed this guidance and has submitted it to the Office of Management and Budget (OMB) for review. The guidance provides additional clarity on what is meant by “surface coating” and identifies which entities are regulated, among other things.
EPA’s 2019 PFAS Action Plan identifies exploring available data for listing PFAS chemicals on the TRI as a long-term action for the agency. EPA’s PFAS Action Plan update noted that adding PFAS to the TRI would provide information on industrial releases of PFAS chemicals to the public for the first time. In December 2019, EPA published an advanced notice of proposed rulemaking to solicit information on possibly adding PFAS to the TRI, which, according to EPA officials, completed EPA’s PFAS Action Plan planned action to explore available data. However, according to EPA officials, the FY20 NDAA expanded EPA’s action to explore data by requiring EPA to add certain PFAS to the TRI list effective January 1, 2020. EPA incorporated 172 PFAS into the Code of Federal Regulations on June 22, 2020 in response to the FY20 NDAA. EPA officials consider this action complete. The FY20 NDAA adds PFAS to the

51 U.S. facilities in certain industry sectors must submit information on releases of chemicals listed on the TRI to EPA. EPA then compiles the data and makes them available online to the public.


53 According to EPA officials, the agency does not plan to follow up on its December 2019 advance notice of proposed rulemaking with a proposed rule. Instead, the agency is focusing on implementing the ongoing TRI requirements outlined in the FY20 NDAA.

54 The FY20 NDAA specifically identified some of the PFAS to be added to the TRI, and other PFAS were added by EPA because the PFAS met criteria laid out in the act. Specifically, the FY20 NDAA identified 14 PFAS to be added to the TRI and directed EPA to add other PFAS to the TRI if they met two criteria: (1) they were subject to a significant new use rule at either 40 C.F.R. § 721.9582 or § 721.10536 on or before December 20, 2019; and (2) they were identified as active in commerce on the February 2019 TSCA inventory. As of July 2020, only PFAS directly added by the FY20 NDAA under section 7321(b)(1) (“immediate inclusion”) have been added to the TRI. The FY20 NDAA further requires EPA to consider adding PFAS chemicals to the TRI in the future, in addition to the 172 that met the act’s criteria.

55 85 Fed. Reg. 37,354 (June 22, 2020) (codified at 40 C.F.R. pt. 372). In the final rule, EPA codified the TRI reporting threshold—the threshold at which facilities must report PFAS releases—for manufacturing, processing, and otherwise use reporting, at 100 pounds per PFAS, as provided by the NDAA. TRI-reporting facilities will be required to report on releases of the 172 PFAS added to the TRI for the 2020 calendar year. This reporting will be due by July 1, 2021. According to EPA officials, after receiving and analyzing data from the first year of reporting PFAS to the TRI, EPA will reassess the need for any further regulatory action.
TRI any time EPA finalizes a toxicity value\textsuperscript{56} or issues certain significant new use rules and, as a result, EPA will continue listing certain PFAS on the TRI into the future.\textsuperscript{57}

### EPA Proposed a Preliminary Drinking Water Regulatory Determination for PFOA and PFOS

EPA’s 2019 \textit{PFAS Action Plan} identified proposing a preliminary drinking water regulatory determination for two PFAS, PFOA and PFOS, under the Safe Drinking Water Act—an early step in regulating these PFAS in drinking water—as a priority action for the agency in 2019. According to EPA officials, the agency considers this action complete as of March 10, 2020, when EPA published a \textit{Federal Register} notice proposing a preliminary drinking water regulatory determination to regulate PFOA and PFOS under the Safe Drinking Water Act.\textsuperscript{58} According to EPA, the agency plans the following next steps in the process:

- Evaluate public comments received in June 2020 for information that could inform the agency’s final regulatory determination.\textsuperscript{59}
- Submit the final draft of the regulatory determination notice to the Office of Management and Budget (OMB) for interagency review in the fall of 2020.
- Publish a final notice in the \textit{Federal Register} in early 2021.\textsuperscript{60}

\textsuperscript{56}EPA’s \textit{PFAS Action Plan} also includes a planned action to develop additional PFAS toxicity values and finalize draft toxicity assessments for certain PFAS. Draft toxicity assessments for two PFAS, GenX and perfluorobutane sulfonic acid, were published for public comment by EPA on November 21, 2018. According to EPA’s February 2020 \textit{EPA PFAS Action Plan: Program Update}, EPA expected to finalize these two toxicity assessments in 2020.

\textsuperscript{57}The FY20 NDAA directed EPA to, no later than 5 years from the enactment of the act, determine whether revision of the 100-pound reporting threshold is warranted. If EPA determines a revision is warranted, EPA will initiate a revision under Emergency Planning and Community Right-to-Know Act section 313(f)(2) (42 U.S.C. § 11023(f)(2)).

\textsuperscript{58}85 Fed. Reg. 14,098 (Mar. 10, 2020). According to EPA documents, in the proposed regulatory determination for PFOA and PFOS, the agency requested additional information on other PFAS substances and comment on potential monitoring requirements and regulatory approaches for PFAS chemicals. See 85 Fed. Reg. 14,135.

\textsuperscript{59}The comment period for the proposed regulatory determination for PFOA and PFOS closed on June 10, 2020.

\textsuperscript{60}In OMB’s Fall 2020 Regulatory Agenda, EPA confirmed that publication of its final determination would occur by January 2021. Following notice of a final positive regulatory determination, EPA is required to propose a National Primary Drinking Water Regulation within 24 months and to promulgate the final rule within another 18 months. 42 U.S.C. § 300g-1(b)(1)(E).
EPA officials did not indicate a time frame for when EPA might issue a final National Primary Drinking Water Regulation, which is the next step in the process to regulate PFAS in drinking water. The officials stated that the agency is working through the regulatory process outlined in the Safe Drinking Water Act and that the process typically takes a few years to complete. The officials further stated that EPA will follow the regulatory process established by Congress and mandated under the Safe Drinking Water Act, including meeting statutory deadlines and that their intent is to complete the process as expeditiously as possible.

Three of the six selected regulatory-related actions outlined in EPA’s February 2019 PFAS Action Plan are ongoing, and EPA’s progress on the actions varies (see table 3). Specifically, EPA plans to (1) propose additional PFAS to monitor, (2) explore industrial sources that may warrant regulation, and (3) continue the process to designate certain PFAS as hazardous substances.

### Table 3: Selected Regulatory-Related Actions from the Environmental Protection Agency’s (EPA) Per- and Polyfluoroalkyl Substances (PFAS) Action Plan That Are Ongoing

<table>
<thead>
<tr>
<th>Planned action</th>
<th>Description</th>
<th>Relevant statute(s)</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Effluent Limitations Guidelines</td>
<td>Explore industrial sources of PFAS that may warrant potential regulation through EPA’s National Effluent Limitations Guidelines to include in EPA’s Effluent Guidelines Program Plan 14.</td>
<td>Clean Water Act</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Hazardous substances designation</td>
<td>Continue the regulatory process for listing perfluorooctanoic acid and perfluorooctane sulfonate as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).</td>
<td>CERCLA</td>
<td>Ongoing</td>
</tr>
</tbody>
</table>


*While not the primary statute governing this EPA action, the National Defense Authorization Act for Fiscal Year 2020 also contains provisions related to this action.
EPA has identified, as a long-term action, proposing a nationwide drinking water rule for monitoring additional PFAS under EPA’s UCMR5 monitoring cycle. EPA anticipates publishing the final rule by December 2021. According to the plan, monitoring results will improve EPA’s understanding of the frequency and concentration of PFAS in U.S. drinking water.

According to EPA officials, this action will be complete when EPA publishes the proposed rule for UCMR5. In addition to EPA’s planned actions under the PFAS Action Plan, the FY20 NDAA directed EPA to include all PFAS in UCMR5 that met two criteria: (1) the PFAS can be identified through a test method validated by the Administrator for measuring its level in drinking water and (2) the PFAS are not already subject to a national primary drinking water regulation. EPA officials stated that the agency has developed methods to measure 29 PFAS in drinking water. As of August 2020, the agency was developing a proposed rulemaking for UCMR5; EPA officials told us that in July 2020, the agency transmitted the proposed rulemaking for UCMR5 to OMB for

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61EPA previously monitored some PFAS through its UCMR program. Specifically, six PFAS were monitored during the third UCMR cycle (UCMR3): PFOA, PFOS, perfluorobutane sulfonic acid, perfluorononanoic acid, perfluorohexane sulfonic acid, and perfluoroheptanoic acid. EPA included PFOA and PFOS on its fourth CCL, but did not require monitoring for them during its fourth UCMR. The PFAS Action Plan states that the monitoring will utilize newer methods available to detect more PFAS chemicals and at lower minimum reporting levels than previously possible in earlier UCMR monitoring cycles.

62The act further specified that the PFAS to be monitored under UCMR5 shall not count towards the limit of 30 unregulated contaminants to be monitored by public water systems under the Safe Drinking Water Act. Pub. L. No. 116-92, § 7311.

63EPA officials did not address whether the 29 PFAS they intend to include in UCMR5, per the FY20 NDAA provisions, would or would not be in addition to the 30 total unregulated contaminants they could otherwise test for. With the additional authority provided by the FY20 NDAA, EPA could test for 59 unregulated contaminants in its upcoming UCMR5 cycle. As we have previously reported, EPA has not always used its full statutory authority to test for the 30 contaminants allowed under each 5-year UCMR testing cycle. As a result, we recommended that the agency do so. See GAO, Safe Drinking Water Act: EPA Should Improve Implementation of Requirements on Whether to Regulate Additional Contaminants, GAO-11-254 (Washington, D.C.: May 27, 2011). Further, in 2014, we suggested Congress consider amending the Safe Drinking Water Act to allow EPA to monitor for more than 30 contaminants under certain circumstances. See GAO-14-103.
EPA’s 2019 PFAS Action Plan identified, as a long-term action, both examining available information and exploring additional information to identify industrial sources of PFAS that may warrant potential regulation through EPA’s national Effluent Limitations Guidelines and describing those actions in EPA’s Effluent Guidelines Program Plan 14 (2019). According to agency officials, EPA is currently examining available information about PFAS discharges to surface water to identify industrial sources that may warrant further study for potential regulation. If industrial discharges of PFAS are identified, EPA can promulgate technology-based standards to limit those discharges. In October 2019, EPA published its Preliminary Effluent Guidelines Program Plan 14 for public comment. In the preliminary plan, EPA included initial analyses of industrial sources and discharges of PFAS and identified several industrial sources of PFAS, including airports, organic chemical manufacturers, paper and paperboard manufacturers, textile and carpet manufacturers, and semiconductor manufacturers. According to agency officials, this information is part of a multi-industry study to determine which industries are most likely to discharge PFAS into the environment and the specific PFAS compounds currently in use. EPA officials stated that EPA’s decisions regarding which contaminants to include in a UCMR cycle take into account many factors, including availability of occurrence data; potential for the contaminant to occur in drinking water; availability of a completed, validated drinking water method; availability of health assessments or other health-effects information; active use (e.g., pesticides that are registered for use); cost-effectiveness of the potential monitoring approaches; and implementation factors (e.g., laboratory capacity).

EPA must prepare Preliminary Effluent Guidelines Program Plans pursuant to the Clean Water Act. Preliminary plans provide a summary of the EPA’s review of effluent guidelines and pretreatment standards. Based on these reviews, preliminary plans identify any new or existing industrial categories selected for effluent guidelines or pretreatment standards rulemakings and provide a schedule for such rulemakings. Additionally, preliminary plans present any new or existing categories of industry selected for further review and analysis.

According to EPA, technology-based standards are based on the performance of treatment and control technologies; they are not based on risk or impacts upon receiving waters.

that the multi-industry study will provide EPA with data that will be used to inform next steps but did not identify what steps might remain to be taken. The officials told us that they will consider this action to be complete once EPA has published information on industrial sources of PFAS in a publicly available document. According to EPA officials, the agency expects to publish a final Effluent Guidelines Program Plan 14 in early 2021 that will include an update on the current status of EPA’s multi-industry study.

EPA Plans to Continue the Process to Designate Certain PFAS as Hazardous Substances

EPA’s 2019 PFAS Action Plan identified continuing the regulatory development process for listing PFOA and PFOS as hazardous substances under CERCLA, which EPA began in 2018, as a priority action for the agency.68 Designating PFOA and PFOS as hazardous substances under CERCLA would allow EPA to require responsible parties to respond to a release of either contaminant and would make them liable for the costs of response actions.69 EPA officials did not indicate how they would determine when this action is complete for the purposes of the PFAS Action Plan and stated that the decision to continue or conclude this process could occur at any time. In OMB’s 2020 Spring Regulatory Agenda, EPA indicated that it planned to issue a notice of proposed rulemaking for the hazardous substances designation in August 2020. On January 14, 2021, EPA issued an advance notice of proposed rulemaking for the hazardous substances designation to get public comment and data to inform the agency’s ongoing evaluation of PFOA and PFOS.

68According to EPA, the agency has not designated any substance as hazardous under CERCLA since Congress enacted the statute in 1980. According to EPA documents provided to the Senate Committee on Environment and Public Works in March 2019, 180 Superfund sites had been identified by EPA as having PFAS contamination. Accessed June 16, 2020, https://www.epw.senate.gov/public/index.cfm?p=Superfund-Sites-Identified-by-EPA-to-have-PFAS-Contamination.

69According to agency documents, in the absence of the hazardous substances designation rule, EPA has used its existing authorities under CERCLA, Resource Conservation and Recovery Act, Safe Drinking Water Act, and TSCA to take enforcement actions. As of August 2020, EPA reported that it had taken 14 enforcement actions to specifically address PFAS use and contamination under various legal authorities and that EPA plans to continue to do so to protect public health and the environment.
We provided a draft of this report to EPA for review and comment. EPA provided written comments, which are reproduced in appendix III. EPA also provided technical comments, which we incorporated as appropriate.

In its written comments, EPA neither agreed nor disagreed with our findings; however, EPA made several statements related to the focus of our review on the plan’s six regulatory-related actions. Specifically, EPA stated that it is important to consider the regulatory-related actions within the broader context of EPA’s PFAS Action Plan. EPA expressed concern that separating scientific work from our discussion of regulatory-related actions could create misunderstandings within Congress, among the states, and the American public about what is required under statutory requirements from a science and research perspective. EPA also indicated that the agency has taken steps on many of its non-regulatory-related PFAS actions, such as compiling and assessing human and ecological toxicity information on PFAS to support decision-making.

As we describe in our report, EPA’s plan includes 23 actions that can be grouped into three broad categories: regulatory-related, research-related, and risk-based communication. We agree that the actions are interrelated, as some research initiatives could be used to support potential regulatory actions and to improve risk communications. However, we chose to focus specifically on the six regulatory-related actions because they may lead to the issuance of federal regulations—a topic of interest to the Congress. We agree with EPA that the agency’s research-related and risk-based communication-related actions are also important and that continued progress on its other efforts is important for supporting its regulatory-related actions. We made clarifications in the report to address these points and believe that our report provides Congress with useful information for considering options that can best support EPA’s future actions to address PFAS.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees and the Acting Administrator of the Environmental Protection Agency. In addition, the report is available at no charge on the GAO website at https://www.gao.gov.
If you or your staff have any questions about this report, please contact me at (202) 512-3841 or GomezJ@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

J. Alfredo Gómez
Director, Natural Resources and Environment
Appendix I: Overview of the Environmental Protection Agency’s Process for Regulating New Drinking Water Contaminants

Identify contaminants
- Identify unregulated contaminants that are known or anticipated to occur in public water systems, and which may require regulation.
- Consult with the Science Advisory Board and provide opportunity for public comment.
- Publish unregulated contaminants to the Contaminant Candidate List (CCL) every 5 years to prioritize contaminants for regulatory decision-making and potential monitoring.

Monitor contaminants
- Publish a list every 5 years of up to 30 contaminants to be monitored by certain public water systems.6
- Monitor unregulated contaminants in public water systems through the Unregulated Contaminant Monitoring Rule (UCMR) program, and include results in EPA's occurrence database. UCMR data can be used to support the EPA Administrator’s determination on whether or not to regulate particular contaminants.

Make a regulatory determination
- Decide whether or not to regulate a contaminant on the CCL based on the contaminant's: (1) potential health effects; (2) frequency and level of occurrence; and (3) whether regulation presents a meaningful opportunity to reduce risks to human health.
- Publish a preliminary determination on whether or not to regulate those contaminants in the Federal Register; provide time for public comment and consultation with states and other federal agencies.
- Make final determinations on whether or not to regulate at least five CCL contaminants every 5 years.
- Publish a final regulatory determination in the Federal Register.

Regulate

Yes
If EPA decides to regulate: EPA starts the rulemaking process to establish a National Primary Drinking Water Regulation.7

No
If EPA decides not to regulate: EPA may take no further action or may develop a health advisory, as appropriate.8

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6 EPA’s UCMR program collects data on the extent of the occurrence of some unregulated contaminants in all public water systems serving more than 10,000 people and in a nationally representative sample of smaller systems. The National Defense Authorization Act for Fiscal Year 2020 requires monitoring of certain PFAS chemicals for all public water systems serving 3,300 to 10,000 people, subject to laboratory capacity and appropriations. UCMR cycles generally last 5 years, and then new contaminants are selected for a new round of UCMR monitoring. According to EPA officials, while EPA considers contaminants from the most recent CCL when identifying analytes for the UCMR, EPA does not limit the UCMR to only CCL contaminants.

7 EPA is required to propose a National Primary Drinking Water Regulation within 24 months and to issue a final rule within 18 months. EPA is also required to review all National Primary Drinking Water Regulations every 6 years to determine whether changes are needed.

8 The Safe Drinking Water Act authorizes EPA to publish health advisories or take other appropriate actions for contaminants not subject to any National Primary Drinking Water Regulation. EPA need not wait until it makes a regulatory determination to take these actions. EPA health advisories provide information on contaminants that can cause human health effects and are known or anticipated to occur in drinking water. The advisories are nonenforceable and nonregulatory and provide technical information to drinking water system managers and others with primary responsibility for overseeing the water systems with information on the health risk of identified, but unregulated, chemicals.

## Table 4: Summary of Environmental Protection Agency (EPA) Actions on Unregulated Contaminants, 1998–2020

<table>
<thead>
<tr>
<th>Contaminant Candidate List (CCL)</th>
<th>Unregulated Contaminant Monitoring Rule (UCMR) program</th>
<th>Regulatory determinations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td><strong>Identify unregulated contaminants that are known or anticipated to occur in public water systems, and which may require regulation.</strong></td>
<td><strong>Monitor unregulated contaminants in public water systems, and include results in EPA’s National Contaminant Occurrence Database.</strong></td>
</tr>
<tr>
<td><strong>Safe Drinking Water Act procedure</strong></td>
<td><strong>After consulting with the Science Advisory Board and providing opportunity for public comment, publish a CCL every 5 years.</strong></td>
<td><strong>Establish a monitoring program for unregulated contaminants in all large public water systems and a representative sample of systems serving more than 10,000 persons or fewer. Every 5 years, publish a list of up to 30 contaminants to be monitored.</strong></td>
</tr>
<tr>
<td><strong>Outputs, including final actions</strong></td>
<td><strong>1998 (60 contaminants on CCL1)</strong></td>
<td><strong>1999 (26 contaminants on UCMR1)</strong></td>
</tr>
<tr>
<td></td>
<td><strong>2005 (51 contaminants on CCL2)</strong></td>
<td><strong>2007 (25 contaminants on UCMR2)</strong></td>
</tr>
<tr>
<td></td>
<td><strong>2009 (116 contaminants on CCL3)</strong></td>
<td><strong>2012 (30 contaminants on UCMR3)</strong></td>
</tr>
<tr>
<td></td>
<td><strong>2016 (97 contaminants on CCL4)</strong></td>
<td><strong>2016 (30 contaminants on UCMR4)</strong></td>
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*The National Defense Authorization Act for Fiscal Year 2020 requires monitoring for all PFAS in UCMR5 that (1) can be identified through a test method validated by the EPA Administrator for measuring its level in drinking water and (2) that are not subject to a national primary drinking water regulation. The act further provides that PFAS monitoring under UCMR5 shall not count towards the limit of 30 unregulated contaminants to be monitored by public water systems.

*According to EPA officials, this was the first regulatory determination for a CCL3 contaminant.

*According to EPA documents, the final determination for strontium was delayed to “consider additional scientific data and decide whether there is a meaningful opportunity for health risk reduction by regulating strontium in drinking water.”

*EPA’s two preliminary positive determinations were for perfluorooctanesulfonic acid and perfluorooctanoic acid.
Appendix III: Comments from the Environmental Protection Agency

United States Environmental Protection Agency
Washington, D.C. 20460

December 14, 2020

The Administrator

Mr. Alfredo Gomez
Director
Natural Resources and Environment
U.S. Government Accountability Office
Washington, DC 20548

Dear Mr. Gomez:

Thank you for the opportunity to review and comment on U.S. Government Accountability Office’s (GAO) draft report (GAO-21-37), Man-Made Chemicals and Potential Health Risks. The U.S. Environmental Protection Agency is pleased to provide the Agency’s response to the draft report, along with technical comments that the Agency has previously provided GAO.

EPA appreciates the time and effort GAO has put into this report and learning the extensive efforts the Agency is undertaking to address per- and polyfluoroalkyl substances (PFAS). While GAO’s draft report details that the Agency has completed three of the six GAO-identified regulatory related actions for addressing PFAS and that the other three actions are ongoing, the Agency continues to insist that it is very important to present those GAO-identified regulatory actions in the broader context of EPA’s PFAS Action Plan. The PFAS Action Plan outlined 23 actions, the majority of which consist of various projects, assessments, studies, or steps to complete. Providing that context can help avoid any misunderstanding of the extent of EPA’s PFAS work and would allow for more transparency in describing the Agency’s unprecedented and historic steps taken to address PFAS.

It is important to reiterate that many of the actions in the PFAS Action Plan are closely inter-related. For example, all of EPA’s actions are supported by scientific data and technical research, and EPA’s PFAS research initiatives can be used to support regulatory actions and decisions. Robust research is a prerequisite to improving our understanding of the risks associated with these emerging chemicals of concern and helping the Agency make more informed decisions to protect public health. This is why the PFAS Action Plan has placed such a strong emphasis on scientific research. Detaching the vital scientific and technical research from the regulatory-related actions the research supports in this audit and a report for Congress detailing “EPA’s progress on regulatory-related actions in its PFAS Action Plan” is a disservice to that scientific work. It risks creating further misunderstanding within Congress, among the states, and the
Appendix III: Comments from the Environmental Protection Agency

American public of what is required under applicable statutory requirements from a science and research standpoint. Throughout this engagement, EPA has provided GAO with clarification to support GAO’s work, explain EPA’s work, and improve the accuracy of this report. We continue to believe that, while this audit focuses on these six GAO-identified regulatory-related actions, it is important to do so within the context of the much broader efforts the Agency is undertaking on PFAS. Many of these efforts are detailed below and are necessary initial steps to support any regulatory actions the Agency takes.

PFAS-related issues are an important priority for EPA, and we are working aggressively and cooperatively with our federal and state partners to take significant action in order to protect human health and the environment. In 2019, EPA issued the first-ever PFAS Action Plan—a historic step in our nation’s efforts to address PFAS in the environment. The PFAS Action Plan represented a number of important firsts for the Agency. It was the first time EPA has used all of its program offices to address an emerging class of chemicals of concern. It was also the first time the Agency put together a multi-media, multi-program national research, management, and risk communication plan to respond to a challenge like PFAS. By prioritizing work on the PFAS Action Plan, EPA is delivering on President Trump’s commitment to protect the health and well-being of communities across the country that are dealing with PFAS issues.

For close to two years, EPA has built on the momentum of the PFAS Action Plan put in motion, and the Agency’s efforts have been nothing short of unprecedented. The Agency has made progress in all program areas—from groundwater cleanup guidance, to new test methods that are helping to move research efforts forward, to updates to the Toxics Release Inventory, to progress on carrying out the Safe Drinking Water Act (SDWA) regulatory processes. These actions reflect the execution of the comprehensive and coordinated approach we outlined in the PFAS Action Plan.

Additionally, since the release of the PFAS Action Plan, the Agency has worked extensively to ensure it is accurately and effectively communicating this progress to Congress and the public. Key progress and accomplishments include:

- **Technical Assistance and Support**: Just as important as the progress on PFAS at the federal level are EPA efforts to form partnerships with states, tribes, and local communities across the country. EPA has provided assistance to more than 30 states to help address PFAS, and the Agency is continuing to build on this support. EPA has responded to requests for assistance from more than a dozen state and territorial governments by screening for PFAS at high priority sites and training local health agencies to test for PFAS on their own. EPA is also providing cleanup assistance to more than 30 states and the District of Columbia to address PFAS at contaminated groundwater and soil sites.

- **Funding**: As a leader in the nation’s efforts to address PFAS in the environment, EPA recognizes that providing funding to external organizations is a critical component to successfully addressing these chemicals. Under this Administration, EPA’s Office of Research and Development has awarded over $15 million through dozens of grants for PFAS research, including efforts to improve understanding of human and ecological exposure to PFAS, to assess and manage environmental risks posed by PFAS wastes, and to conduct research on PFAS in agriculture. States may also use capitalization grant funds from EPA to address PFAS under the Drinking Water State Revolving Fund.

- **Risk Communications and Community Engagement**: Risk communication and engagement are critical for EPA to effectively support communities across the United States that are
addressing PFAS. As outlined in the PFAS Action Plan, EPA is actively working to enhance the way in which the Agency communicates about potential human health risks that may be associated with PFAS. EPA is working collaboratively to develop a risk communication toolbox that includes multimedia materials and messaging for federal, state, tribal, and local partners to use with the public. In 2020, EPA developed and launched a premier, scientifically-grounded risk communication training platform and trained over 100 EPA employees, including a training session focused specifically on PFAS issues. The 17.5 hour course covers governing principles from the science or risk communication, the science of science communication, and the process for risk communication at EPA.

- **Research:** EPA’s goal under the PFAS Action Plan has been to develop and apply scientific information and tools to enable federal, state, local, and tribal governments to work together to make informed decisions to protect public health and the environment. Under the PFAS Action Plan, EPA has taken steps to prioritize PFAS research, including research to develop additional analytical methods, to evaluate toxicity and health effects, and to understand impacts to rural and agricultural communities. EPA continues to compile and assess human and ecological toxicity information on PFAS to support risk management decisions. The Agency is also validating analytical methods for surface water, groundwater, wastewater, soils, sediments and bio solids; developing new methods to test for PFAS in air and emissions; and improving laboratory methods to discover unknown PFAS. EPA is also developing exposure models to understand how PFAS moves through the environment to impact people and ecosystems. EPA is working to develop tools to assist officials with the cleanup of contaminated sites, and in July 2020, EPA added new treatment information for removing PFAS from drinking water. The full extent of EPA’s research supporting the PFAS Action Plan and various program initiatives can be found at https://www.epa.gov/chemical-research/research-and-polyfluoroalkyl-substances-pfas.

- **Environmental Cleanup:** EPA has made considerable progress under the PFAS Action Plan as it relates to cleanups. In December 2019, EPA issued the Interim Recommendations for Addressing Groundwater Contaminated with PFOA and PFOS under federal cleanup programs, a priority action under the PFAS Action Plan. EPA also continues working on the proposed rule to designate PFOA and PFOS as hazardous substances under CERCLA, while developing analytical methods for environmental media and conducting treatment and disposal research. In July 2020, EPA submitted the Interim Guidance on the Destruction and Disposal of PFAS and Materials Containing PFAS to Office of Management and Budget (OMB) for interagency review. The guidance would provide information on technologies that may be feasible and appropriate for the destruction or disposal of PFAS and PFAS-containing materials and identify ongoing research and development activities related to destruction and disposal technologies.

- **Drinking Water:** EPA is following through on its commitment to evaluate and address PFAS in drinking water. The Agency’s work includes efforts to expand drinking water test methods, to work under SDWA to propose maximum contaminant levels to regulate PFOA and PFOS, to produce new toxicity assessments, and to continue monitoring for PFAS.

- **Monitoring:** In July 2020, EPA transmitted the Unregulated Contaminant Monitoring Rule 5 (UCMR 5) proposal to OMB for interagency review. EPA anticipates proposing nationwide drinking water monitoring for PFAS that uses new methods that can detect PFAS at lower concentrations than previously possible.
• **Chemical Review and Disclosure**: EPA has taken significant actions under the Toxics Release Inventory (TRI) and the Toxic Substances Control Act (TSCA) programs. Since releasing the *PFAS Action Plan*, the Agency has taken steps to update the TRI to include PFAS and to finalize a Significant New Use Rule (SNUR) for PFAS chemicals. In June 2020, EPA issued a final regulation that added a list of 172 PFAS chemicals to Toxics Release Inventory reporting. That same month, EPA issued a final regulation that can stop products containing certain PFAS reentering the marketplace without EPA’s explicit permission.

• **Enforcement**: EPA continues to use enforcement tools, when appropriate, to address PFAS exposure in the environment and assist states in enforcement activities. EPA has already taken actions to address PFAS, including issuing SDWA orders and providing support to states. To date, across the nation, EPA has addressed PFAS in 15 cases using a variety of enforcement tools under SDWA, TSCA, RCRA, and CERCLA (where appropriate), and will continue to do so to protect public health and the environment.

Again, I want to thank you and your team for the efforts GAO has taken to understand the Agency’s extensive work to address PFAS. EPA continues to aggressively implement the *PFAS Action Plan*—the most comprehensive cross-Agency plan ever to address an emerging chemical of concern. This first-of-its-kind plan and the progress that has been made under the *PFAS Action Plan* demonstrate the Agency’s leadership role at the national level to address this emerging environmental concern.

If you have any questions, please contact Travis Voyles in the Office of Congressional and Intergovernmental Relations at (202) 564-6399 or voyles.travis@epa.gov.

Sincerely,

Andrew R. Wheeler

Enclosure: Technical Comments
Appendix IV: GAO Contacts and Staff Acknowledgments

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<tr>
<th>GAO Contact</th>
<th>J. Alfredo Gómez, (202) 512-3841 or <a href="mailto:gomezj@gao.gov">gomezj@gao.gov</a>.</th>
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<td>Staff Acknowledgments</td>
<td>In addition to the individual named above, Diane Raynes (Assistant Director), Tanya Doriss (Analyst-in-Charge), Lauren Anderson, Antoinette C. Capaccio, John W. Delicath, Cindy K. Gilbert, Richard P. Johnson, and Dan C. Royer made key contributions to this report.</td>
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