

FY 2020-2021 Agency Priority Goal Action Plan

Reduce Per- and Polyfluoroalkyl Substances (PFAS) Risks to the Public

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Fiscal Year 2020, Quarters 1& 2

Overview

Goal Statement

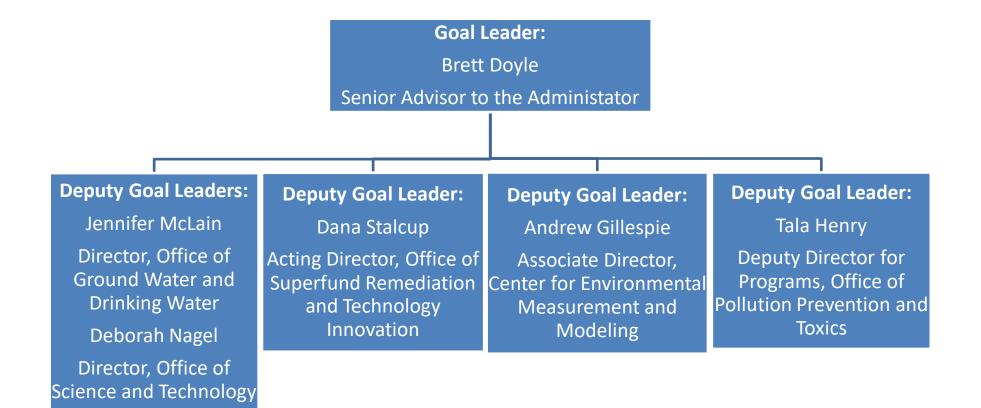
• By September 30, 2021, EPA will meet several of the designated Priority Action milestones in the EPA PFAS Action Plan to establish a framework to understand and address PFAS.

Challenge

- PFAS are a large group of man-made chemicals used in consumer products and industrial processes. In use since the 1940s, PFAS are resistant to heat, oils, stains, grease, and water—properties which contribute to their persistence in the environment.
- Uncertainty of the extent of contamination from PFAS, toxicological information about PFAS compounds, and future regulatory regimes for PFAS are a continuing concern for the federal government, states, tribes, and local communities.
- While EPA has some health and occurrence data for PFOA and PFOS, EPA lacks verified health and occurrence data, as well as validated analytical methods for hundreds of PFAS chemicals. These data gaps must be overcome to support decision making in the regulatory process. Additionally, research of varying quality on PFAS chemicals is being generated by non-USG entities at a relatively rapid rate. EPA assesses new scientific data as it is generated and, if appropriate, amends its research plans accordingly. Work schedules can shorten or lengthen depending upon novel data.
- Additionally, EPA regulatory determinations and chemical toxicological profiles are subject to public comment. The Agency reviews and responds to comments before finalizing regulatory and toxicological decisions. Reviewing and responding to unanticipated, substantive comments can result in delays.

Opportunity

- EPA is committed to reduce PFAS risks to the public through implementation of the Agency's <u>February 2019 PFAS Action</u> <u>Plan</u> and through active engagement and partnership with other federal agencies, states, tribes, industry groups, associations, local communities, and the public. EPA's PFAS Action Plan is EPA's first multi-media, multi-program, national research, management and risk communication plan to address a challenge like PFAS.
- EPA will work with partners to accomplish the Agency's goals through pollution prevention, characterization and remediation of contamination in the environment, evaluation of human health and ecological risks, reducing exposures, development of treatment and remediation technologies, dissemination of risk communication materials, and use of enforcement authorities and regulatory approaches as appropriate.



Strategy 1 – Propose National Drinking Water Regulatory Determination for PFOA and PFOS: Move forward with the drinking water standard setting process outlined in the Safe Drinking Water Act (SDWA) for perfluorooctanoic acid (PFOA) and perfluorooctane Sulfonate (PFOS). The next step in the process involves determining: (1) whether a contaminant may have adverse health effects; (2) whether a contaminant is found in public water systems with a frequency and at levels of concern; and (3) whether, in the sole judgment of the Administrator, there is a meaningful opportunity for health risk reduction through a national drinking water regulation.

Strategy 2 – Finalize interim cleanup recommendations to address groundwater contaminated with PFOA and PFOS: EPA has finalized Interim Recommendations for Addressing Groundwater Contaminated with PFOA and PFOS to support site-specific cleanup efforts. The guidance provides interim recommendations at sites being evaluated and remediated under the EPA Superfund and Resource Conservation and Recovery Act (RCRA) corrective action programs, and may also be useful for other federal agencies, states, and tribes.

Strategy 3 – Finalize toxicity assessments for GenX chemicals and PFBS; and develop draft toxicity values for PFBA, PFHxA, PFHxS, PFNA, and PFDA:

- Produce a new toxicity assessment for GenX chemicals and an updated toxicity assessment for perfluorobutane sulfonic acid (PFBS) to facilitate hazard characterization and future risk management decisions. This is needed because industry has phased out the use of PFOS and PFOA in favor of shorter-chain PFAS such as GenX chemicals and PFBS. Toxicity values for these replacement chemicals will help inform risk management decisions of federal agencies, states, and tribes to protect human health.
- Continue to use public peer-reviewed available toxicity information to work towards the development of additional PFAS toxicity assessments for perfluorobutanoic acid (PFBA), perfluorohexanoic acid (PFHxA), perfluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), and perfluorodecanoic acid (PFDA) through the Agency's Integrated Risk Information System (IRIS) program.

Goal Structure and Strategies (continued)

Strategy 4 – Review new PFAS chemicals under PMN and finalize the Long-Chain Perfluoroalkyl Carboxylate (LCPFAC) Significant New Use Rule (SNUR) for existing chemicals:

- Continue to review all new chemical substances under the Toxic Substances Control Act (TSCA) before they can be allowed to commercialize. EPA has already designated significant new uses for more than 400 PFAS, including for certain PFAS substances that have been through the new chemical review process but have not yet been commercialized. Anyone who plans to manufacture or import a new PFAS for a use designated as a significant new use must first provide EPA with notice, known as a premanufacture notice (PMN) for new chemicals, or a Significant New Use Notice for a chemical subject to a SNUR. EPA is required under TSCA to review PMNs in a 90-day period with the goal of identifying whether there are unreasonable risks and applying appropriate controls to mitigate risks where identified.
- Issue a supplemental proposal to the 2015 SNUR on PFAS chemicals in the second quarter of FY 2020 and work toward the target to finalize this SNUR by June 2020, as required by the National Defense Authorization Act for FY 2020. In 2015, EPA proposed the SNUR to complement the long-chain PFAS-phaseout under the 2010/2015 PFOA Stewardship Program. The proposed SNUR, if finalized, will require manufacturers and processors of these chemicals and perfluoroalkyl sulfonate to notify EPA before starting or resuming new uses of these chemicals in any products. EPA must review and make an affirmative determination on the notice before that new use can commence, if at all.

Summary of Progress – FY 2020 Q1

EPA achieved both of the planned milestones in FY 2020 Q1.

| Milestones by strategy | | FY 2020 Q1 | FY 2020 Q2 | FY 2020 Q3 | FY 2020 Q4 | FY 2021 Q1 | FY 2021 Q2 | FY 2021 Q3 | FY 2021 Q4 | Pref Dir | Trend | Total |
|---|--------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|------------|-------|-------|
| Strategy 1 – Propose National Drinking Water | Target | 1 | 1 | - | - | - | 1 | - | - | \uparrow | ١ | 3 |
| Regulatory Determination for PFOA and PFOS | Actual | 1 | | | | | | | | | | 1 |
| Strategy 2 – Finalize interim cleanup | Target | 1 | - | - | - | - | - | - | - | 1 | | 1 |
| recommendations to address groundwater contaminated with PFOA and PFOS | Actual | 1 | | | | | | | | | | 1 |
| Strategy 3 – Finalize toxicity assessments for | Target | - | - | - | 1 | 2 | 2 | 2 | 1 | 1 | | 8 |
| GenX chemicals and PFBS & develop draft toxicity values for PFBA, PFHxA, PFHxS, PFNA, and PFDA | Actual | | | | | | | | | | | - |
| Strategy 4 – Finalize LCPFAC SNUR for existing | Target | - | 1 | 1 | - | - | | - | - | 1 | | 2 |
| chemicals | Actual | | | | | | | | | | / | - |
| T -1-1 | Target | 2 | 2 | 1 | 1 | 2 | 3 | 2 | 1 | 1 | | 14 |
| Total | Actual | 2 | | | | | | | | I | | 2 |

Accomplishments:

- EPA transmitted the proposed National Drinking Water Regulatory Determination for Contaminant Candidate List 4 (CCL4) Federal Register Notice, with preliminary determinations for PFOA and PFOS, to OMB on December 3, 2019. This action follows through on EPA's commitment in the PFAS Action Plan to evaluate PFOA and PFOS for potential regulation under the law. EPA publishes preliminary regulatory determinations for public comment and considers those comments prior to making final regulatory determinations. If EPA makes a positive regulatory determination for any contaminant, it will begin the process to establish a national primary drinking water regulation for that contaminant.
- EPA finalized Interim Recommendations for Addressing Groundwater Contaminated with PFOA and PFOS under federal cleanup programs on December 20, 2019. These recommendations provide clear and consistent guidance for federal cleanup sites being evaluated and addressed under Superfund and other federal cleanup programs.

Challenges:

• Nothing specific for Q1.

Summary of Progress – FY 2020 Q2

EPA achieved both planned milestones in FY 2020 Q2.

| Milestones by strategy | | FY 2020 Q1 | FY 2020 Q2 | FY 2020 Q3 | FY 2020 Q4 | FY 2021 Q1 | FY 2021 Q2 | FY 2021 Q3 | FY 2021 Q4 | Pref Dir | Trend | Total |
|--|--------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|----------|-------|-------|
| Strategy 1 – Propose National Drinking Water | Target | 1 | 1 | - | - | - | 1 | - | - | ↑ | | 3 |
| Regulatory Determination for PFOA and PFOS | Actual | 1 | 1 | | | | | | | | 1 | 2 |
| Strategy 2 – Finalize interim cleanup | Target | 1 | - | - | - | - | - | - | - | ^ | | 1 |
| recommendations to address groundwater contaminated with PFOA and PFOS | Actual | 1 | | | | | | | | | 11 | 1 |
| Strategy 3 – Finalize toxicity assessments for | Target | - | - | - | 1 | 2 | 2 | 2 | 1 | ^ | _/ | 8 |
| GenX chemicals and PFBS & develop draft toxicity values for PFBA, PFHxA, PFHxS, PFNA, and PFDA | Actual | | | | | | | | | | | - |
| Strategy 4 – Finalize LCPFAC SNUR for existing | Target | - | 1 | 1 | - | - | | - | - | ↑ | | 2 |
| chemicals | Actual | | 1 | | | | | | | | | 1 |
| T -1-1 | Target | 2 | 2 | 1 | 1 | 2 | 3 | 2 | 1 | ^ | | 14 |
| Total | Actual | 2 | 2 | | | | | | | | | 4 |

Accomplishments:

- EPA proposed the preliminary National Drinking Water Regulatory Determination for Contaminant Candidate List 4 (CCL4) Federal Register Notice, with preliminary determinations to regulate PFOA and PFOS, on February 20, 2020. This notice was published in the Federal Register on March 11, 2020. This action follows through on EPA's commitment in the PFAS Action Plan to evaluate PFOA and PFOS for potential regulation under the law. EPA publishes preliminary regulatory determinations for public comment and considers those comments prior to making final regulatory determinations. If EPA makes a positive final regulatory determination for any contaminant, it will begin the process to establish a national primary drinking water regulation for that contaminant.
- EPA has completed final independent external peer review for the draft PFBS toxicity assessment, following public comment, with a goal of finalizing the assessment in FY 2020 Q3.
- EPA proposed the LCPFAC SNUR on February 20, 2020, to ensure EPA is notified before anyone begins or resumes the import of articles containing long-chain PFAS chemical substances in surface coatings. As part of the Agency's review, EPA has the authority to place restrictions on the import of products containing these chemicals as part of a surface coating.

Summary of Progress – FY 2020 Q2 (continued)

Challenges:

- The estimated completion date for the final GenX chemicals toxicity assessment was delayed from FY 2020 Q4 to FY 2021 Q1 to reflect additional time needed to evaluate new toxicity literature, consider an analysis from the National Institute of Environmental Health Sciences (NIEHS)/National Toxicology Program (NTP) Pathology Working Group, and conduct and respond to additional external peer review.
- EPA anticipates finalizing the LCPFAC SNUR in FY 2020 Q3; however, this expedited timeframe depends on accelerated internal and interagency review.

Key Milestones

Strategy 1 – Propose National Drinking Water Regulatory Determination for PFOA and PFOS

| Key Milestones | Due Date | Status | Change from Last Quarter | Comments |
|---|------------|-----------|-----------------------------|--|
| Transmit Federal Register Notice (FRN) on the proposed regulatory determinations for CCL4 contaminants (Regulatory Determination 4) to OMB for Interagency Review. Regulatory Determination 4 will include PFOA and PFOS | Q1/FY 2020 | Completed | N/A | On December 3, 2019, EPA transmitted the FRN to OMB. |
| Administrator signature on the Pproposed Regulatory Determination 4 FRN | Q2/FY 2020 | Completed | N/A | The FRN was published on March 11, 2020. |
| Prepare final regulatory determination notice for Administrator signature in the Federal Register | Q2/FY 2021 | On Track | N/A | |

Strategy 2 – Finalize interim cleanup recommendations to address groundwater contaminated with PFOA and PFOS

| Key Milestones | Due Date | Status | Change from Last Quarter | Comments |
|--|------------|-----------|-----------------------------|---|
| Finalize interim recommendations for addressing groundwater contaminated by PFOA and PFOS. | Q1/FY 2020 | Completed | N/A | EPA issued a final interim groundwater guidance for public comment in December 2019. The comment period closed in June 2019 and EPA is currently evaluating these comments. |

Strategy 3 – Finalize draft toxicity assessments for GenX chemicals and PFBS; and additional toxicity values for PFBA, PFHxA, PFHxS, PFNA, and PFDA

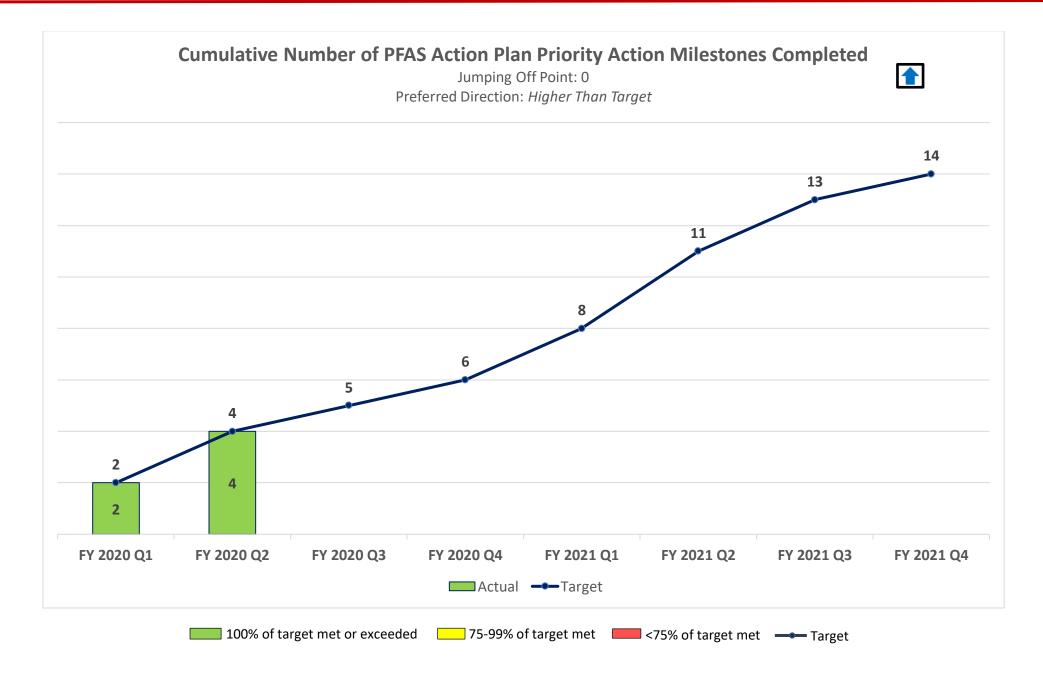
| Key Milestones | Due Date | Status | Change from Last Quarter | Comments |
|--|------------|----------|-----------------------------|---|
| Publish final Toxicity Assessment for PFBS | Q4/FY 2020 | On Track | N/A | EPA published a draft toxicity assessment for PFBS in FY 2019. After receiving public comments on the draft, EPA repeated external peer review on the assessment in FY 2020 Q2 and finalization of the assessment in FY 2020 Q4. |

Key Milestones (continued)

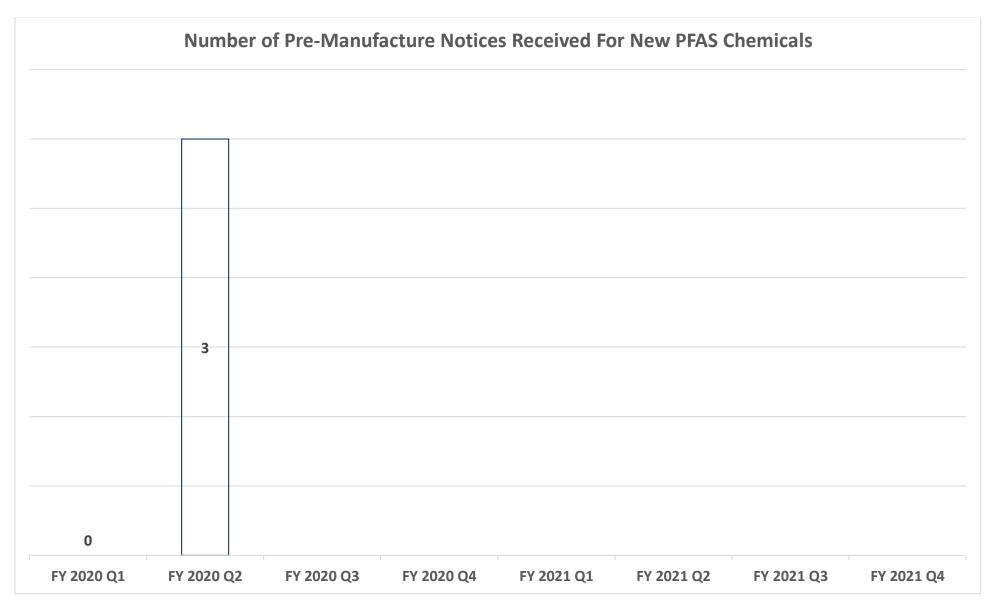
| Key Milestones | Due Date | Status | Change from Last Quarter | Comments |
|--|------------|----------|-----------------------------|---|
| Publish final GenX Toxicity Assessment | Q1/FY 2021 | On Track | N/A | These are best estimates on timing. EPA received the analysis on its draft assessment from the Environmental Health Services (NIEHS)/National Toxicology Program (NTP) Pathology Working Group in FY 2020 Q1 and is currently evaluating that analysis. The document will then undergo additional external peer review followed by interagency review. |
| Public release of draft toxicity assessments for PFBA and PFHxA for public comment | Q1/FY 2021 | On Track | N/A | These are best estimates on timing. The Systematic Review Protocol (which presents the methods for conducting the systematic reviews and dose-response analyses for the draft IRIS assessment) were released for a 45-day public comment period on November 8, 2019. |
| Submit draft toxicity assessments for PFBA and PFHxA for external peer review | Q2/FY 2021 | On Track | N/A | See above. |
| Public release of draft toxicity assessments for PFDA and PFHxS for public comment | Q2/FY 2021 | On Track | N/A | These are best estimates on timing. The Systematic Review Protocol (which presents the methods for conducting the systematic reviews and dose-response analyses for the draft IRIS assessment) were released for a 45-day public comment period on November 8, 2019. |
| Submit draft toxicity assessments for PFDA and PFHxS for external peer review | Q3/FY 2021 | On Track | N/A | See above. |
| Public release of draft toxicity assessment for PFNA | Q3/FY 2021 | On Track | N/A | <i>These are best estimates on timing.</i> The Systematic Review Protocol (which presents the methods for conducting the systematic reviews and dose-response analyses for the draft IRIS assessment) were released for a 45-day public comment period on November 8, 2019. |
| Submit Draft toxicity assessment for PFNA for external peer review | Q4/FY 2021 | On Track | N/A | See above. |

Strategy 4 – Review new PFAS chemicals under PMN and finalize the LCPFAC SNUR for existing chemicals

| Key Milestones | Due Date | Status | Change from Last Quarter | Comments |
|--|------------|-----------|-----------------------------|--|
| Supplemental proposed SNUR for LCPFAC and perfluoroalkyl sulfonate chemicals | Q2/FY 2020 | Completed | N/A | Supplemental proposed rule sent to OMB for review on September 25, 2019; EPA issued the proposal on February 20, 2020. |
| Final SNUR for LCPFAC chemicals | Q3/FY 2020 | On Track | N/A | EPA expects to finalize the SNUR in FY 2020 Q3. |



Key Indicators (continued)



C Actual

Data Accuracy and Reliability

• Data sources for key milestones are Federal Register notices and internal tracking systems. There are no quantitative calculations, significant data limitations or data quality issues

Contributing Programs

- $\circ~$ EPA Office of Water
- $\circ~$ EPA Office of Research and Development
- $\circ~$ EPA Office of Land and Emergency Management
- o EPA Office of Chemical Safety and Pollution Prevention

Other Federal Agencies / Stakeholders / Congressional Consultations

- $\circ~$ Agency for Toxic Substances and Disease Registry (HHS)
- Department of Defense