SUMMARY OF EXPRESS TERMS

This notice of proposed rulemakings amends 10 NYCRR Subpart 5-1 to include maximum contaminant levels (MCL) of 10 parts per trillion (ppt) of Perfluorooctanesulfonic acid (PFOS), 10 ppt for Perfluorooctanoic acid (PFOA) and 1 part per billion (ppb) for 1,4-dioxane. Additionally, a new subdivision was added to allow water systems to request a deferral from the MCL for PFOS, FPOA and 1,4-dioxane and updates to additional tables and Appendix 5-C to ensure clarity with implementation of the MCLs.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 225 of the Public Health Law, Subpart 5-1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

A new subdivision (p) is added to Section 5-1.51 to read as follows:

(p) A system implementing corrective actions to comply with the MCL for Perfluorooctanesulfonic acid (PFOS), Perfluorooctanoic acid (PFOA), and 1,4-dioxane listed in section 5-1.52 table 3 of this subpart may request that the State defer actions for determining MCL violations prescribed in section 5-1.52 table 3 of this subpart for up to 24 months past the effective date of the PFOS, PFOA or 1,4-dioxane MCL. The system shall make such requests in writing within 90 days of the effective date of such MCL. Requests shall document that a deferral period is necessary for a system to implement corrective actions to achieve compliance with the MCL for PFOS, PFOA or 1,4-dioxane and include a timeline with specific milestones for State review and approval. A public notice shall be distributed within 30 days of receiving notification from the State that a deferral has been granted. Systems operating with a deferral approved by the State shall comply with any interim monitoring, public notification or other conditions required by the State, including but not limited to a timeline for implementation of a corrective action plan. Deferrals granted under this subdivision may be renewed, upon request, for up to an additional twelve months if the system establishes to the satisfaction of the State that it is taking all practical steps to meet the corrective action plan on which the initial deferral was conditioned. Failure to meet any deferral conditions shall constitute a violation of this section and may result in immediate deferral revocation. Notice of revocation of a deferral shall will be issued in writing by the State.

Section 5-1.52, Table 3 is amended to read as follows:

Table 3. Organic Chemicals Maximum Contaminant Level Determination

Contaminants	MCL (mg/L)	Type of water system	Determination of MCL violation
General organic chemicals		Community, NTNC and Noncommunity	If the results of a monitoring sample analysis exceed the MCL, the supplier of water shall collect one to three more samples from the same sampling point, as soon as practical, but within 30 days. An MCL violation occurs when at least one of the confirming samples is positive[1] and the average of the initial sample and all confirming samples exceeds the MCL.
Principal organic contaminant (POC)	0.005		
Unspecified organic contaminant (UOC)	0.05		
Total POCs and UOCs	0.1		
Disinfection byproducts[2,3]		Community and NTNC	For systems required to monitor quarterly, the results of all analyses at each monitoring location per quarter shall be arithmetically averaged and shall be reported to the State within 30 days of the public water system's receipt of the analyses. A violation occurs if the average of the four most recent sets of quarterly samples at a particular monitoring location (12-month locational running annual average (LRAA)) exceeds the MCL. If a system collects more than one sample per quarter at a monitoring location, the system shall average all samples taken in the quarter at that location to determine a quarterly average to be used in the LRAA calculation. If a system fails to complete four consecutive quarters of monitoring, compliance with the MCL will be based on an average of the available data from the most recent four quarters. An MCL violation for systems on annual or less frequent monitoring that have been increased to quarterly monitoring as outlined in Table 9A, is determined after four quarterly samples are taken.
Total trihalomethanes	0.080		
Haloacetic acids	0.060		
		Transient noncommunity	Not applicable.

Table 3. Organic Chemicals Maximum Contaminant Level Determination (continued)

Contaminants	MCL (mg/L)	Type of Water System	Determination of MCL violation
Specific Organic Chemicals		Community, NTNC and Noncommunity	If the results of a monitoring sample analysis exceed the MCL, the supplier of water shall collect one to three more samples from the same sampling point, as soon as practical, but within 30 days. An MCL violation occurs when at least one of the confirming samples is positive[1] and the average of the initial sample and all confirming samples exceeds the MCL.
Alachlor	0.002		
Aldicarb	0.003		
Aldicarb sulfone	0.002		
Aldicarb sulfoxide	0.004		
Atrazine[4]	0.003		
Benzo(a)pyrene	0.0002		
Carbofuran	0.04		
Chlordane	0.002		
Di(2-ethylhexyl)phthalate	0.006		
Dibromochloropropane (DBCP)	0.0002		
2,4-D	0.05		
Dinoseb	0.007		
1,4-Dioxane	0.0010		
Diquat	0.02		
Endrin	0.0020.0000		
Ethylene dibromide (EDB)	5		
Heptachlor	0.0004		
Heptachlor epoxide	0.0002		
Hexachlorobenzene	0.001		
Lindane	0.0002		
Methoxychlor	0.04		
Methyl-tertiary-butyl-ether (MTBE)	0.010		
Pentachlorophenol	0.001		
Perfluorooctanesulfonic acid (PFOS)	0.0000100		
Perfluorooctanoic acid (PFOA)	0.0000100		
Polychlorinated biphenyls (PCBs)[5]	0.0005		
Propylene glycol	1.0		
Simazine	0.004		
Toxaphene	0.003		
2,4,5-TP (Silvex)	0.01		
2,3,7,8-TCDD (Dioxin)	0.00000003		
Vinyl chloride	0.002		

Table 3 (continued)

[1] A sample is considered positive when the quantity reported by the State approved laboratory is greater than or equal to the method detection limit.
[2] For systems monitoring yearly or less frequently, the sample results for each monitoring location is considered the LRAA for that monitoring location. Systems required to conduct monitoring at a frequency that is less than quarterly shall monitor in the calendar month identified in the monitoring plan developed under section 5- 1.51(c). Compliance calculations shall be made beginning with the first compliance sample taken after the compliance date.
[3] Systems that are demonstrating compliance with the avoidance criteria in section 5-1.30(c), shall comply with the TTHM and HAA5 LRAA MCLs; however the LRAA MCLs are not considered for avoidance purposes. For avoidance purposes, TTHMs and HAA5s are based on a running annual average of analyses from all monitoring locations.
[4] Syngenta Method AG–625, "Atrazine in Drinking Water by Immunoassay," February 2001, available from Syngenta Crop Protection, Inc., 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419. Telephone: 336–632–6000, may not be used for the analysis of atrazine in any system where chlorine dioxide is used for drinking water treatment. In samples from all other systems, any result for atrazine generated by Method AG–625 that is greater than one-half the maximum contaminant level (MCL) (in other words, greater than 0.0015mg/L or 1.5 µg/L) must be confirmed using another approved method for this contaminant and should use additional volume of the original sample collected for compliance monitoring. In instances where a result from Method AG–625 triggers such confirmatory testing, the confirmatory result is to be used to determine compliance
[5] If PCBs (as one of seven Aroclors) are detected in any sample analyzed using EPA Method 505 or 508, the system shall reanalyze the sample using EPA Method 508A to quantitate PCBs (as decachlorobiphenyl). Compliance with the PCB MCL shall be determined based upon the quantitative results of analyses using Method 508A.

Section 5-1.52, Table 9C is repealed and replaced with a new Table 9C to reads as follows:

Table 9C. Additional Organic Chemicals - Minimum Monitoring Requirements

Contaminant		Type of water system	Initial requirement[1]	Continuing requirement where detected[1,2,3,4]	Continuing requirement where not detected[1]
Alachlor Aldicarb Aldicarb sulfone Aldicarb sulfoxide Aldrin Atrazine Benzo(a)pyrene Butachlor Carbaryl Carbofuran Chlordane Dalapon Di(2-ethylhexyl)adipate Di(2-ethylhexyl)phthalate Dibromochloropropane Dicamba 2,4-D Dieldrin Dinoseb 1,4-Dioxane Diquat Endothall Endrin	Ethylene Dibromide Glyphosate Heptachlor Heptachlor epoxide Hexachlorobenzene Hexachlorocyclopentadiene 3-Hydroxycarbofuran Lindane Methomyl Methoxychlor Metolachlor Metribuzin Oxamyl (vydate) Pentachlorophenol Perfluorooctanesulfonicacid (PFOS) Perfluorooctanoic acid (PFOA) Picloram Polychlorinated biphenyls Propachlor Simazine 2,3,7,8-TCDD (Dioxin) 2,4,5-TP (Silvex) Toxaphene	Community and Nontransient Noncommunity serving 3,300 or more persons[3]	Quarterly sample per source, for one year[5]	Quarterly	One sample every eighteen months per source[6,7,8]
		Community and Nontransient Noncommunity serving fewer than 3,300 persons and more than 149 service connections	Quarterly samples per entry point, for one year[6,7,8]	Quarterly	Once per entry point every three years[6,7,8]
		Community and Nontransient Noncommunity serving fewer than 3,300 persons and fewer than 150 service connections	Quarterly samples per entry point for one year[6,7,8]	Quarterly	Once per entry point every three years[6,7,8]
		Noncommunity excluding NTNC	State discretion[9]	State discretion[9]	State discretion[9]

Table 9C (continued)

[1]The location for sampling of each ground water source of supply shall be between the individual well and at or before the first service connection and before mixing with other sources, unless otherwise specified by the State to be at the entry point representative of the individual well. Public water systems which take water from a surface water body or watercourse shall sample at points in the distribution system representative of each source or at entry point or points to the distribution system after any water treatment plant.

[2]The State may decrease the quarterly monitoring requirement to annually provided that system is reliably and consistently below the MCL based on a minimum of two quarterly samples from a ground water source and four quarterly samples from a surface water source. Systems which monitor annually must monitor during the quarter that previously yielded the highest analytical result. Systems serving fewer than 3,300 persons and which have three consecutive annual samples without detection may apply to the State for a waiver in accordance with footnote 6.

[3]If a contaminant is detected, repeat analysis must include all analytes contained in the approved analytical method for the detected contaminant.

[4]Detected as used in the table shall be defined as reported by the State approved laboratory to be greater than or equal to the method detection limit.

[5]The State may allow a system to postpone monitoring for a maximum of two years, if an approved laboratory is not reasonably available to do a required analysis within the scheduled monitoring period.

[6]The State may waive the monitoring requirement for a public water system that submits information every three years to demonstrate that a contaminant or contaminants was not used, transported, stored or disposed within the watershed or zone of influence of the system.

[7]The State may reduce the monitoring requirement for a public water system that submits information every three years to demonstrate that the public water system is invulnerable to contamination. If previous use of the contaminant is unknown or it has been used previously, then the following factors shall be used to determine whether a waiver is granted.

a. Previous analytical results.
b. The proximity of the system to a potential point or nonpoint source of contamination. Point sources include spills and leaks of chemicals at or near a water treatment facility or at manufacturing, distribution, or storage facilities, or from hazardous and municipal waste landfills and other waste handling or treatment facilities. Nonpoint sources include the use of pesticides to control insect and weed pests on agricultural areas, forest lands, home and gardens, and other land application uses.
c. The environmental persistence and transport of the pesticide, PCBs, PFOA, PFOS or 1,4-dioxane.
d. How well the water source is protected against contamination due to such factors as depth of the well and the type of soil and the integrity of the well casing.
e. Elevated nitrate levels at the water supply source.
f. Use of PCBs in equipment used in production, storage or distribution of water.

[8]The State may allow systems to composite samples in accordance with the conditions in Appendix 5-C of this Title.

[9]State discretion shall mean requiring monitoring when the State has reason to believe the MCL has been violated, the potential exists for an MCL violation or the contaminant may present a risk to public health.

Section 5-1.52 Table 13 is amended to read as follows:

Table 13 – REQUIRED NOTIFICATIONS

Contaminant/Situation (Subpart 5-1 citations)	**Single sample exceeds MCL/MRDL[1]**	**MCL/MRDL/TT[1] violation**	**Failure to meet monitoring requirements and/or failure to use applicable testing procedure**
Public Health Hazard (Section 5-1.1(bz))[2]	Not applicable	State Tier 1	State Tier 1
Escherichia coli (E. coli) in distribution system (Section 5-1.52, Tables 6, 11 and 11B)	State[3] Not applicable, or Tier 1[4]	State Tier 1	State Tier 3, or Tier 1[5]
E. coli or other fecal indicator detected in ground water source at system not providing both 4-log virus treatment and process compliance monitoring (Section 5-1.52, Tables 6, 11 and 11B)	Tier 1[2,3,5,6]	Tier 1[6]	State Tier 3, or Tier 1[2,5,7]
Total coliform in distribution system (Section 5-1.52, Tables 6, 11 and 11B)	Not applicable	State[8] Tier 2, or Tier 1[9]	State Tier 3, or Tier 2 as directed by State
Entry Point Turbidity monthly average (Section 5-1.52, Tables 4 and 10)	State[10]	State Tier 2	State Tier 3
Entry Point Turbidity two-day average (Section 5-1.52, Tables 4 and 10)	State	State Tier 2, or Tier 1[11]	State Tier 3
Raw Water Turbidity (Subdivision 5-1.30(d) and Section 5-1.52, Table 10A)	State	State Tier 2, or Tier 1[11]	State Tier 3
Filtered Water Turbidity Single exceedance of the maximum allowable Turbidity level (Section 5-1.52, Tables 4A and 10A)	State	State Tier 2, or Tier 1[11]	State Tier 3
Filtered Water Turbidity Treatment Technique violation (Section 5-1.52, Tables 4A and 10A)	Not applicable	State Tier 2	State Tier 3

Table 13 (cont.)

Contaminant/Situation (Subpart 5-1 citations)	Single sample exceeds MCL/MRDL[1]	MCL/MRDL/TT[1] violation	Failure to meet monitoring requirements and/or failure to use applicable testing procedure
Distribution Point Turbidity (Section 5-1.52, Tables 5, 10 and 10A)	Not applicable	State Tier 2	State Tier 3
Treatment Technique violations other than turbidity[12,13] (Sections 5-1.12, 5-1.30, 5-1.32, 5-1.81, and 5-1.83 and Subdivision 5-1.71(d))	Not applicable	State Tier 2, or Tier 1[2,13]	State Tier 3[13], or Tier 2[12]
Free chlorine residual less than 0.2 mg/L at the entry point[14] (Subdivision 5-1.30(d))	Not applicable	State	Not applicable
Free chlorine residual less than required minimum for a ground water system or ground water source required to provide 4-log virus treatment[15] (Subdivision 5-1.30(a))	Not applicable	State Tier 2, or Tier 1[9]	Tier 2
Inorganic chemicals and physical characteristics listed in Tables 8A and 8B (Section 5-1.52, Tables 1, 8A, and 8B)	State	State Tier 2	State Tier 3
Chloride, iron, manganese, silver, sulfate, and zinc (Section 5-1.52, Tables 1 and 8D)	Not applicable	State Tier 3	State Tier 3
Sodium (Section 5-1.52, Tables 1 and 8D)	State if the level exceeds 20 mg/L	Tier 2 if the level exceeds 270 mg/L	Tier 3
Nitrate, Nitrite, Total Nitrate and Nitrite (Section 5-1.52, Tables 2 and 8C)	State	State Tier 1	State Tier 1, or Tier 3[16]
Lead and Copper (Sections 5-1.40 to 1.48)	Not applicable	State Tier 2	State Tier
Organic Chemicals Group 1 and 2 (Section 5-1.52, Table 9C)	State	State Tier 2	State Tier 3

Table 13 (cont.)

Contaminant/Situation (Subpart 5-1 citations)	**Single sample exceeds MCL/MRDL[1]**	**MCL/MRDL/TT[1] violation**	**Failure to meet monitoring requirements and/or failure to use applicable testing procedure**
Acrylamide and Epichlorohydrin (Subdivision 5-1.51(m))	Not applicable	State Tier 2	Not applicable
Operation under a variance [or], exemption or deferral (sections 5-1.90 to 5-1.96 and section 5-1.51(p))	Not applicable	Tier 3	Not applicable
Violation of conditions of a variance [or], exemption or deferral (sections 5-1.90 to 5-1.96 and section 5-1.51(p))	Not applicable	State Tier 2	Not applicable
Disruption of water service of four hours or more (Subdivision 5-1.23(b))	Not applicable	State[19]	Not applicable

[1]MCL-maximum contaminant level, MRDL-maximum residual disinfectant level, TT-treatment technique

[2]Community systems must describe in their annual water supply statement (see section 5-1.72(e) and (f)) any Public Health Hazard that is determined to be a violation, and any uncorrected significant deficiency, and must indicate whether corrective action has been completed. This notice must be repeated every year until the annual report documents that corrective action has been completed in accordance with section 5-1.22 of this Subpart.

[3]State notification must be made by the supplier of water within 24 hours of learning of an *E. coli* positive sample.

[4]Public notification normally does not have to be issued for an *E. coli* positive sample prior to the results of the repeat samples. However, there may be situations where the State determines that a Tier 1 notification is necessary to protect the public health. The supplier of water must provide the Tier 1 notification no later than 24 hours after learning of the State's determination.

[5]Failure to test for *E. coli* requires a Tier 1 notification if testing is not performed after any repeat sample tests positive for coliform. All other *E. coli* monitoring and testing procedure violations require Tier 3 notification.

[6]At a ground water system, Tier 1 notification is required after initial detection of *E. coli* or other fecal indicator in raw source water, if the system does not provide 4-log virus treatment and process compliance monitoring. Confirmation of *E. coli* or other fecal indicator in the source water requires Tier 1 notification. Failure to take confirmatory samples may be a public health hazard requiring Tier 1 notification.

[7]Notice of the fecal indicator positive raw water sample must be made in the annual water supply statement (see section 5-1.72(e)), until the annual report documents that corrective action has been completed.

[8]State notification must be made by the supplier of water within 24 hours of learning of the violation.

Table 13 (cont)

[9]Tier 2 notification is normally required; however, there may be situations where the State determines that a Tier 1 notification is necessary to protect the public health. The supplier of water must provide the Tier 1 notification no later than 24 hours after learning of the State's determination.

[10]If the daily entry point analysis exceeds one NTU, a repeat sample must be taken as soon as practicable, and preferably within one hour. If the repeat sample exceeds one NTU, the supplier of water must make state notification.

[11]Systems must consult with the State within 24 hours after learning of the violation. Based on this consultation, the State may subsequently decide to elevate the violation from a Tier 2 to a Tier 1 notification. If consultation does not take place within the 24-hour period, the water system must distribute a Tier 1 notification no later than 48 hours after the system learns of the violation.

[12]These violations include the following: failure to comply with the treatment technique or monitoring requirements in section 5-1.30(a), (b), (c), and (g) of this Subpart; failure to comply with the avoidance criteria in section 5-1.30(c) of this Subpart; failure to cover a finished water storage facility or treat its discharge required in section 5-1.32 of this Subpart; failure to report to the state information required in section 5-1.72(c)(3) of this Subpart; failure to maintain records required in section 5-1.72(d)(7) of this Subpart; and failure to meet the treatment and bin classification requirements associated with *Cryptosporidium* in section 5-1.83 of this Subpart. Failure to collect three or more samples for *Cryptosporidium* analysis as required in section 5-1.81 of this Subpart is a Tier 2 violation requiring public notification. Failure to perform any other monitoring and testing procedure as required in section 5-1.81 of this Subpart is a Tier 3 violation.

[13]Any significant deficiency that is not corrected, or where correction has not begun according to a State-approved corrective action plan within 120 days, or as directed by the State, is a TTV and must be addressed in accordance with section 5-1.12. If the deficiency is a public health hazard, the deficiency must be addressed as directed by the State and Tier 1 notification is required.

[14]Applies to systems that have surface water or groundwater directly influenced by surface water as a source and use chlorine. The system must make State notification whether the residual was restored to at least 0.2 mg/L within four hours.

[15]Required minimum chlorine residual at point that demonstrates adequate CT for disinfected water from ground water sources at first customer.

[16]Failure to take a confirmation sample within 24 hours for nitrate or nitrite after an initial sample exceeds the MCL requires a Tier 1 notification. Other monitoring violations for nitrate or nitrite require a Tier 3 notification.

[17]Failure to monitor for chlorine dioxide at the entrance to the distribution system the day after exceeding the MRDL at the entrance to the distribution system requires a Tier 2 notification. Other monitoring violations for chlorine dioxide at the entrance to the distribution system require a Tier 3 notification.

[18]If any daily sample taken at the entrance to the distribution system exceeds the MRDL for chlorine dioxide and one or more samples taken in the distribution system the next day exceed the MRDL, Tier 1 notification is required. Failure to take the required samples in the distribution system the day after the MRDL is exceeded at the entry point also triggers Tier 1 notification.

[19]Tier 1 notification is required if the situation meets the definition of a public health hazard.

Section 5-1.91 (d) is amended to read as follows:

(d) The technologies listed in this section are the best technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for organic chemicals listed in section 5-1.52 table 3 of this Subpart:

BEST AVAILABLE TECHNOLOGIES (BATs)

Contaminant	Best Available Technologies		
	PTA[1]	GAC[2]	OX[3]
Alachlor		X	
Aldicarb		X	
Aldicarb sulfone		X	
Aldicarb sulfoxide		X	
Atrazine		X	
Benzene	X	X	
Benzo(a)pyrene		X	
Carbofuran		X	
Carbon tetrachloride	X	X	
Chlordane		X	
Dalapon		X	
Di(2-ethylhexyl)adipate	X	X	
Di(2-ethylhexyl)phthalate		X	
2,4-D		X	
Dibromochloropropane	X	X	
1,1-Dichloroethylene	X	X	
para-Dichlorobenzene	X	X	
o-Dichlorobenzene	X	X	
1,2-Dichloroethane	X	X	
cis-1,2-Dichloroethylene	X	X	
trans-1,2-Dichloroethylene	X	X	
Dichloromethane	X		
1,2-Dichloropropane	X	X	
Dinsoeb		X	
1,4-Dioxane			X
Endothal		X	
Endrin		X	

Ethylbenzene	X	X	
Ethylene dibromide	X	X	
Glyphosate			X
Heptachlor		X	
Heptachlor epoxide		X	
Hexachlorobenzene		X	
Hexachlorocyclopentadiene	X	X	
Lindane		X	
Methoxychlor		X	
Monochlorobenzene	X	X	
Oxamyl (Vydate)		X	
PCBs		X	
Pentachlorophenol		X	
Perfluorooctanesulfonic acid (PFOS)		X	
Perfluorooctanoic acid (PFOA)		X	
Picloram		X	
Simazine		X	
Styrene	X	X	
2,3,7,8-TCDD (Dioxin)		X	
Tetrachloroethylene	X	X	
Toluene	X	X	
Toxaphene		X	
2,4,5-TP		X	
1,2,4-Trichlorobenzene	X	X	
1,1,1-Trichloroethane	X	X	
1,1,2-Trichloroethane	X	X	
Trichloroethylene	X	X	
Vinyl chloride	X		
Xylenes (total)	X	X	
TTHM, HAA5, Bromate, Chlorite[4]			

[1]Packed Tower Aeration

[2]Granular Activated Carbon

[3]Oxidation (Chlorination or Ozonation) and Advanced Oxidation Process (AOP)

[4]For surface water systems or ground water systems influenced by surface water, GAC10, as defined in section 5-1.1 of this Subpart, is the BAT for compliance with the TTHM and HAA5 MCL as a Running Annual Average (RAA). The other BAT for RAA compliance is enhanced coagulation for TTHM and HAA5 precursor removal, as described in section 5-1.60 of this Subpart. For compliance with the MCLs for TTHM and HAA5 as LRAAs, the following are the BATs: enhanced coagulation or enhanced softening, plus GAC10; GAC20, as defined in section 5-1.1 of this Subpart; or nanofiltration with a molecular weight cutoff less than or equal to 100 Daltons. Refer to section 5-1.65 of this Subpart for BATs for TTHM, HAA5, Bromate, and Chlorite.

The title of subdivision (B) of section (II) of Appendix 5-C is amended to read as follows:

B. Water Sample Compositing Requirements for Pesticides, Dioxin, [and] PCBs, PFOA, PFOS, and 1,4-Dioxane

SUMMARY OF REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for the proposed revisions is set forth in Public Health Law (PHL) sections 201 and 225. Section 201(1)(l) of the PHL establishes the powers and duties of the New York State Department of Health (Department), which include the supervision and regulation of the sanitary aspects of public water systems. Section 225 of the PHL sets forth the powers and duties of the Public Health and Health Planning Council (PHHPC), which include the authority to establish, amend and repeal sanitary regulations to be known as the State Sanitary Code (SSC), subject to the approval of the Commissioner of Health. Further, section 225(5)(a) of the PHL allows the SSC to deal with any matter affecting the security of life or health, or the preservation or improvement of public health, in New York State.

Legislative Objective:

The legislative objective of sections 201 and 225 of the PHL is to ensure that PHHPC, in conjunction with the Commissioner of Health, protect public health by adopting drinking water sanitary standards. In accordance with that objective, this regulation amends the SSC by revising Part 5 to enhance current protections governing public water systems. Furthermore, this amendment will update the SSC in accordance with the recommendations of the Drinking Water Quality Council, by establishing specific maximum contaminant levels (MCLs) for perfluorooctanoic acid (PFOA), perfluorooctanesulfonic acid (PFOS) and 1,4-dioxane.

Needs and Benefits:

In 2017, New York State (NYS) identified PFOA, PFOS and 1,4-dioxane as emerging contaminants in drinking water. That same year, the Drinking Water Quality Council (DWQC) was created, with direction to recommend MCLs for these emerging contaminants. After discussions and deliberations, the DWQC recommended MCLs to the Department for PFOA, PFOS and 1,4-dioxane. Specifically, the DWQC recommended: an MCL of 10.0 parts per trillion (ppt) (or, expressed in different units, 0.0000100 milligrams per liter (mg/L)) for PFOA; 10.0 ppt (or 0.0000100 mg/L) for PFOS; and 1.0 part per billion (ppb) (or 0.0010 mg/L) for 1,4-dioxane.

From 2015 through 2018, the Department coordinated targeted sampling of 278 public water systems for PFOA and PFOS. The 278 public water systems were mainly medium (serving 3,300 to 10,000 persons) to small (serving less than 3,300 persons) community water systems and non-transient noncommunity systems typically with a groundwater source located near a potential source of PFOA and/or PFOS. The results of this testing are shown in Figures 1A and 1B.

Figure 1A.

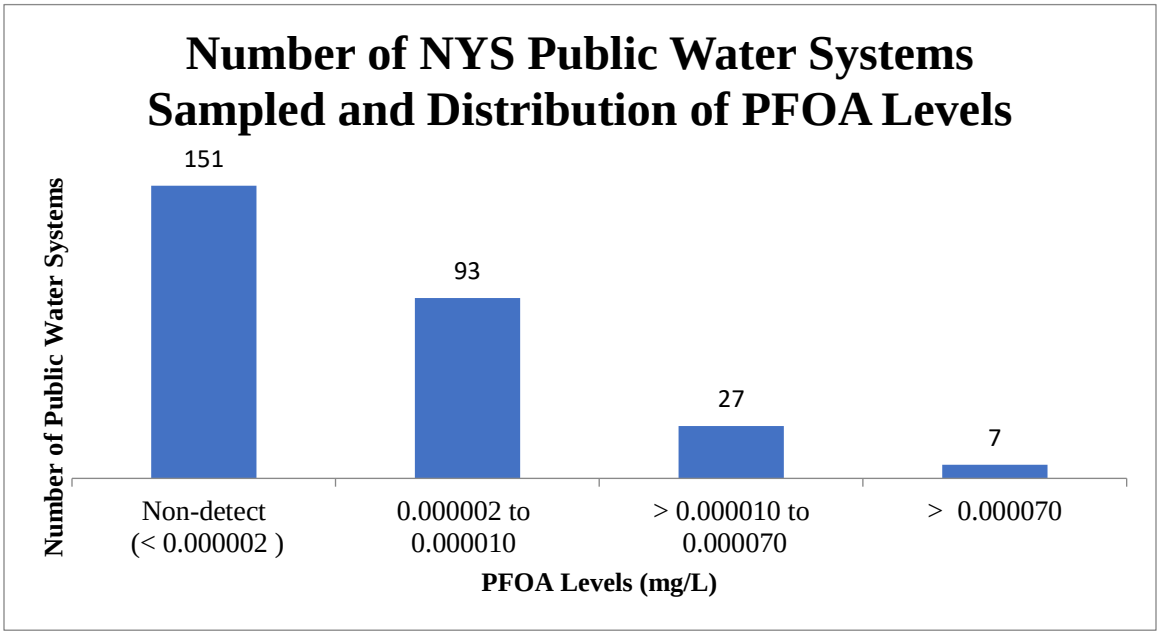
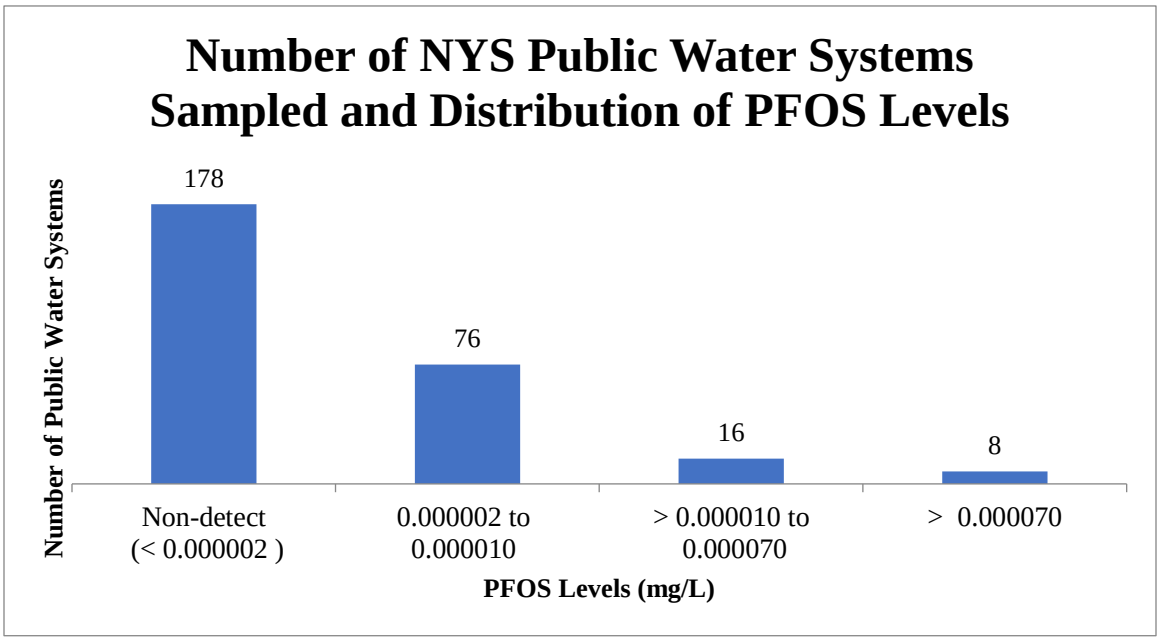


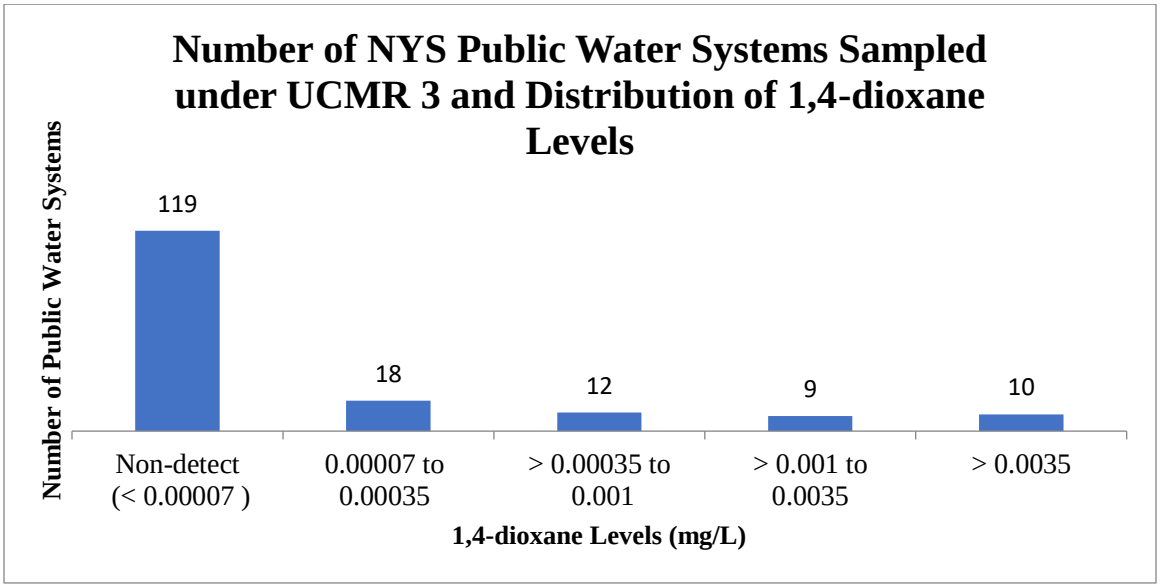
Figure 1B.



From 2013 through 2015 public water systems across NYS, under the United States Environmental Protection Agency (US EPA) Unregulated Contaminant Monitoring Rule

3 (UCMR 3), tested for 1,4-dioxane. All large public water systems (serving 10,000 persons or more) and 32 randomly selected medium and small water systems (serving less than 10,000 persons) in NYS conducted testing. Figure 2 shows that 11 percent (%) of the water systems tested had 1,4-dioxane levels above the DWQC's recommended MCL of 0.0010 mg/L.

Figure 2.



Based on the UCMR3 data, 51% of the samples from Long Island public water systems had levels of 1,4-dioxane above the reporting level of 0.00007 mg/L compared to 6% for NYS excluding Long Island.

The Department provided the DWQC with technical information on a range of health-based drinking water values for PFOA, PFOS and 1,4-dioxane after an evaluation of the available health effects information on the chemicals from toxicological studies. These values included current national and state guidelines and advisory levels, as well as

potential health based values developed by the Department. Based on their review of this information, the DWQC recommended an MCL of 0.0000100 mg/L for PFOA and PFOS as individual compounds, which is within the range of the potential health based water values presented to the DWQC by the Department (0.000006 to 0.000070 mg/L for PFOA and 0.000008 to 0.000070 mg/L for PFOS). The DWQC recommended an MCL of 0.0010 mg/L for 1,4-dioxane, which is within the range of current national and state guidelines and advisory levels presented by the Department (0.00035 to 0.2 mg/L).

In the absence of federal regulations governing PFOA, PFOS and 1,4-dioxane in drinking water, and after consideration of the recommendations provided by the DWQC, the Department is proposing to amend 10 NYCRR Part 5 to establish MCLs for these contaminants. The Department is proposing an MCL of 0.0000100 mg/L for PFOA and PFOS as individual contaminants, and 0.0010 mg/L for 1,4-dioxane. These MCLs will apply to all public water supplies regulated by the Department and provide a sufficient margin of protection against adverse health effects in the most sensitive populations, including fetuses during pregnancy, breastfed infants, and infants bottle fed with formula reconstituted using tap water. In addition, the MCLs provide a sufficient margin of protection for lifetime exposure through drinking water for the general population.

Compliance Costs

Cost to Private Regulated Parties:

There are approximately 7,200 privately owned public water systems in NYS. Of these, an estimated 2,100 systems serve residential suburban areas, manufactured housing communities and apartment buildings, residential and non-residential health care

facilities, industrial and commercial buildings, private schools and colleges, and other facilities. The remaining 5,100 privately owned public water systems serve restaurants, convenient stores, motels, campsites and other transient systems. Costs will include initial monitoring, continued routine monitoring and treatment in the event of a MCL exceedance for PFOS, PFOA and/or 1,4-dioxane.

Monitoring and treatment costs for privately-owned public water systems is dependent upon the system size, the number of affected entry points/sources and the concentration of each contaminant. The exact costs for monitoring and treatment of PFOS, PFOA and 1,4-dioxane for public water systems, including privately-owned public water systems, cannot be determined due to several variables. The cost for a single PFOA/PFOS analysis is between $200-$300 per sample. The cost of a single 1,4-dioxane analysis is between $100-$250.

It is estimated that approximately 21% of all public water systems, including privately-owned public water systems, will have levels of PFOA or PFOS above the proposed MCLs of 0.0000100 mg/L. For small systems serving less than 3,300 persons, capital and annual maintenance costs are estimated to be approximately $400,000 and $25,000, respectively. For medium systems (serving 3,300 or more persons but less than 10,000 persons), capital and annual maintenance costs are estimated to be approximately $2,400,000 and $125,000, respectively. For large systems (serving 10,000 persons or more), capital and annual maintenance costs are estimated to be approximately $15,000,000 and $725,000, respectively.

It is estimated that eighty-nine (89) public water *facilities*, (a single public water system may be comprised of multiple public water facilities), will have a detection of 1,4-dioxane above the proposed MCL of 0.0010 mg/L. The average cost of treatment for 1,4-dioxane is estimated to be $3,570,000 per system, with an estimated average annual operation and maintenance cost of approximately $150,000 per system.

Public water systems will likely make rate adjustments to accommodate these additional capital and operational costs.

Cost to State Government:

State agencies that operate public water systems will be required to comply with the proposed amendments. There are approximately 250 State-owned or operated facilities with a public water system. Examples of such facilities are State-owned schools, buildings, correctional facilities, Thruway services areas, and any other State-owned structure or property that serves an average of at least 25 individuals daily at least 60 days out of the year.

Costs will include initial monitoring for PFOA, PFOS and/or 1,4-dioxane, continued routine monitoring, and treatment in the event of a MCL exceedance. These potential costs will be the same as the costs to private regulated parties.

The proposed regulation will also impose administrative costs to the Department relating to implementation and oversight of the drinking water monitoring requirements including

review and approval of sampling schedules; review and reporting of sample results; providing technical assistance to the public water suppliers; review and approval of plans (i.e., treatment plans); and activities associated with enforcement and public notification of MCL exceedances.

Additionally, the Department and NYS Department of Environmental Conservation (NYSDEC) will incur costs associated with the investigation, remediation, and long-term monitoring associated with the release of these contaminants.

Although the proposed regulations do not apply to private wells, costs will be incurred by NYSDEC, as the lead agency for investigating, remediating, and monitoring of contaminated sites, as the MCLs will be used by the NYSDEC as guidance to determine whether a private well in NYS is contaminated by PFOA, PFOS and/or 1,4-dioxane. There are an estimated 800,000 private water supply wells in NYS. At this time, it is not possible to estimate the number of private wells that might be affected by contamination and, therefore, associated costs to NYSDEC cannot be determined.

Cost to Local Government:

The regulations will apply to local governments—including towns, villages, counties, cities, and authorities or area wide improvement districts—which own or operate a public water system subject to this regulation. There are approximately 1,500 public water systems that are owned or operated by local governments.

Costs will include initial monitoring for PFOA, PFOS and/or 1,4-dioxane, continued routine monitoring, and treatment in the event of a MCL exceedance. These potential costs will be the same as the costs to private regulated parties.

Local health departments that regulate drinking water will also incur administrative costs related to local implementation and oversight of the drinking water monitoring requirements including review and approval of sampling schedules; review and reporting of sample results; providing technical assistance to the public water suppliers; review and approval of plans (i.e., treatment plans); review and approval of MCL deferrals; and activities associated with enforcement and public notification.

Local Government Mandates:

Local governments will be required to comply with this regulation as noted above.

Paperwork:

The additional monitoring, reporting, recordkeeping and paperwork needed for PFOA, PFOS and 1,4-dioxane is expected to be minimal because operators of public water supplies are currently required to keep such records for existing MCLs, and these regulations only add three additional chemicals. The reporting and recordkeeping requirements will increase if MCLs are exceeded and/or treatment is required.

Duplication:

There will be no duplication of existing State or federal regulations.

Alternatives:

One alternative is to maintain the existing MCL of 0.05 mg/L that applies to all unspecified organic chemicals when no chemical-specific MCL exists. Another alternative is to wait for the US EPA to issue a federal MCL. Based on DWQC deliberations and the additional analysis done by the Department it was determined that the current MCL of 0.05 mg/L, which is a generic standard for a broad class of organic chemicals is not protective of public health for these three specific chemicals. Waiting for the US EPA to set a new MCL was impractical due to the prevalence and concerns surrounding PFOA, PFOS and 1,4-dioxane. Therefore, the Department determined that adoption of the DWQC MCL recommendations for PFOA, PFOS and 1,4-dioxane is in the best interest of protecting the public health of NYS residents.

Federal Standards:

There is no federal MCL for PFOA, PFOS or 1,4-dioxane.

Compliance Schedule:

The MCLs will be immediately effective upon publication of a Notice of Adoption in the New York State Register. Public water systems serving 10,000 persons or more must begin monitoring within 60 days of adoption. Water systems serving 3,300 to 9,999 people must begin monitoring within 90 days of adoption and water systems serving less than 3,300 must begin monitoring within 6 months of adoption.

Based on public comments received, the Department has included a provision for a public water system to defer an MCL violation. A public water system can request, from the State, a deferral within 90 days of the effective date of the MCL if the public water system has sample results that exceed the MCL for PFOA, PFOS or 1,4-dioxane, and they have a plan in place to achieve compliance with the MCL; the deferral may be issued for up to two years with the potential for a one-year extension based on a demonstrated need.

Contact Person: Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Rm. 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for the proposed revisions is set forth in Public Health Law (PHL) sections 201 and 225. Section 201(1)(l) of the PHL establishes the powers and duties of the New York State Department of Health (Department), which include the supervision and regulation of the sanitary aspects of public water systems. Section 225 of the PHL sets forth the powers and duties of the Public Health and Health Planning Council (PHHPC), which include the authority to establish, amend and repeal sanitary regulations to be known as the State Sanitary Code (SSC), subject to the approval of the Commissioner of Health. Further, section 225(5)(a) of the PHL allows the SSC to deal with any matter affecting the security of life or health, or the preservation or improvement of public health, in New York State.

Legislative Objective:

The legislative objective of sections 201 and 225 of the PHL is to ensure that PHHPC, in conjunction with the Commissioner of Health, protect public health by adopting drinking water sanitary standards. In accordance with that objective, this regulation amends the SSC by revising Part 5 to enhance current protections governing public water systems. Furthermore, this amendment will update the SSC in accordance with the recommendations of the Drinking Water Quality Council by establishing specific maximum contaminant levels (MCLs) for perfluorooctanoic acid (PFOA), perfluorooctanesulfonic acid (PFOS) and 1,4-dioxane.

Needs and Benefits:

In 2017, New York State (NYS) identified PFOA, PFOS and 1,4-dioxane as emerging contaminants in drinking water. That same year, the Drinking Water Quality Council (DWQC) was created, with direction to recommend MCLs for these emerging contaminants. After discussions and deliberations, the DWQC recommended MCLs to the Department for PFOA, PFOS and 1,4-dioxane. Specifically, the DWQC recommended: an MCL of 10.0 parts per trillion (ppt) (or, expressed in different units, 0.0000100 milligrams per liter (mg/L)) for PFOA; 10.0 ppt (or 0.0000100 mg/L) for PFOS; and 1.0 part per billion (ppb) (or 0.0010 mg/L) for 1,4-dioxane.

PFOA, PFOS and 1,4-dioxane are anthropogenic chemicals that have been manufactured or used throughout the United States. PFOA and PFOS have been used for their emulsifier and surfactant properties in fire-fighting foam, polishes, and cleaners. PFOA has also been used in fluoropolymers (e.g. Teflon), cosmetics, lubricants, paints, coatings, laminates, adhesives and photographic films. 1,4-dioxane has been used as a stabilizer for chlorinated solvents, as a laboratory reagent and as a solvent in the manufacture of other chemicals. 1,4-dioxane is also found in paint strippers, antifreeze, dyes, greases, detergents, cosmetics and other consumer products.

PFOA and PFOS are no longer manufactured in the United States, but there may be some limited ongoing uses of these chemicals. The use of 1,4-dioxane as a solvent and solvent stabilizer has decreased because of the phase out of many chlorinated solvents, but it is

still used as a chemical intermediate and laboratory solvent, and can be found in some consumer products.

From 2015 through 2018, the Department coordinated targeted sampling of 278 public water systems for PFOA and PFOS. The 278 public water systems were mainly medium (serving 3,300 to 10,000 persons) to small (serving less than 3,300 persons) community water systems and non-transient noncommunity systems typically with a groundwater source located near a potential source of PFOA and/or PFOS. The results of this testing are shown in Figures 1A and 1B.

Figure 1A.

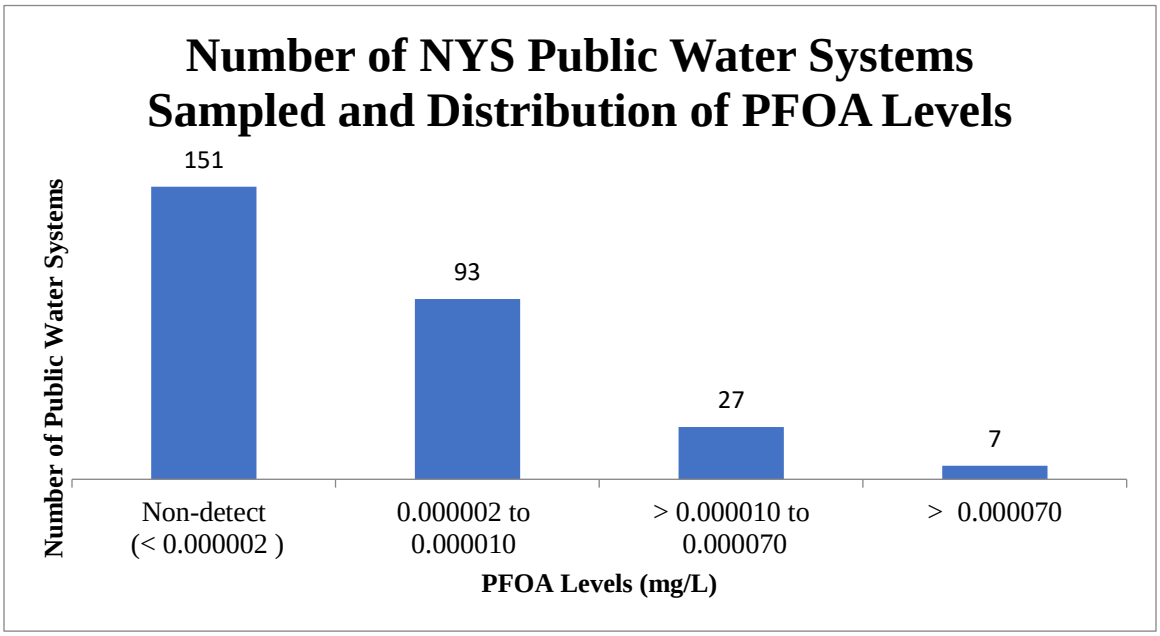
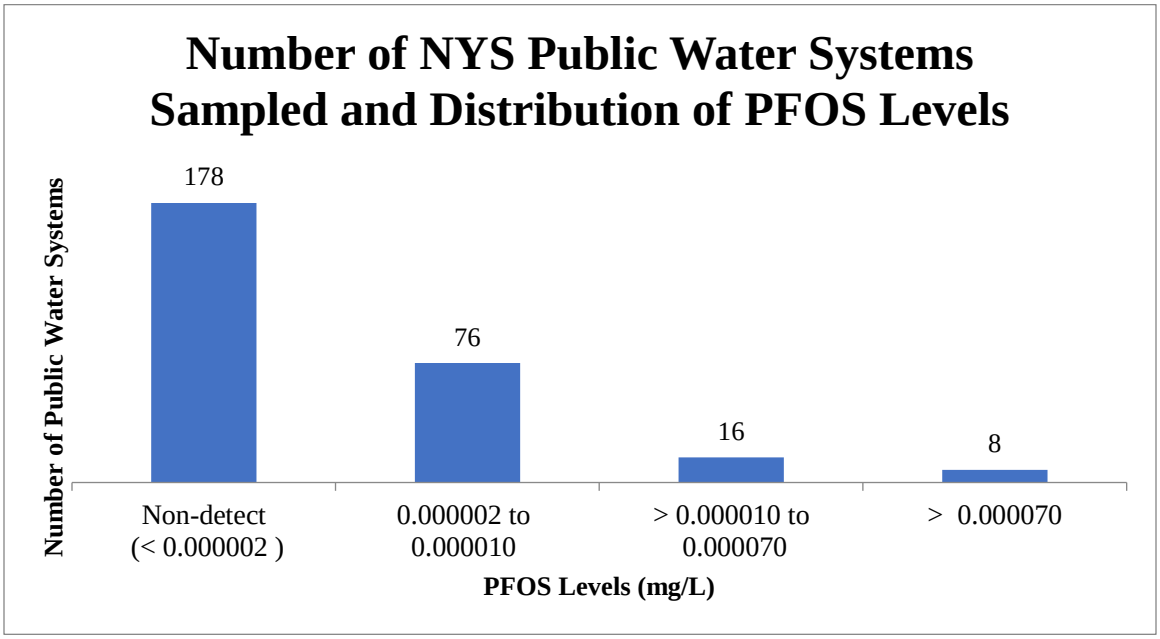
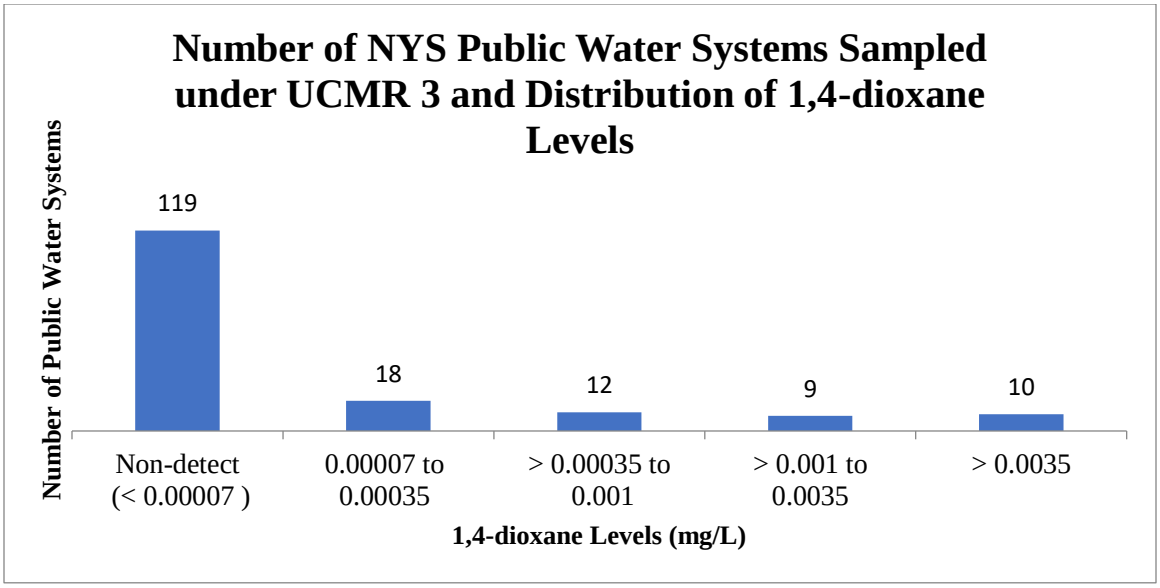


Figure 1B.



From 2013 through 2015 public water systems across NYS, under the United States Environmental Protection Agency (US EPA) Unregulated Contaminant Monitoring Rule 3 (UCMR 3), tested for 1,4-dioxane. All large public water systems (serving 10,000 persons or more) and 32 randomly selected medium and small water systems (serving less than 10,000 persons) in NYS conducted testing. Figure 2 shows that 11 percent (%) of the water systems tested had 1,4-dioxane levels above the DWQC's recommended MCL of 0.0010 mg/L.

Figure 2.



Based on the UCMR3 data, 51% of the samples from Long Island public water systems had levels of 1,4-dioxane above the reporting level of 0.00007 mg/L compared to 6% for NYS excluding Long Island.

The toxicity of PFOA has been extensively reviewed, evaluated and summarized by several authoritative bodies, including the US EPA, the Agency for Toxic Substances and Disease Registry (ATSDR), Health Canada, and the states of New Jersey and Minnesota. These evaluations indicate associations between increased PFOA exposure in humans and an increased risk for several types of health effects. These include effects on the liver, kidney, immune system, thyroid gland, cholesterol levels, uric acid levels, pre-eclampsia (a complication of pregnancy that includes high blood pressure), ulcerative colitis, development effects, and kidney and testicular cancer. Exposure to PFOA has also been shown to cause several adverse health effects in laboratory animals. PFOA caused cancer of the liver, pancreas, and testis in rats exposed for their lifetimes. Noncancer health effects caused by PFOA exposure in animals include liver toxicity, kidney toxicity,

developmental toxicity and immune system toxicity. The US EPA considers PFOA to have suggestive evidence of carcinogenic potential.

The toxicity of PFOS has also been extensively reviewed, evaluated and summarized by several authoritative bodies, including the US EPA, ATSDR, Health Canada, European Food Safety Authority, the Organization for Economic Co-operation and Development and the states of New Jersey and Minnesota. These evaluations indicate associations between increased PFOS exposure in humans and an increased risk for several health effects, including increases in total serum cholesterol, triglycerides, and uric acid, altered immune response, and effects on reproduction and development. PFOS exposure has also been shown to cause several adverse health effects in laboratory animals including liver and thyroid cancer in rats exposed for their lifetimes. Noncancer effects caused by PFOS in animals include effects on the liver, immune system, cholesterol levels, and the developing nervous system, and reduced survival in offspring born to rats. The US EPA considers PFOS to have suggestive evidence of carcinogenic potential.

The toxicity of 1,4-dioxane has been extensively reviewed, evaluated and summarized by the US EPA and ATSDR. 1,4-dioxane causes liver cancer in several species of laboratory animals (rats, mice and guinea pigs) exposed to high levels for their lifetimes. Other cancers caused by 1,4-dioxane in laboratory animals include breast cancer and cancer of the peritoneum and nasal cavity. Laboratory animals exposed to large amounts of 1,4-dioxane in drinking water for long periods of time also had noncancer health effects on the liver, kidney, nasal cavity and respiratory system. Based on sufficient evidence for

carcinogenicity in animals, the USEPA classifies 1,4-dioxane as likely to be carcinogenic to humans by all routes of exposure, and the United States Department of Health and Human Services includes 1,4-dioxane in its list of chemicals that are reasonably anticipated to be human carcinogens.

The Department provided the DWQC with technical information on a range of health-based drinking water values for PFOA, PFOS and 1,4-dioxane after an evaluation of the available health effects information on the chemicals from toxicological studies. These values included current national and state guidelines and advisory levels, as well as potential health based values developed by the Department. Based on their review of this information, the DWQC recommended an MCL of 0.0000100 mg/L for PFOA and PFOS as individual compounds, which is within the range of the potential health based water values presented to the DWQC by the Department (0.000006 to 0.000070 mg/L for PFOA and 0.000008 to 0.000070 mg/L for PFOS). The DWQC recommended an MCL of 0.0010 mg/L for 1,4-dioxane, which is within the range of current national and state guidelines and advisory levels presented by the Department (0.00035 to 0.2 mg/L).

In the absence of federal regulations governing PFOA, PFOS and 1,4-dioxane in drinking water, and after consideration of the recommendations provided by the DWQC, the Department is amending 10 NYCRR Part 5 to establish MCLs for these contaminants. The Department is proposing an MCL of 0.0000100 mg/L for PFOA and PFOS as individual contaminants, and 0.0010 mg/L for 1,4-dioxane. These MCLs will apply to all public water supplies regulated by the Department and provide a sufficient margin of

protection against adverse health effects in the most sensitive populations, including fetuses during pregnancy, breastfed infants, and infants bottle fed with formula reconstituted using tap water. In addition, the MCLs provide a sufficient margin of protection for lifetime exposure through drinking water for the general population.

These regulations will amend 10 NYCRR 5-1.52, Table 3, to list PFOA, PFOS and 1,4-dioxane and their proposed MCLs. In addition, these regulations will amend 10 NYCRR 5-1.52, Table 9C, to include these three contaminants in the current minimum monitoring requirements for additional organic chemicals. Table 9C was also amended to remove references to "Group 1" and "Group 2" chemicals as these groupings are outdated and no longer relevant. The MCLs apply to finished water. Initial monitoring for community and non-transient noncommunity public water systems will be quarterly for one year depending on system size. Monitoring at transient noncommunity public water systems will be at the Department's discretion. Previous testing conducted using an Environmental Laboratory Approval Program (ELAP) approved method and laboratory may satisfy some or all of the initial monitoring requirements at the Department's discretion, or the local health department's discretion in consultation with the Department. Specifically, sample results for PFOA and PFOS analyzed after June 1, 2016 may be used to satisfy the initial monitoring requirements for 2019-20. Sample results for 1,4-dioxane analyzed after June 14, 2017 may be used to satisfy the initial monitoring requirements for 2019-20.

Compliance Costs

Cost to Private Regulated Parties:

There are approximately 7,200 privately owned public water systems in NYS. Of these, an estimated 2,100 systems serve residential suburban areas, manufactured housing communities and apartment buildings, residential and non-residential health care facilities, industrial and commercial buildings, private schools and colleges, and other facilities. The remaining 5,100 privately owned public water systems serve restaurants, convenient stores, motels, campsites and other transient systems. Costs will include initial monitoring, continued routine monitoring and treatment in the event of a MCL exceedance for PFOS, PFOA and/or 1,4-dioxane.

Monitoring and treatment costs for privately-owned public water systems is dependent upon the system size, the number of affected entry points/sources and the concentration of each contaminant. The exact costs for monitoring and treatment of PFOS, PFOA and 1,4-dioxane for public water systems, including privately-owned public water systems, cannot be determined due to several variables. The cost for a single PFOA/PFOS analysis is between $200-$300 per sample. The cost of a single 1,4-dioxane analysis is between $100-$250.

It is estimated that approximately 21% of all public water systems, including privately-owned public water systems, will have levels of PFOA or PFOS above the MCLs of 0.0000100 mg/L. For small systems serving less than 3,300 persons, capital and annual maintenance costs are estimated to be approximately $400,000 and $25,000, respectively.

For medium systems (serving 3,300 or more persons but less than 10,000 persons), capital and annual maintenance costs are estimated to be approximately $2,400,000 and $125,000, respectively. For large systems (serving 10,000 persons or more), capital and annual maintenance costs are estimated to be approximately $15,000,000 and $725,000, respectively.

It is estimated that eighty-nine (89) public water *facilities*, (a single public water system may be comprised of multiple public water facilities), will have a detection of 1,4-dioxane above the MCL of 0.0010 mg/L. The average cost of treatment for 1,4-dioxane is estimated to be $3,570,000 per system, with an estimated average annual operation and maintenance cost of approximately $150,000 per system.

Public water systems will likely make rate adjustments to accommodate these additional capital and operational costs.

Cost to State Government:

State agencies that operate public water systems will be required to comply with the proposed amendments. There are approximately 250 State-owned or operated facilities with a public water system. Examples of such facilities are State-owned schools, buildings, correctional facilities, Thruway services areas, and any other State-owned structure or property that serves an average of at least 25 individuals daily at least 60 days out of the year.

Costs will include initial monitoring for PFOA, PFOS and/or 1,4-dioxane, continued routine monitoring, and treatment in the event of a MCL exceedance. These potential costs will be the same as the costs to private regulated parties.

The proposed regulation will also create administrative costs to the Department relating to implementation and oversight of the drinking water monitoring requirements including review and approval of sampling schedules; review and reporting of sample results; providing technical assistance to the public water suppliers; review and approval of plans (i.e., treatment plans); and activities associated with enforcement and public notification.

Additionally, the Department and NYS Department of Environmental Conservation (NYSDEC) will incur costs associated with the investigation, remediation, and long-term monitoring associated with the release of these contaminants.

Although the proposed regulations do not apply to private wells, costs will be incurred by NYSDEC, as the lead agency for investigating, remediating, and monitoring of contaminated sites, as the MCLs will be used by the NYSDEC as guidance to determine whether a private well in NYS is contaminated by PFOA, PFOS and/or 1,4-dioxane. There are an estimated 800,000 private water supply wells in NYS. At this time, it is not possible to estimate the number of private wells that might be affected by contamination and therefore costs to NYSDEC cannot be determined.

Cost to Local Government:

The regulations will apply to local governments—including towns, villages, counties, cities, and authorities or area wide improvement districts—which own or operate a public water system subject to this regulation. There are approximately 1,500 public water systems that are owned or operated by local governments.

Costs will include initial monitoring for PFOA, PFOS and/or 1,4-dioxane, continued routine monitoring, and treatment in the event of a MCL exceedance. These potential costs will be the same as the costs to private regulated parties.

Local health departments that regulate drinking water will also incur administrative costs related to local implementation and oversight of the drinking water monitoring requirements including review and approval of sampling schedules; review and reporting of sample results; providing technical assistance to the public water suppliers; review and approval of plans (i.e., treatment plans); and activities associated with enforcement and public notification of MCL exceedances and deferrals.

Local Government Mandates:

Local governments will be required to comply with this regulation as noted above.

Paperwork:

The additional monitoring, reporting, recordkeeping and paperwork needed for PFOA, PFOS and 1,4-dioxane is expected to be minimal because operators of public water

supplies are currently required to keep such records for existing MCLs, and these regulations only add three additional chemicals. The reporting and recordkeeping requirements will increase if MCLs are exceeded and/or treatment is required.

Duplication:

There will be no duplication of existing State or federal regulations.

Alternatives:

One alternative is to maintain the existing MCL of 0.05 mg/L that applies to all unspecified organic chemicals when no chemical-specific MCL exists. Another alternative is to wait for the US EPA to issue a federal MCL. Based on DWQC deliberations and the additional analysis done by the Department it was determined that the current MCL of 0.05 mg/L, which is a generic standard for a broad class of organic chemicals is not protective of public health for these three specific chemicals. Waiting for the US EPA to set a new MCL was impractical due to the prevalence and concerns surrounding PFOA, PFOS and 1,4-dioxane. Therefore, the Department determined that adoption of the DWQC MCL recommendations for PFOA, PFOS and 1,4-dioxane is in the best interest of protecting the public health of NYS residents.

Federal Standards:

There is no federal MCL for PFOA, PFOS or 1,4-dioxane.

Compliance Schedule:

The MCLs will be immediately effective upon publication of a Notice of Adoption in the New York State Register. Public water systems serving 10,000 persons or more must begin monitoring within 60 days of adoption. Water systems serving 3,300 to 9,999 people must begin monitoring within 90 days of adoption and water systems serving less than 3,300 must begin monitoring within 6 months of adoption.

Based on public comments received, the Department has included a provision for a public water system to defer an MCL violation. A public water system can request, from the State, a deferral within 90 days of the effective date of the MCL if the public water system has sample results that exceed the MCL for PFOA, PFOS or 1,4-dioxane, and they have a plan in place to achieve compliance with the MCL; the deferral may be issued for up to two years with the potential for a one-year extension based on a demonstrated need.

Contact Person: Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Rm. 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect on Small Business and Local Governments:

Many of the public water systems affected by the new regulations are owned or operated by either small businesses or local governments. The Department does not maintain information on the exact number of the public water systems owned by small businesses. There are approximately 1500 water systems owned by local governments.

Reporting and Recordkeeping and Other Compliance Requirements:

The obligations on small businesses and local governments are the same as for all owners or operators of public water systems. The regulations require additional monitoring, reporting, recordkeeping and public notification requirements for three additional contaminants, PFOA, PFOS and 1,4-dioxane. These requirements will increase if MCLs are exceeded and/or treatment is required.

Local health departments that regulate drinking water will also incur administrative costs related to local implementation and oversight of the drinking water monitoring requirements including review and approval of sampling schedules; review and reporting of sample results; providing technical assistance to the public water suppliers; review and approval of plans (i.e., treatment plans); and activities associated with enforcement and public notification of MCL exceedances and deferrals.

Professional Services:

Public water systems impacted by the amended regulations will require the services of a laboratory to analyze samples for PFOA, PFOS and 1,4-dioxane. The laboratory must be approved by the Department under its Environmental Laboratory Approval Program (ELAP). Sufficient laboratory capability and capacity is anticipated to be available to process the initial staggered testing demands and future testing. If an MCL is exceeded, a licensed professional will be required to design changes to the public water system to meet the MCL.

Compliance Costs:

Cost to Private Regulated Parties and Local Governments:

A small business or local government will incur the same costs as other regulated parties. Costs will include initial monitoring, continued routine monitoring, and treatment in the event of a MCL exceedance for PFOS, PFOA and 1,4-dioxane.

Monitoring and treatment costs for small businesses and local government owned public water systems is dependent upon the system size, the number of affected entry points/sources and the concentration of each contaminant. The exact costs for monitoring and treatment of PFOS, PFOA and 1,4-dioxane for public water systems, including privately-owned public water systems, cannot be determined due to several variables. The cost for a single PFOA/PFOS analysis is between $200-$300 per sample. The cost of a single 1,4-dioxane analysis is between $100-$250. For small systems serving less than 3,300 persons, capital and annual maintenance costs are estimated to be approximately $400,000 and $25,000, respectively. For medium systems (serving 3,300 or more persons

but less than 10,000 persons), capital and annual maintenance costs are estimated to be approximately $2,400,000 and $125,000, respectively. For large systems (serving 10,000 persons or more), capital and annual maintenance costs are estimated to be approximately $15,000,000 and $725,000, respectively.

It is estimated that eighty-nine (89) public water *facilities*, (a single public water system may be comprised of multiple public water facilities), will detect 1,4-dioxane above the MCL of 0.0010 mg/L. The average cost of treatment for 1,4-dioxane is estimated to be $3,570,000 per system, with an estimated average annual operation and maintenance cost of approximately $150,000 per system.

Public water systems will likely make rate adjustments to accommodate these additional capital and operational costs.

Local health departments that regulate drinking water will also incur administrative costs related to local implementation and oversight of the drinking water monitoring requirements including review and approval of sampling schedules; review and reporting of sample results; providing technical assistance to the public water suppliers; review and approval of plans (i.e., treatment plans), and activities associated with enforcement, including public notification of MCL exceedances and deferrals.

Economic and Technological Feasibility:

These regulations are economically and technologically feasible for small businesses and local governments. Analytical methods exist for accurate sample analysis to detect PFOA, PFOS and 1,4-dioxane. There are also technologically feasible treatment solutions for all three contaminants. Treatment may present a greater challenge to smaller systems that typically have less resources including financial and technical expertise than larger systems.

Minimizing Adverse Impact:

The Department has included several provisions that minimize the impacts on regulated parties. Previous testing conducted using an ELAP approved method and laboratory may satisfy some or all of the initial monitoring requirements at the Department's discretion, or the local health department's discretion in consultation with the Department; sampling frequency will decrease after the first year if a contaminant (or the contaminants) is/are not detected at a public water system; the start of initial sampling is proposed to be staggered, requiring large systems to test first (within 60 days of adoption) and providing more time for smaller systems such that water systems serving between 3,300 to 10,000 persons should sample within 90 days of adoption and water systems serving less than 3,300 persons must begin sampling within 6 months of adoption.

In addition, New York State offers programs to support public water systems with infrastructure investments including but not limited to treatment and development/connection to alternate sources of water. Programs include the Drinking

Water State Revolving Fund which provides market rate, low to no interest loans and grants available to many municipally and privately-owned public water systems based on need and financial hardship. In addition, the New York State Clean Water Infrastructure Act of 2017 invests $2.5 billion in clean and drinking water infrastructure projects and water quality protection across the State. It provides funding to the New York State Water Infrastructure Improvement Act of 2017 (WIIA) for grants to assist municipalities with water quality infrastructure. A separate $200 million has been provided to support grants for drinking water projects that will address emerging contaminants such as PFOA, PFOS or 1,4-dioxane.

Small Business and Local Government Participation:

Small business and local governments were not specifically consulted on this proposal, however the MCLs set forth in this proposed rule were recommendations from the Drinking Water Quality Council (DWQC) which met numerous times in a public forum and were also recorded. The recordings are publicly available on the Department's web-site. During each DWQC meeting, members of the public were allowed to comment, and comments were provided to the Department outside of the meetings. Based on the information available it is not possible to determine the number of small businesses that participated during the meetings or provided comments, but from sign in sheets at the meetings some businesses did participate in the meetings. All comments provided by the public were made available to the DWQC for their consideration.

RURAL AREA FLEXABILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

These regulations apply to rural areas of the state, where approximately 6,400 small public water systems are located, in the same manner as the rest of the state.

Reporting, Record keeping and Other Compliance Requirements

Reporting and Recordkeeping:

The obligations imposed on rural area public water systems are the same as for all owners or operators of public water systems. The regulations require additional monitoring, reporting, recordkeeping and public notification requirements for three additional contaminants, PFOA, PFOS and 1,4-dioxane. These requirements will increase if MCLs are exceeded and/or treatment is required.

Professional Services:

Like all public water systems, rural area public water systems impacted by the amended regulations will require the services of a laboratory to analyze samples for PFOA, PFOS and 1,4-dioxane. The laboratory must be approved by the Department under its Environmental Laboratory Approval Program (ELAP). Sufficient laboratory capability and capacity is anticipated to be available to process the initial staggered testing demands and future testing. If an MCL is exceeded, a licensed professional will be required to design changes to the public water system to meet the MCL.

Compliance Costs:

Rural area public water systems will incur the same costs as other regulated parties. Costs will include initial monitoring, continued routine monitoring, and treatment in the event of a MCL exceedance for PFOS, PFOA and 1,4-dioxane. There are approximately 7,200 privately-owned water systems. Of these, an estimated 2,100 systems serve residential suburban areas, manufactured housing communities and apartment buildings, residential and non-residential health care facilities, industrial and commercial buildings, private schools and colleges, and other facilities. The remaining 5,100 privately-owned systems, such as those at restaurants, motels and campsites, serve transient populations.

Monitoring and treatment costs for rural area public water systems is dependent upon the system size, the number of affected entry points/sources and the concentration of each contaminant. The exact costs for monitoring and treatment of PFOS, PFOA and 1,4-dioxane for public water systems, including rural area public water systems, cannot be determined due to several variables. The cost for a single PFOA/PFOS analysis is between $200-$300 per sample. The cost of a single 1,4-dioxane analysis is between $100-$250. For small systems serving less than 3,300 persons, capital and annual maintenance costs are estimated to be approximately $400,000 and $25,000, respectively. For medium systems (serving 3,300 or more persons but less than 10,000 persons), capital and annual maintenance costs are estimated to be approximately $2,400,000 and $125,000, respectively. For large systems (serving 10,000 persons or more), capital and annual maintenance costs are estimated to be approximately $15,000,000 and $725,000, respectively.

It is estimated that eighty-nine (89) public water *facilities*, (a single public water system may be comprised of multiple public water facilities), will have a detection of 1,4-dioxane above the MCL of 0.0010 mg/L. The average cost of treatment for 1,4-dioxane is estimated to be $3,570,000 per system, with an estimated average annual operation and maintenance cost of approximately $150,000 per system.

Economic and Technological Feasibility:

These regulations are economically and technologically feasible for rural area public water systems. Analytical methods exist for accurate sample analysis to detect PFOA, PFOS and 1,4-dioxane. There are also technologically feasible treatment solutions for all three contaminants. Treatment may present a greater challenge to smaller systems that typically have less resources including financial and technical expertise than larger systems.

Minimizing Adverse Economic Impact on Rural Areas:

The Department has included several provisions that minimize the impacts on regulated parties. Previous testing conducted using an ELAP approved method and laboratory may satisfy some or all of the initial monitoring requirements at the Department's discretion, or the local health department's discretion in consultation with the Department; sampling frequency will decrease after the first year if a contaminant (or the contaminants) is/are not detected at a public water system; the start of initial sampling is proposed to be staggered, requiring large systems to test first (within 60 days of adoption) and providing more time for smaller systems such that water systems serving between 3,300 to 10,000

persons should sample within 90 days of adoption and water systems serving less than 3,300 persons must begin sampling within 6 months of adoption.

In addition, New York State offers programs to support public water systems with infrastructure investments including but not limited to treatment and development/connection to alternate sources of water. Programs include the Drinking Water State Revolving Fund which provides market rate, low to no interest loans and grants available to many municipally and privately-owned public water systems based on need and financial hardship. In addition, the New York State Clean Water Infrastructure Act of 2017 invests $2.5 billion in clean and drinking water infrastructure projects and water quality protection across the State. It provides funding to the New York State Water Infrastructure Improvement Act of 2017 (WIIA) for grants to assist municipalities with water quality infrastructure. A separate $200 million has been provided to support grants for drinking water projects that will address emerging contaminants such as PFOA, PFOS or 1,4-dioxane.

Rural Area Participation:

Rural area stakeholders were not specifically consulted on this proposal, however the MCLs set forth in this proposed rule were recommendations from the Drinking Water Quality Council (DWQC) which met numerous times in a public forum and were also recorded. The membership of the DWQC included members from rural areas. The recordings are publicly available on the Department's web-site. During each DWQC meeting, members of the public could comment, and comments were provided to the

Department outside of the meetings. Based on the information available it is not possible to determine the exact number of rural stakeholders that participated during the meetings or provided comments, but from sign in sheets at the meetings rural communities attended DWQC meetings. All comments provided by the public were made available to the DWQC for their consideration.

JOB IMPACT STATEMENT

Nature of the Impact:

The Department expects there to be a positive impact on jobs or employment opportunities. A subset of public water system owners will likely hire firms or individuals to assist with regulatory compliance. Public water systems impacted by this amendment will require the professional services of a certified or approved laboratory to perform the analyses for PFOA, PFOS and 1,4-dioxane, which may create a need for additional laboratory capability and capacity. Additionally, a subset of owners will require the services of a licensed professional engineer to design facilities to meet the MCLs through treatment, or to access an alternate source.

Categories and Numbers Affected:

The Department anticipates no negative impact on jobs or employment opportunities as a result of the proposed regulations.

Regions of Adverse Impact:

The Department anticipates no negative impact on jobs or employment opportunities in any particular region of the state.

Minimizing Adverse Impact:

Not applicable.

SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (Department) received over 2,000 comments from public water suppliers, local health departments, chemical manufacturers, local and State elected officials, environmental advocacy groups, the New York Section of the American Water Works Association (AWWA), the New York Association of State and County Health Officials (NYSACHO) and members of the public, on the revised rulemaking amending Subpart 5-1 of Title 10 of the New York State Codes, Rules and Regulations (NYCRR).

A large number of comments requested a lowering of the proposed PFOA and PFOS maximum contaminant levels (MCLs) to less than 2 parts per trillion (ppt) combined for PFOA and PFOS. In addition, these commenters requested that the MCL for 1,4-dioxane be lowered to 0.3 or 0.35 parts per billion (ppb). Additional commenters questioned the scientific understanding of the Advanced Oxidation Process, used to treat 1,4 -dioxane contamination.

Based on the comments received, the Department has made no revisions to the revised rulemaking.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (Department) received more than 2,000 comments from public water suppliers, chemical manufacturers and industry groups, environmental advocacy groups, and members of the public, on the proposed rulemaking amending Subpart 5-1 of Title 10 of the New York State Codes, Rules and Regulations (NYCRR). These comments and the Department's responses are summarized below.

Comment: Commenters suggested that the deferral provision would cause delay implementation and negatively impact public health.

Response: The deferral provision will not delay implementation of the new MCLs. The deferral is intended only for those public water suppliers (PWS) that have taken the proactive step of collecting samples, know that they will be in violation of the proposed MCL and have a corrective action plan in place. The deferral will formalize plans for mitigation and compliance that are already in place and makes implementation of corrective action legally enforceable. The PWS must be in compliance with the MCL by the end of the deferral period. The deferral ensures corrective action is implemented quickly and incentivizes strict compliance with the agreed upon timetable by postponing the issuance of a notice of violation unless the terms of the agreement are not met.

If a water supplier fails to make progress in accordance with the conditions of the deferral, the deferral will be revoked. Once the deferral is revoked, the supplier will be required to make public notice within 30 days and each calendar quarter thereafter until

the water supplier complies with the MCL. Under the existing enforcement process, a stipulated agreement can be extended by the LHD without input from the Department. As a result, there is more, not less transparency when a system with a deferral is not making progress.

No changes were made to the proposed regulation in response to this comment.

Comment: Commenters requested a combined MCL of <2 parts per trillion (ppt) for Perfluorooctanesulfonic acis (PFOS) and Perfluorooctanoic acid (PFOA).

Response: The proposed MCL of 10 ppt provides a strong margin of protection against adverse health effects and a large margin of protection for lifetime exposure through drinking water for the general population. Additionally, the approved analytical method for PFOA and PFOS has a detection limit of 2 ppt. Therefore, it would not be technically feasible to set an MCL below the method detection limit. Furthermore, the Department's proposed MCL is consistent with the Drinking Water Quality Council's (DWQC) proposed MCL recommendation. No changes were made to the proposed regulation in response to this comment.

Comment: Commenters requested an MCL of 0.3 or 0.35 parts per billion (ppb) for 1,4-dioxane.

Response: The proposed MCL of 1 ppb provides a strong margin of protection against adverse health effects and a sufficient margin of protection for lifetime exposure through drinking water for the general population. The Department's proposed MCL is consistent

with the Drinking Water Quality Council's proposed MCL recommendation. The Department also notes that other comments request consideration of higher 1,4-dioxane drinking water MCLs. No changes were made to the proposed regulation in response to this comment.

Comment: Commenters suggest that the rulemaking process lacked transparency.

Response: The Drinking Water Quality Council (DWQC)was established by New York State Public Health Law § 1113 (PHL § 1113), to provide recommendations to the New York State Department of Health on emerging contaminants in drinking water. DWQC meetings are open to the public. A public comment session has been held at the end of each meeting. Webcasts of the meetings are posted on the New York State Department of Health web site for one year within two weeks following the meeting. The toxicological, occurrence and cost information considered by the DWQC is available at this web location. On December 18, 2018 the DWQC recommended MCLs of 10 ppt for PFOA, 10 ppt of PFOS and 1 ppb for 1,4-dioxane in a public forum.

The Department subsequently accepted the DWQC recommended MCLs and initiated the rulemaking progress in accordance with the State Administrative Procedures Act that included public comment periods for the both the initial proposed rulemaking and this revised rulemaking.

No changes were made to the proposed regulation in response to this comment.

Comment: Several commenters suggested that all water systems should be required to begin testing within 60 days of adoption.

Response: The regulations allow small public water systems to six months to test for PFOA, PFOS and 1.4 dioxane. These systems were provided greater flexibility as they are often in rural areas without easy access to testing. Cost also has more significant impact to these systems. Laboratory capacity will also be strained if all water systems begin testing at the same time. No changes were made to the proposed regulation in response to this comment.

Comment: Some commenters suggested that full cost accounting including environmental degradation, illness and health care costs of PFOA, PFOS and 1,4–dioxane exposures as well as job losses and diminished property values should be factored into the proposed rulemaking. **Response:** This comment is seeking cost analyses that go beyond the requirements of the State Administrative Procedure Act (SAPA). Further, the Department selected the MCLs proposed in this rulemaking on the basis of the recommendations of the DWQC, which considered a range of economic impacts beyond those mandated by SAPA. No changes were made to the proposed regulation in response to this comment.

Comment: Several commenters requested that the Department establish MCLs for additional per- and polyfluoroalkyl substances (PFAS).

Response: The Department will take this suggestion under advisement. No changes were made to the proposed regulation in response to this comment.

Comment: Some commenters suggested that all water systems in New York State should be required to test in order to establish a statewide baseline, as prior test results likely did not use more current and sensitive testing methods and may not reflect potential migration of contaminants.

Response: All Community Water Systems that serve 15 or more service connections or 25 or more individuals will be required to test as a result of this regulation. Nontransient Noncommunity water systems, which represents systems such as schools, daycares and office buildings, will also be required to test The Department will only accept test results that were analyzed in accordance Environmental Laboratory Approval Program (ELAP) methods, which means the detection limits will meet current regulatory requirements. Those PWSs that detect PFOA, PFOS or 1,4-dioxane above the method detection limit (MDL) will be required to monitor quarterly and thus any pollutant mobility concerns will be closed monitored. Those systems that do not detect compounds at levels greater than the MDL will be permitted to reduce monitoring in accordance with Section 5-1.52 Table 9D. This approach is consistent among all synthetic organic contaminants regulated by Subpart 5-1. No changes were made to the proposed regulation in response to this comment.

Comment: Several commenters suggested that lower MCLs should be revisited and established as testing methods and technologies become more sophisticated and sensitive to these toxic chemicals and should always reflect new emerging science as well as the most sensitive endpoints and the multiple sources of exposure.

Response: The Department acknowledges the comment and will work through the DWQC for their recommendations on any future changes to these MCL levels. No changes were made to the proposed regulation in response to this comment.

Comment: Some commenters suggested that the Advanced Oxidation Process (AOP), used to treat 1,4 dioxane is not fully proven or tested.

Response: AOPs have been studied for decades, and proven effective at rapidly degrading organic micropollutants, including 1,4-dioxane. These technologies are employed in several states for both direct potable use and indirect potable reuse. AOP systems employ technologies that are familiar to water treatment operators, including chemical addition; UV light; and use of carbon contactors. These technologies are time tested and proven manageable by public water systems producing potable water that complies with all applicable drinking water standards. No changes were made to the proposed regulation in response to this comment.

Comment: Some commenters expressed concern that the cost of AOP operation and maintenance is high due to high electricity use, chemical use, chemical storage, system maintenance and system monitoring.

Response: The Department acknowledges the operational cost of AOP and has factored that into the cost estimate for operation and maintenance of this treatment technology. No changes were made to the proposed regulation in response to this comment.

Comment: Some commenters expressed concerns that byproducts from Advance Oxidation Process (AOP) are not well understood and suggests the Department carefully evaluate this treatment.

Response: The potential for byproduct production is assessed through initial pilot testing of each AOP system. In addition, the Department has been working with the University at Stony Brook's Center for Clean Water Technologies, to better understand AOP, which resulted in our knowledge of treatment byproducts increasing over the last several years. No changes were made to the proposed regulation in response to this comment.

Comment: One commenter questioned how AOP would impact New York State's climate change objectives.

Response: This comment is outside the scope of the proposed rulemaking. No changes were made to the proposed regulation in response to this comment.

Comment: A commenter suggested that identifying alternate drinking water supplies was a preferable solution to addressing emerging contaminants.

Response: Where feasible, public water suppliers can choose to pursue alternative sources or interconnections with other water suppliers to achieve compliance with MCLs. For many water suppliers, in particular small water suppliers in rural areas, neither alternate sources nor interconnecting with another supplier is a feasible alternative. It has been the Department's longstanding policy to promote consolidation when feasible. No changes were made to the proposed regulation in response to this comment.

Comment: One commenter suggested that public water suppliers who receive compliance deferrals, extensions or exceedances should notify their customers and report on efforts to achieve compliance.

Response: The Department will take this comment under advisement when developing guidance for public notification. No changes were made to the proposed regulation in response to this comment.

Comment: One commenter questioned why the revised regulation's deferral provisions included both PFOA/PFOS and 1,4 Dioxane.

Response: Water suppliers statewide made public comments at DWQC meetings regarding the need for additional time for some water suppliers to comply with all the proposed MCLs. In addition, the Department received many comments in response to the initial rulemaking package requesting additional time for both 1,4-dioxane and PFOA/PFOS treatment. The deferral is consistent with the Safe Drinking Water Act (SDWA), which allows up to three years from the date of promulgation for a water system to comply. The deferral option is for up to 2 years deferral of the violation, but each deferral request will be reviewed separately. No changes were made to the proposed regulation in response to this comment.

Comment: Some commenters requested public input prior to the Department issuing a water supplier with a deferral for compliance.

Response: The proposed deferral process is consistent with the current process of MCL enforcement, in which bilateral or stipulated agreements are negotiated by LHDs and

District Offices for establishing compliance timetables. These agreements are not subject to public comment. In addition, the SDWA requires compliance within 3 years of promulgation. The deferral provision aligns the State requirements with the SDWA while adding public notification requirements. No changes were made to the proposed regulation in response to this comment.

Comment: A commenter requested a more detailed summary of the public comments received on the first proposed rulemaking for 1,4-dioxane.

Response: The Department has provided a summary of public comments as required in the State Administrative Procedures Act. A full copy of all comments is available by submitting a request to the Department's Records Access Office at:

Records Access Appeals Officer
New York State Department of Health
Corning Tower, Room 2364
Albany, New York 12237-0044
Fax: (518) 486-9144
foil@health.ny.gov

No changes were made to the proposed regulation in response to this comment.

Comment: Several commenters requested further information on how the Department derived the proposed standards for PFOA, PFOS and 1,4-dioxane.

Response: The proposed standards for PFOA, PFOS and 1,4-dioxane were recommended by the New York State Drinking Water Quality Council (DWQC). The Department

presented the DWQC with peer-reviewed technical information on the toxicity of the chemicals and health-based water values, along with occurrence data, estimated treatment/monitoring costs, analytical capabilities and other information. The DWQC weighed all these considerations in making its drinking water standard recommendations, which were accepted by the Department.

All of the DWQC meetings and deliberations (including the Department's presentations) were announced in advance, were open to the public, were livestreamed, and are archived on the Department's website (https://www.health.ny.gov/environmental/water/drinking/dwqc/) in an effort to make the entire process available to the public with a high degree of transparency. The ranges of health-based water values provided by the Department to the DWQC over the course of multiple meetings in 2017 and 2018 were based on toxicity data available in the peer-reviewed scientific literature, and the publicly available work of several authoritative bodies (i.e., state, national, or international regulatory or advisory public health organizations). Key information was provided on the studies on which the values were based, as well as the choice of toxicological endpoints and the exposure assumptions used. Throughout this process, the Department remained committed to providing a balanced and objective summary of the information and noted areas of disparate scientific opinion about the toxicity of the contaminants. The Department also stressed the fundamental difference between health-based water values (values based solely on health considerations) and drinking water standards (regulatory values based on a combination of health and risk management considerations). As such, there is no single derivation or

calculation yielding the proposed standard for each chemical. No changes were made to the proposed regulation in response to this comment.

Comment: One commenter stated that no health-based drinking water values presented by the Department for PFOA and PFOS was as low as the proposed standards, regardless of the target population used for the study (infant, adult, lactating woman).

Response: As indicated in the Regulatory Impact Statement, and during the October 17, 2018 meeting of the DWQC, the low end of the range of health-based values presented by the Department for PFOA, PFOS and 1,4-dioxane was 4 parts per trillion (ppt), 8 ppt, and 0.35 parts per billion (ppb), respectively. The proposed MCLs were 10 ppt, 10 ppt and 1 ppb respectively. No changes were made to the proposed regulation in response to this comment.

Comment: One commenter noted that serum per- and polyfluoro alkyl substances (PFAS) levels in the U.S. population have declined over the last 15 years.

Response: The comment is noted, and the Department is aware of the decline in U.S. population PFAS serum levels in recent years (CDC 2020). However, this decline does not obviate the need for PFOA and PFOS public drinking water standards in the absence of federal standards. New York State standards will aid in uncovering contamination and addressing the health risks associated with PFOA and PFOS exposure in public water systems. No changes were made to the proposed regulation in response to this comment.

Comment: One commenter stated that the body of scientific evidence does not show that PFOA and PFOS cause adverse health effects in humans.

Response: The scientific evidence demonstrating the human health risks associated with exposure to PFOA and PFOS is robust and consists of a large number of peer-reviewed studies. The overall weight of evidence on the health effects of PFOA and PFOS comes from numerous animal studies (multiple health effects caused in different species, in both sexes, and at low exposure levels) and epidemiology studies (positive associations between PFOA or PFOS serum levels and adverse health effects in humans). Establishing causality for health effects in humans is not a pre-requisite for regulation of contaminants in drinking water, and lack of clear causality does not diminish the strong evidence that exposure to high levels of PFOA or PFOS poses human health risks. Further, there are numerous contaminants that have public water standards in regulation at the federal and state level for which causality between exposure and human health effects has not been established, but there is a sufficient weight of evidence that exposure in water systems poses a public health risk and should be mitigated. Moreover, several national and international authoritative bodies have reviewed the weight of evidence on the health effects of both chemicals, and based on their toxicity, have proposed guidelines or standards to address PFOA and PFOS contamination in drinking water. This demonstrates large scale agreement within the scientific community that the toxicity of PFOA and PFOS is of public health concern. The public health risks of exposure to high levels of PFOA or PFOS in drinking water can be reasonably mitigated through regulation. No changes were made to the proposed regulation in response to this comment.

Comment: Several commenters stated that the Department did not use the most recent and best science developing the proposed standard for 1,4-dioxane. Specifically, the Department did not consider recent assessments by Health Canada (2018), which concluded 1,4-dioxane causes cancer in animals by a threshold mode of action, and the US EPA (2019), which derived an estimate of cancer potency for 1,4-dioxane about one-fifth that of the potency estimate currently on the US EPA Integrated Risk Information System (US EPA IRIS 2013a,b). The results of these recent assessments suggest significantly higher health-based water values compared to the proposed 1,4-dioxane standard.

Response: The Department is aware of the recent assessments done by Health Canada (2018) and the US EPA (2019). The Department reviewed and evaluated these assessments, as well as the recent toxicological literature on 1,4-dioxane (including studies on the mode of action for carcinogenesis). No changes to the proposed standard are being made based on this review.

The Health Canada assessment (Health Canada 2018) derived a health-based water value of 50 ppb for 1,4-dioxane based on noncancer liver toxicity in rats, after concluding that a non-linear (threshold) risk assessment for the formation of mouse liver tumors was appropriate. The Department has reviewed the evidence in this assessment and in the recent scientific literature supporting a threshold mode of action, and has concluded that it is insufficient to justify departure from the default assumption of low dose linearity used by the US EPA to derive their estimate of 1,4-dioxane cancer potency (US EPA 2013a,b). The US EPA, in its draft assessment of 1,4-dioxane (US EPA 2019), reviewed

the recent cancer mode of action data and also concluded the evidence for a threshold mechanism is still insufficient to depart from the default assumption of low dose linearity. The default recommendation is used when data on mode-of-action are unavailable, when a mode-of-action analysis provides evidence of linearity at low doses, or when a mode-of action analysis does not provide unequivocal evidence of nonlinearity at low doses (US EPA 2005). In addition to this conclusion on mouse liver tumors, the Department also notes that the mode of action for other types of tumors caused by 1,4-dioxane in animals (e.g., kidney, nasal cavity, mammary gland tumors) is also not unequivocally known. The Department will consider new information on the carcinogenic mode of action for 1,4-dioxane as it becomes available in the future when evaluating whether it is appropriate and feasible to update/revise the standard.

Under the Toxic Substances Control Act (TSCA), the US EPA (2019) derived a draft cancer potency estimate for 1,4-dioxane that is about five-fold lower than the potency estimate currently on the US EPA Integrated Risk Information System (US EPA IRIS 2013a,b). Both derivations are based on the same cancer study in rodents (Kano et al., 2009), but differ in the choice of data sets (e.g., species, sex, and selected tumors) and approaches to dose-modeling. The 2019 draft estimate is based on the combined nasal, peritoneal, subcutaneous and liver tumors in male rats, while the US EPA IRIS estimate is based on liver tumors in female mice. The female mice data provided the most sensitive carcinogenic response to 1,4-dioxane, but US EPA (2019) stated that these data were not used in the draft TSCA derivation due to modeling approaches used in the US EPA IRIS derivation (i.e., choice of a benchmark response [50%], omitting the highest

dose group, and not using the linearized multistage model). The Department reviewed the US EPA 2019 draft risk evaluation, including the cancer potency derivation, and concluded that the preferred basis for health-based water values for 1,4-dioxane is still the US EPA IRIS estimate of cancer potency because the 2019 TSCA evaluation is draft, and its initial determinations may change as the assessment "becomes more refined through the public and peer review process" (US EPA 2019). It therefore does not constitute an US EPA update to the current potency estimate (as suggested by a commenter). IRIS assessments remain the preferred source of toxicity information used by the US EPA (US EPA 2020). Furthermore, the US EPA IRIS assessment concluded that the female mouse tumor data provided the most sensitive carcinogenic response of the species and sexes tested. The dose-response modeling approach used in the US EPA IRIS derivation is generally consistent with cancer risk assessment practices and US EPA benchmark dose guidance (US EPA, 2012, 2013b). Thus, in the absence of presentation of a strong biological rationale for exclusion of these data in the US EPA (2019) assessment, a rationale based on model-fitting alone is not sufficient justification for omitting the female mouse liver tumor data set from the quantitative assessment of 1,4-dioxane carcinogenicity.

As a point of clarification, the Department presented several water values based on the US EPA IRIS assessment and cancer potency factor to the Drinking Water Quality Council. Values based on noncancer endpoints and the assumption of a threshold mode of action were also presented to the Drinking Water Quality Council by the Department. The Drinking Water Quality Council proposed the MCL of 1 ppb after consideration of all the health-based values, occurrence data, estimated treatment/monitoring costs,

analytical capabilities and other information. No changes were made to the proposed regulation in response to this comment.

Comment: One commenter objected to the use of the Agency for Toxic Substances and Disease Registry (ATSDR) draft minimal risk levels for PFOA and PFOS to develop standards (and health advisories) because such minimal risk levels are not final, and because the minimal risk levels and standards/health advisories are derived using different methods and are not directly comparable.

Response: The Department presented several toxicity values derived by authoritative bodies for PFOA and PFOS to the DWQC. The draft ATSDR minimal risk levels were also presented to the DWQC as a point of information but were not used to generate the ranges of health-based water values because they had not been finalized. The Department also pointed out the inherent differences between toxicity values (such as the draft minimal risk levels) health-based water values and drinking water standards. The DWQC considered the toxicity information, the health-based water values, occurrence data, estimated treatment/monitoring costs, analytical capabilities and other information in making its drinking water standard recommendations, which were accepted by the Department. No changes were made to the proposed regulation in response to this comment.

Comment: One commenter stated support for the Department's approach to regulated PFOA and PFOS as individual chemicals and opposed regulating these and other PFAS chemicals as a group.

Response: The Department notes this comment. No changes were made to the proposed regulation in response to this comment.

References

CDC (Centers for Disease Control and Prevention). 2020. National Health and Nutrition Environmental Survey. National Center for Health Statistics. Available at https://wwwn.cdc.gov/nchs/nhanes/.

Health Canada. 2018. 1,4-Dioxane in Drinking Water - Guideline Technical Document for Public Consultation. Available at https://www.canada.ca/en/health-canada/programs/consultation-1-4-dioxane-drinking-water/document.html.

Kano H, Y Umeda, T Kasai, et al. 2009. Carcinogenicity studies of 1,4-dioxane administered in drinking-water to rats and mice for 2 years. Food Chem Toxicol 47: 2776-2784.

MA DEP (Massachusetts Department of Environmental Protection). 2020. Standards and Guidelines for Contaminants in Massachusetts Drinking Waters. Winter 2020.

Available at https://www.mass.gov/doc/2020-standards-and-guidelines-for-contaminants-in-massachusetts-drinking-waters/download.

NYS DOH (New York State Department of Health). 2020. Drinking Water Quality Council. Available on-line at https://www.health.ny.gov/environmental/water/drinking/dwqc/.

US EPA (United States Environmental Protection Agency). 2005. Guidelines for Carcinogen Risk Assessment. March 2005. EPA/630/P-03/001F. Available at https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment.

US EPA (United States Environmental Protection Agency). 2012. Benchmark Dose Technical Guidance. June 2012. EPA/100/R-12/001. Available at https://www.epa.gov/risk/benchmark-dose-technical-guidance.

US EPA (United States Environmental Protection Agency). 2019. Draft Risk Evaluation for 1,4-Dioxane. Assessing and Managing Chemicals under TSCA. Available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/draft-risk-evaluation-14-dioxane.

US EPA (United States Environmental Protection Agency). 2020. Basic Information about the Integrated Risk Information System. Available at https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system.

US EPA IRIS (United States Environmental Protection Agency Integrated Risk Information System). 2013a. 1,4-Dioxane CASRN 123-91-1. Available at https://cfpub.epa.gov/ncea/iris/search/index.cfm?keyword=.

US EPA IRIS (United States Environmental Protection Agency Integrated Risk Information System). 2013b. Toxicological Review of 1,4-Dioxane (with Inhalation Update) (CASRN 123-91-1). September 2013. EPA/635/R-11/003F. Available at https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0326tr.pdf.