

**PENNSYLVANIA DEPARTMENT OF ENVIRONMENTAL PROTECTION**  
**EVALUATION REPORT**  
**ON THE**  
**DELAWARE RIVERKEEPER NETWORK PETITION FOR**  
**RULEMAKING**  
**TO SET AN MCL FOR PFOA**

**April 16, 2021**

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## **A. DESCRIPTION OF THE PETITION FOR RULEMAKING PROCEDURE**

Any person may petition the Environmental Quality Board (“EQB”) to initiate a rulemaking proceeding for the issuance, amendment, or repeal of a regulation administered and enforced by the Pennsylvania Department of Environmental Protection (“Department”). 71 P.S. § 510-20(h). The EQB has developed a policy for processing petitions for rulemaking. *See* 25 Pa. Code Chapter 23 (relating to Policy for Processing Petitions – Statement of Policy). Among other things, a petition for rulemaking must contain the following information: (1) the petitioner’s name, address, and telephone number; (2) a description of the action requested including suggested regulatory language if the petition requests the EQB to adopt or amend regulations; (3) the reason the petitioner is requesting the action from the EQB; and (4) the types of persons, businesses, and organizations likely to be impacted by the proposal. 25 Pa. Code § 23.1 (relating to Petitions).

When a petition for rulemaking is submitted, the Department examines the petition before it is submitted to the EQB to determine if it meets the following conditions: (1) the petition is complete as required by § 23.1; (2) the petition requests an action that can be taken by the EQB; and (3) the requested action does not conflict with Federal law. 25 Pa. Code § 23.2 (relating to Departmental review).

The Department then notifies the EQB and the petitioner of its determination. If the Department determines that the petition is not appropriate, the notification will state why and give the petitioner 30 days to modify the request. 25 Pa. Code § 23.3 (relating to Notification).

Where the Department determines that a petition is appropriate, the petitioner may make a five-minute presentation to the EQB and the Department will also make a recommendation as to whether to accept the petition. 25 Pa. Code § 23.4 (relating to Oral presentation).

The EQB may refuse to accept a petition if: (1) the EQB has within the past two years considered the issue addressed in the petition; (2) the action requested by the petitioner is currently under litigation; (3) the requested action is inappropriate for policy or regulatory considerations; or (4) the petition involves an issue previously considered by the EQB, and it does not contain information that is new or sufficiently different to warrant reconsideration of that issue. 25 Pa. Code § 23.5 (relating to Board determination).

If the EQB accepts the petition, a notice of acceptance will be published in the *Pennsylvania Bulletin* and a report will be prepared. 25 Pa. Code § 23.6 (relating to Notice of acceptance and Department report).

Once the report is completed, the Department will send a copy of it to the petitioner who may then submit to the Department a written response to the report within 30 days of the mailing of the report. 25 Pa. Code § 23.7 (relating to Response to report).

The Department will prepare a recommendation to the EQB based on the report and comments received from the petitioner. If regulatory amendments are recommended, the Department will develop a proposed rulemaking for EQB consideration within 6 months after the Department mailed its report to the petitioner. If regulatory amendments are not recommended, the Department will present its recommendation and basis to the EQB at the first meeting occurring at least 45 days after the Department mailed its report to the petitioner. 25 Pa. Code § 23.8 (relating to Board consideration).

## **B. DESCRIPTION OF THE DELAWARE RIVERKEEPER NETWORK PETITION**

### **1. Procedural Description**

On May 8, 2017, the EQB received a petition to promulgate a rule to set a drinking water maximum contaminant level (MCL) for perfluorooctanoic acid (PFOA) not to exceed 6 parts per trillion (ppt or nanograms per liter (ng/L)).

The petition was submitted by Tracy Carluccio, Deputy Director on behalf of the Delaware Riverkeeper Network (DRN), 925 Canal Street, Suite 3701, Bristol, PA 19007.

On June 22, 2017, the Department sent a letter to Ms. Carluccio that notified DRN that the petition met the established criteria in Section 23.2 of the EQB's petition policy. The letter also set August 15, 2017 as the date the EQB would consider the petition.

At the August 15, 2017 EQB meeting, Ms. Carluccio, on behalf of DRN, made a brief presentation as to why the EQB should accept the petition for further study. The Department recommended that the EQB accept the petition for further study. The EQB voted unanimously to accept the petition for further study.

On August 26, 2017, the Department published a notice of acceptance of the petition in the *Pennsylvania Bulletin*. See 47 Pa.B. 4986 (August 26, 2017).

### **2. Petition Description**

The petition asserts that the EQB should promulgate a rule “to set an MCL for PFOA not to exceed 6 ppt.” In support of this petition, Ms. Carluccio, on behalf of DRN, cites PFOA monitoring data from the U.S. Environmental Protection Agency's (EPA) Unregulated Contaminant Monitoring Rule 3 (UCMR 3), 77 FR 26072 (May 2, 2012), information and data from several contamination sites in Bucks and Montgomery counties and other sites across the

state, and scientific studies and reports to support the conclusions that PFOA is in many public water systems in Pennsylvania, that the EPA's Health Advisory Level (HAL) of 70 ppt is ineffective at protecting public health, and that a more protective standard not to exceed 6 ppt should be set for PFOA to protect Pennsylvania citizens. *See* Petition, p. 15. *Please Note: No suggested regulatory language was provided by DRN.*



## **C. DEPARTMENT RESPONSE TO THE PETITION**

### **1. PFOA**

PFOA is a man-made chemical in a large family of chemicals called per- and poly-fluoroalkyl substances (PFAS), which are used to make products more resistant to stains, grease, and water. Major U.S. manufacturers voluntarily agreed to phase out production of PFOA by the end of 2015. However, exposure remains possible due to its widespread use and legacy in the environment from former manufacturing sites and sites where PFOA was used. PFOA has been found in both groundwater and surface water in Pennsylvania and across the country. PFOA is a concern because it readily dissolves in water, bioaccumulates, and is persistent in the environment.

The Department became aware of PFOA detections in public water systems as a result of EPA's UCMR 3 rule. The Federal Safe Drinking Water Act (Federal SDWA) requires EPA to establish criteria for a program to monitor not more than 30 unregulated contaminants every 5 years. The purpose of the rule is to gather occurrence data and refine analytical methods in order to inform a regulatory determination. Monitoring for 28 chemicals and two viruses was conducted by select public water systems (those serving greater than 10,000 people and a random selection of smaller systems) from January 2013 through December 2015. This included 175 public water systems in Pennsylvania. The UCMR rules are direct implementation rules with EPA as the lead agency and states providing assistance. Six (6) out of 175 public water systems had detections for PFOA:

- Warminster Municipal Authority
- Warrington Township Water & Sewer Department
- Horsham Water & Sewer Authority
- United Water -- Harrisburg (now Suez)

- Doylestown Township Municipal Authority
- Aqua PA – Bristol

## **2. Status of an MCL for PFOA**

The Department is authorized to administer and enforce environmental regulations under the Pennsylvania Safe Drinking Water Act (Pennsylvania SDWA), 35 P.S. § 721.5. The EQB is authorized to adopt such rules and regulations, governing the provision of drinking water to the public, as it deems necessary for the implementation of the Pennsylvania SDWA, 35 P.S. § 721.4. Under the SDWA, an MCL is defined as the maximum permissible level of a contaminant in water which is delivered to any user of a public water system.

The Federal SDWA authorizes EPA to set national health-based standards to protect against contaminants that may be found in drinking water, 42 U.S.C. § 300g-1. Under the Federal SDWA, EPA promulgates primary MCLs, which are enforceable standards. EPA may also publish health advisories, which are non-enforceable and non-regulatory, for contaminants not subject to any national primary drinking water regulation. The Federal SDWA grants States primary enforcement responsibility (primacy) for public water systems when EPA determines that a State meets certain requirements, including adopting drinking water regulations that are no less stringent than the national primary drinking water regulations promulgated by EPA, 42 U.S.C. § 300g-2.

The Pennsylvania SDWA was enacted in 1984. The Pennsylvania SDWA imposed a mandatory duty upon the Department to adopt a public water supply program that includes certain program elements necessary to assume primacy under the Federal SDWA, including MCLs. The Department established a public water supply program that met the criteria and was granted primacy by EPA on November 30, 1984. 50 FR 342 (January 3, 1985).

The Pennsylvania SDWA provides direction regarding how MCLs are to be developed, 35 P.S. § 721.4(a). Under the Pennsylvania SDWA, the EQB *shall* adopt MCLs no less stringent than those promulgated under the Federal SDWA for all contaminants regulated under the national primary drinking water regulations. In addition, the EQB *may* adopt MCLs for any contaminant that an MCL has not been promulgated. EPA has not promulgated an MCL for PFOA under the national primary drinking water regulations. EPA has published a health advisory for PFOA, which established a combined lifetime HAL of 70 ppt for PFOA and perfluorooctanesulfonic acid (PFOS). 81 FR 33250 (May 25, 2016).

As referenced above, the Petition for Rulemaking was presented at the August 15, 2017 EQB meeting, at which the Department recommended that the EQB accept the petition for further evaluation to help inform whether additional measures are needed to protect public health. During the meeting, the Department stated that it had never in its history set an MCL and would require toxicology expertise to evaluate the rulemaking petition and prepare the report. It was expected that this would require independent work, research, and review. The Department provided updates to the EQB on June 19, 2018 and June 18, 2019, where the Department expressed the need for more time and provided a summary of the challenges and actions taken to secure the necessary expertise to evaluate the rulemaking petition and prepare this report. These and other actions taken by the Department to address PFOA are described below in Section 3.

### **3. Department actions to address PFOA**

#### **a. Actions to implement EPA's HAL as an interim measure**

Following EPA's publication in May 2016 of the final HAL of 70 ppt for the combined concentration of PFOA and PFOS, the Department developed its strategy in July 2016 for

addressing PFOA and PFOS levels in public water systems that exceed the HAL. The Department's strategy is based on existing authority and long-standing policies and procedures for implementing HALs. The Department's authority to address unregulated contaminants includes the following:

- Pennsylvania SDWA, Section 10. Emergencies and imminent hazards.

*(b) Department may order temporary emergency actions.—The department, upon receipt of information that a contaminant which is present in or is likely to enter a public water system may present an imminent and substantial risk to the health of persons, may take or order a public water system to take such temporary emergency actions as it deems necessary in order to protect the health of such persons. The department may assess the responsible water supplier with costs of temporary actions taken by the department, except where such action is in the normal course of its duties.*

*(c) Department may implement emergency measures.—The department shall be authorized to implement whatever measures may be necessary and appropriate to notify the public of an emergency or imminent hazard and to assess costs of notification on the responsible water supplier.*

- Title 25 Pa. Code § 109.4. General requirements.

*Public water suppliers shall:*

- (1) Protect the water sources under the supplier's control.*
- (2) Provide treatment adequate to assure that the public health is protected.*
- (3) Provide and effectively operate and maintain public water system facilities.*

*(4) Take whatever investigative or corrective action is necessary to assure that safe and potable water is continuously supplied to the users.*

- Title 25 Pa. Code § 109.302. Special monitoring requirements.

*(b) The Department may require a public water supplier to conduct additional monitoring to provide information on contamination of the water supply where a potential health hazard may exist in the water supply and monitoring required under § 109.301 may not be adequate to protect the public health.*

*(c) The Department may require a public water supplier to conduct special monitoring for an unregulated contaminant if the Department has reason to believe the contaminant is present in the public water system and creates a health risk to the users of the public water system.*

The Department's long-standing risk management strategy for unregulated contaminants can be found in the following guidance: *Health Effects and Risk Management Guidance* ([383-0400-104](#)).

As per the guidance and long-standing protocols, when levels exceed a lifetime HAL, a Tier 2 situation has occurred. Water supplier follow-up actions may include:

- One-hour reporting of sample results to the Department (25 Pa. Code § 109.701(a)(3)) to ensure the Department is immediately alerted to the situation and can provide the necessary oversight regarding investigative and corrective actions
- Collection of confirmation samples (25 Pa. Code § 109.302(c))
- Issuance of Tier 2 Public Notification (PN) within 30 days of receipt of sample results exceeding the HAL (25 Pa. Code § 109.409)
- Quarterly monitoring at each entry point (EP) to the distribution system that exceeded the HAL (25 Pa. Code § 109.302(d)) to continue to track contaminant levels

- If levels continue to exceed the HAL, additional actions may be needed to reduce levels to below the HAL (taking contaminated sources off-line, blending, installing treatment, etc.) (25 Pa. Code § 109.4)

Taken together, these actions implemented EPA's HAL prior to submission of the petition, and served as an interim measure while the Department evaluated whether the HAL is sufficiently protective.

**b. Toxicology services contract**

At the time of submission of the petition, neither the Department nor the Pennsylvania Department of Health (DOH) employed a full-time toxicologist. The DOH had access to a retired toxicologist on a very limited basis (90 days per year) as an annuitant. The DOH recognized the need to hire one or more full time toxicologists and initiated the hiring process in late 2017. The DOH began interviewing candidates in January of 2018, but had difficulty filling the position for various reasons. The DOH was finally able to fill the toxicologist position in July of 2019.

While the DOH was working to fill the toxicologist position, the Department moved forward in early 2019 with plans to secure additional toxicology resources to assist in evaluating the petition. The Department developed a scope of work and began soliciting interest in a toxicology services contract in May of 2019. The Department reviewed the submitted quotes for services in July of 2019 and awarded the contract to Drexel University. The contract was finalized and executed in December of 2019. The contract was for a one-year period and included: (1) a review and analysis of work by other states and federal agencies that had developed PFAS action levels and MCLs; and (2) an independent review of the data, science, and studies, and development of recommended maximum contaminant level goals (MCLG) for select PFAS. MCLGs are non-

enforceable as they are developed solely based on health effects and do not take into consideration other factors, such as limitations with analytical methods and available treatment technologies and cost. MCLGs are the starting point for determining MCLs. Please refer to Section D.2. for more information about MCLGs and the process to set MCLs.

The scope of work included the review of several PFAS in addition to PFOA to provide the Department with more complete health effects information for additional PFAS of concern, to better position the Department to address co-occurring PFAS, to align with state sampling efforts, and to create efficiencies in evaluating multiple PFAS simultaneously. The additional PFAS include PFOS, perfluorobutane sulfonic acid (PFBS), perfluorononanoic acid (PFNA), perfluorohexanesulfonic acid (PFHxS), and perfluoroheptanoic acid (PFHpA). The contract continued throughout 2020, with Drexel providing updates to Department and DOH staff every few months. The project experienced some delays due to the COVID-19 pandemic. The project deliverables were completed and submitted to the Department at the end of January 2021. The deliverables include the “Drexel PFAS Workbook”, which contains the review and analysis of work by other states and federal agencies, and the “MCLG Drinking Water Recommendations for PFAS in the Commonwealth of Pennsylvania” report. These documents are included in the Appendix to this report. Here is a brief summary of Drexel’s report.

**Drexel’s MCLG Drinking Water Recommendations for PFAS Report:** The report was developed by the Drexel PFAS Advisory Group (DPAG), which is a unique multidisciplinary team consisting of experts in the fields of medical toxicology, epidemiology, environmental toxicology, drinking water standards, and risk assessment. The DPAG evaluated existing and proposed standards from across the country. The DPAG was also charged with developing recommended

MCLGs. In order to do this, the DPAG reviewed the pertinent literature and work done across the country, and independently developed recommended MCLGs.

As mentioned previously and as further discussed in the report, MCLGs are non-enforceable as they are developed solely based on health effects and do not take into consideration other factors, such as limitations with analytical methods and available treatment technologies and cost. MCLGs are the starting point for determining MCLs. The DPAG's recommended MCLG for PFOA is 8 ppt. The DPAG conducted a literature search and review of the available evidence and recommendations from various agencies and developed an MCLG recommendation based on Non-Cancer endpoints. The report includes a discussion of the relevant inputs. The DPAG selected Koskela (2016) and Onishchenko (2011) as the critical studies. Table 1 below represents DPAG's development of the Non-Cancer MCLG for PFOA.



**Table 1.** The Drexel PFAS Advisory Group’s development of the Non-Cancer MCLG for PFOA

PFOA	
Dose Response Modeling Method	LOAEL
POD	The average serum concentration was estimated in the mice (8.29 mg/L) using a three-compartment pharmacokinetic model (Wambaugh et al. 2013) using animal species, strain, sex-specific parameters. (ATSDR 2018)
HED = POD x DAF (mg/kg/d)	DAF = Ke x Vd Ke = 0.000825175 (8.2 x 10 <sup>-4</sup> ) based on a human serum half-life of 840 days (Bartell et al. 2010) Vd = 0.17 L/kg (Thompson et al. 2010) HED <sub>LOAEL</sub> = POD <sub>LOAEL</sub> x DAF HED <sub>LOAEL</sub> = POD <sub>LOAEL</sub> x Ke x Vd HED <sub>LOAEL</sub> = 8.29 mg/L x 0.000825175 x 0.17 L/kg HED <sub>LOAEL</sub> = 0.001163 mg/kg/d or 1.163 x 10 <sup>-3</sup> mg/kg/d
Uncertainty Extrapolation	
Human Variability (UFH)	10 (standard)
Animal to Human (UFA)	3 (DAF applied)
Subchronic to Chronic (UFS)	1 (Chronic effect studied)
LOAEL to NOAEL (UFL)	10 (standard)
Database (UFD)	1
Total Composite (UFT)	300
RfD = HED/UFT (mg/kg/d)	RfD = 0.001163 mg/kg/d/300 RfD = 3.9 ng/kg/day (3.9 x 10 <sup>-6</sup> mg/kg/d)
THSV = POD / UFT	THSV = 8.29 mg/L / 300 THSV = 0.028 mg/L
Receptor	Infant exposure via breastmilk for 1 year, from mother chronically exposed via water, followed by lifetime of exposure via drinking water. Protective for short-term, subchronic and chronic. (also protective of formula fed infant). Goeden Model Parameters: Placental transfer of 87% and breastmilk transfer of 5.2% (MDH (2020 PFOA)). The Human Serum half-life is set at 840 days (Bartell et al. 2010). The Volume of distribution of 0.17 L/kg (Thompson et al. [2010]) Other factors include, 95th percentile drinking water intake, consumers only, from birth to more than 21 years old. Upper percentile (mean plus two standard deviations) breast milk intake rate. Time-weighted average water ingestion rate from birth to 30-35 years of age is used to calculate maternal serum concentration at delivery. (Goeden et al. [2019]) A Relative Source Contribution of 50% (0.5) is applied and based on studies which showed that infants RSC is similar to NHANES 95th percentiles for 3-11 (2013-2014) and over 12 years old (2015-2016) participants. (CDC 2019)
Chronic Non-Cancer MCLG	The model produces a Chronic Non-Cancer MCLG of 8 ng/L (ppt). This protects health during the growth and development of a breast fed infant. Figure 2

**c. PFAS sampling plan**

During this same time period, the Department announced it would begin sampling for PFAS at public water systems across the state. The PFAS Sampling Plan was developed in early 2019 and the final plan was posted to the Department's [PFAS webpage](#) in April of 2019.

The PFAS Sampling Plan is intended to prioritize sites for PFAS sampling and generate statewide occurrence data. Several factors were considered in developing the plan including:

- Location of potential sources of PFAS contamination (PSOC)
- Known locations of PFAS contamination
- Relative risk to users of nearby public water system sources of drinking water
- Selection of public water system sources to serve as a control group
- Available funds - \$500,000

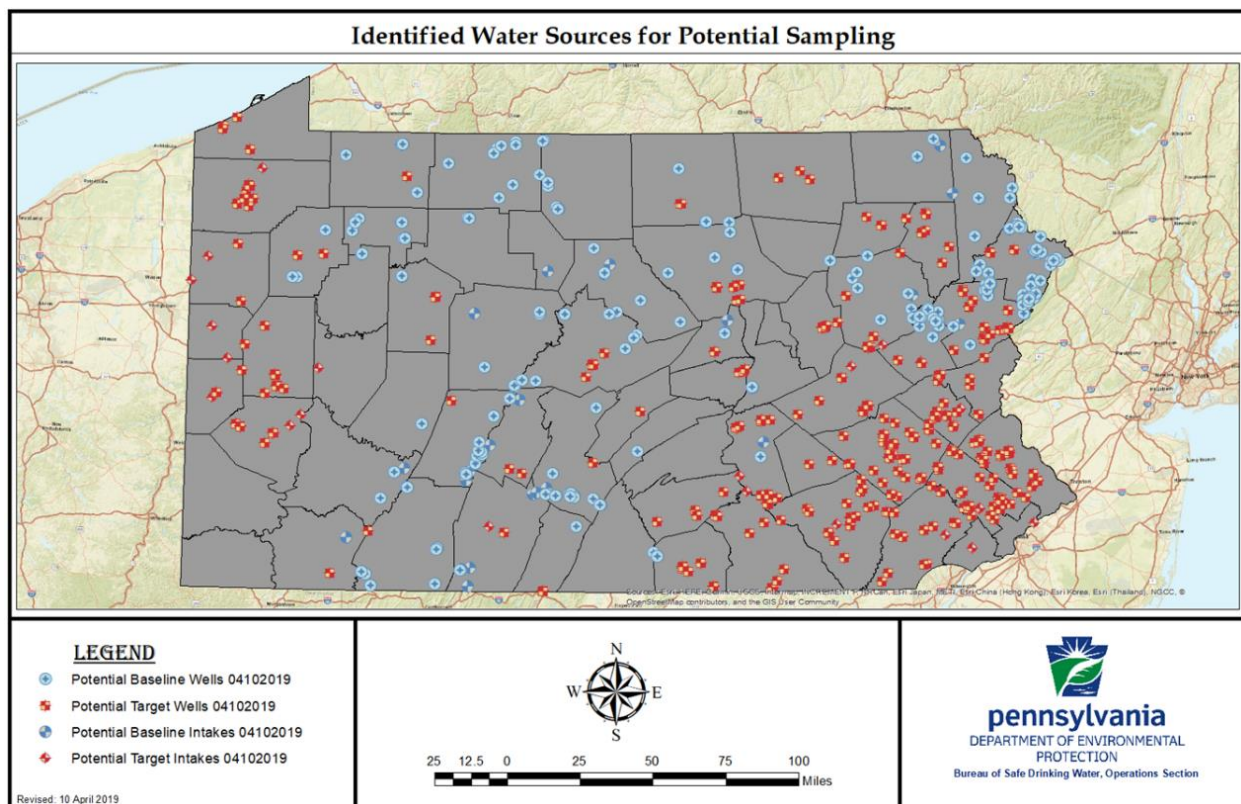
The selection process involved a combination of spatial analysis and programmatic review. The spatial analysis included the creation of a Geographic Information System (GIS) project using ArcMap 10.4.1 that focused on public water system source locations and information about PSOCs. The sampling pool was prioritized based on relative risk and included community water systems and nontransient noncommunity water systems.

In order to prioritize sampling, the selection process included an assessment of the potential risk from nearby PSOCs. Several layers containing locational and other information specific to PSOCs were created or otherwise included in the GIS. These layers include the following industries and land uses:

- Military bases
- Fire training schools/sites
- Airports
- Landfills
- HSCA sites
- Superfund sites

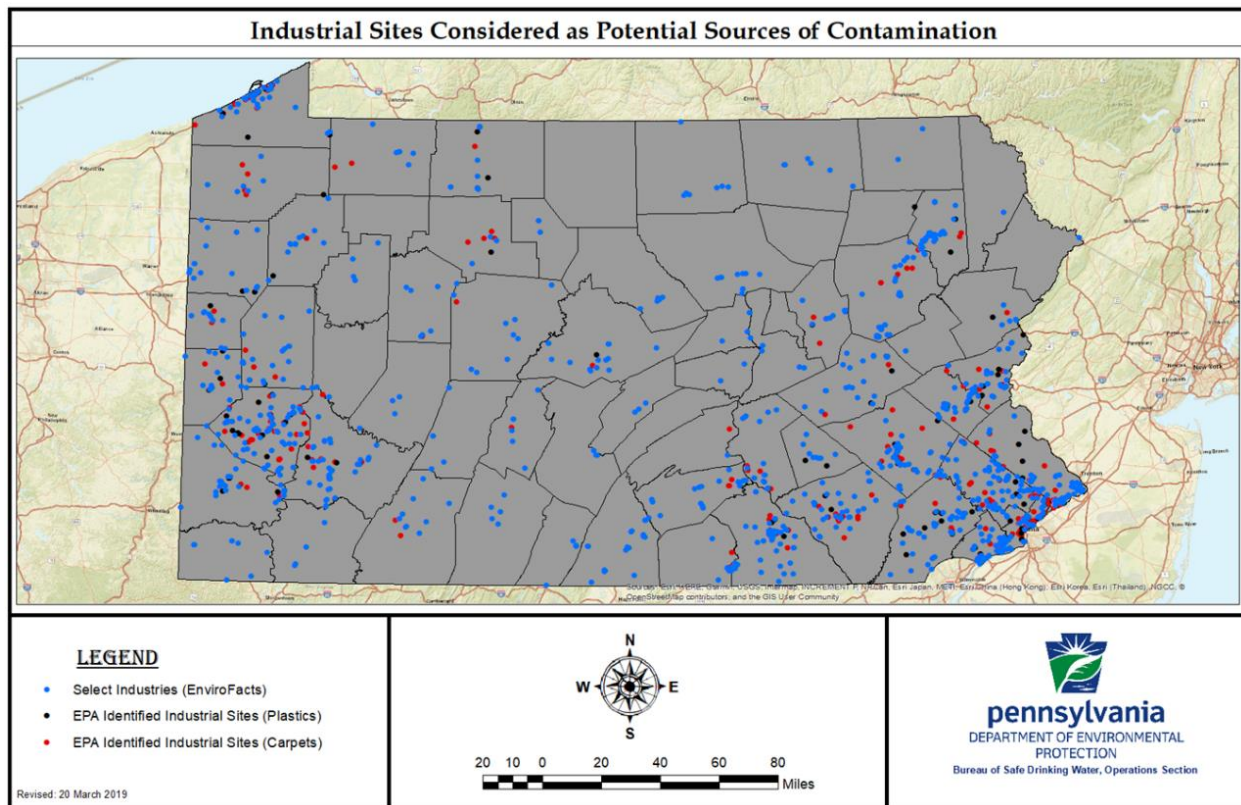
- Manufacturing facilities:
  - Apparel and other products made from fabrics
  - Chemicals
  - Electronic and electrical equipment
  - Fabricated metal products
  - Paper products
  - Plastic products
  - Textile and leather products
  - Upholstered furniture

Based on the compilation of PSOCs, the information was used to select public water system sources that are located within ½ mile of a PSOC. The targeted sample pool included approximately 493 public water system sources. A second query was performed to identify baseline sources to serve as a control group. Baseline sources are located in a HUC-12 watershed (a watershed assigned a 12-digit [hydrologic unit code](#), or HUC, by the U.S. Geological Survey) with at least 75% forested land and at least five miles from a PSOC. Figure 1 is a map of the pool of public water system sources for sampling.



**Figure 1.** Public water system sources identified for sampling.

The Sampling Plan also includes maps of the various GIS data layers of PSOCs. Figure 2 is an example of the map of industrial sites.



**Figure 2.** Potential sources of PFAS contamination (PSOC).

The final plan included the collection of samples from 360 targeted public water system sources and 40 baseline sources for a total of 400 samples. Sampling began in June of 2019 and included analysis of six (6) PFAS (PFOS, PFOA, PFNA, PFHxS, PFHpA, and PFBS) to be consistent with EPA’s UCMR 3. However, the Department had the opportunity in 2020 to expand the sampling to 18 PFAS by using EPA Method 537.1. Sampling was repeated for the public water systems that were sampled in 2019, and sampling continued for the remainder of the water systems throughout 2020. Note that sampling was halted in March of 2020 due to the pandemic and stay-at-home orders. Sampling resumed in August of 2020 under an approved return to work plan with

appropriate health and safety measures. The first release of 2020 sample results was posted to the Department’s PFAS webpage on March 12, 2021 and included 114 samples collected from February through September 2020. Here is the link: [Statewide Sampling Plan 2020 Results](#).

Sampling was completed by the end of March 2021. However, results for approximately 20 samples are still pending, and the review of quality assurance data for other recently reported results is ongoing. Table 2 presents a brief summary of the PFOA sample results to date (Note: The Department anticipates that all results will be received and confirmed in time to include a complete summary of PFOA samples in the final report presented to the EQB):

**Table 2.** Summary of PFOA sample results to date

	PFOA	Units
<b>Average</b>	3.2	ng/l
<b>Median</b>	ND	ng/l
<b>Minimum</b>	ND	ng/l
<b>Maximum</b>	59.6	ng/l
<b># Detects</b>		
	40	
<b>Average Detect Value</b>	9.0	ng/l
<b>Median Detect Value</b>	6.5	ng/l
<b>Min Detect Value</b>	4.0	ng/l
<b>Max Detect Value</b>	59.6	ng/l

**d. BOL PFAS analytical capabilities**

The Department’s Bureau of Laboratories (BOL) also worked to purchase and install lab equipment to conduct PFAS testing. BOL was able to achieve proficiency for EPA Method 537.1 and received accreditation from New Jersey in December of 2019. BOL was instrumental in assisting with completing the work under the PFAS Sampling Plan.

## **D. DEPARTMENT ANALYSIS OF THE PETITION FOR RULEMAKING**

### **1. The Petition Contends that an MCL should be set for PFOA not to exceed 6 ppt**

DRN contends that EPA's HAL of 70 ppt has been shown to be ineffective at protecting the public health. Petition p. 2. DRN references two studies and reports to support this: the New Jersey Drinking Water Quality Institute (NJDWQI) report and the Cambridge Environmental Consulting (CEC) study. Petition p. 15.

According to DRN, the NJDWQI transmitted to the New Jersey Department of Environmental Protection its recommendation of an MCL for PFOA of 14 ppt. And while DRN referenced the NJDWQI work as supportive of its conclusion, it also stated that NJDWQI's recommendation may not be protective enough.

DRN also referenced a report prepared by CEC of an evaluation of the NJDWQI work. The CEC study disagreed with several of NJDWQI's findings and concluded that the proposed drinking water MCL for PFOA of 14 ppt is not adequately protective of all population segments. Instead, the CEC study recommended that the proposed MCL for PFOA should be lowered to 1 ppt, or alternatively, should be no higher than 6 ppt. Petition p. 19.

### **2. Recommendation**

The Petition for Rulemaking recommends that the EQB should promulgate a rule to set an MCL for PFOA not to exceed 6 ppt. Petition p. 18. However, DRN fails to recognize the process that the Department must follow when setting an MCL. Specifically, the Department must consider other factors in addition to health effects when proposing an MCL as required by the Federal SDWA and Pennsylvania's Regulatory Review Act (RRA), 71 P.S. §§ 745.1—745.15.



Among other things, the Department must consider technical limitations such as available analytical methods and detection and reporting limits, treatability of the contaminant and available treatment technologies, and costs. 71 P.S. § 745.5b.

In addition to state requirements, the Department needs to consult the Federal SDWA and its implementing regulations. *See* 42 U.S.C. §§ 300f—300j-9; *see also* 40 CFR Parts 141, 142, and 143. For example, within the definitions in the Federal SDWA:

- “MCLG” means the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons served would occur, and which allows an adequate margin of safety. MCLGs are non-enforceable health goals.
- “MCL” means the maximum permissible level of a contaminant in water which is delivered to any user of a public water system.

EPA further explains the difference between MCLGs and MCLs and how the agency sets standards at the following link: [www.epa.gov/sdwa/how-epa-regulates-drinking-water-contaminants](http://www.epa.gov/sdwa/how-epa-regulates-drinking-water-contaminants). In establishing an MCL, the Department would also be informed by EPA’s procedure to establish an MCL as detailed below. It is important to understand the process of setting an MCL because similar criteria are required of the Department under the RRA. In addition, in order to retain primacy, the Department’s standard setting process would need to be as stringent as the federal process.

After reviewing health effects data, EPA sets an MCLG. MCLGs are non-enforceable public health goals. MCLGs consider only public health and not the limits of detection and treatment technology effectiveness. Therefore, MCLGs sometimes are set at levels which water systems cannot meet because of technological limitations.

Once the MCLG is determined, EPA sets an enforceable standard. In most cases, the standard is an MCL. The MCL is set as close to the MCLG as feasible. Taking cost into consideration, EPA must determine the feasible MCL. This is defined by the Federal SDWA as the level that may be achieved with:

- use of the best available technology or treatment approaches
- other means which EPA finds are available (after examination for efficiency under field conditions, not solely under laboratory conditions)

As a part of the rule analysis, the Federal SDWA also requires EPA to prepare a health risk reduction and cost analysis in support of any standard. EPA must analyze the quantifiable and non-quantifiable benefits that are likely to occur as the result of compliance with the proposed standard. EPA must also analyze certain increased costs that will result from the proposed drinking water standard. In addition, EPA must consider:

- Incremental costs and benefits associated with the proposed and alternative MCL values
- The contaminant's adverse health effects on the general population and sensitive subpopulations
- Any increased health risk to the general population that may occur as a result of the new MCL
- Other relevant factors such as data quality and the nature of the risks

Where the benefits of a new MCL do not justify the costs, EPA may adjust the MCL for a particular class or group of systems to a level that maximizes health risk reduction benefits at a cost that is justified by the benefits.



The setting of an MCL is not as simple as just picking a number. MCL rules must include the necessary provisions to define applicability, the means to comply, and how compliance will be determined. For example, which water systems must comply with the MCL, what are the approved analytical methods, which treatment technologies are approved, how will systems monitor for the contaminant, and how will compliance be determined? All of these details are missing from the Petition for Rulemaking, so it is unclear how the recommended MCL would apply or be implemented.

In analyzing the Petition for Rulemaking, the Department has determined that DRN did not consider all of the relevant factors when recommending the MCL for PFOA not to exceed 6 ppt. As a result, it is recommended that the number advocated for in the Petition for Rulemaking not be the basis for a proposed rulemaking to establish an MCL for PFOA.

## **E. CONCLUSION**

The Department has implemented a number of actions to address PFOA and protect public health. As a result of the work done by Drexel University on behalf of the Department and the occurrence data generated from the PFAS Sampling Plan, the Department believes that additional measures are needed to further protect the public. However, DRN did not include all of the relevant factors that the Department must consider when proposing an MCL. As a result, it is recommended that the number advocated for in the Petition for Rulemaking not be the basis for a proposed rulemaking to establish an MCL for PFOA. While the Department agrees that it should move forward with a proposed rulemaking to set an MCL for PFOA, it does not believe that DRN's proposed MCL was developed appropriately. The Department's proposed rulemaking should be based on available data, studies, and science, and should consider all factors such as health effects, technical limitations, and cost as required under the Federal SDWA and RRA. As a result, the Department recommends that the EQB move forward with a proposed rulemaking to establish an MCL for PFOA. The Department anticipates that it will have a proposed rulemaking developed by the fourth quarter of 2021.

## **F. APPENDIX**

1. Maximum Contaminant Level Goal Drinking Water Recommendations for Per- and Polyfluoroalkyl Substances (PFAS) in the Commonwealth of Pennsylvania, The Drexel PFAS Advisory Board, January 2021.
2. Drexel PFAS Workbook, June 2020.