Assessment of Public Comments

Division of Water Technical and Operational Guidance Series (TOGS) Related to the Control of PFOA, PFOS, and 1,4-Dioxane

Background

The New York State Department of Environmental Conservation (NYSDEC) issued three new/amended Division of Water (DOW) Technical and Operational Guidance Series (TOGS) documents on October 6, 2021. The new/amended TOGS issued include:

- TOGS 1.1.1: Ambient Water Quality Standards and Guidance Values and Groundwater Effluent Limitations. (Addendum)
- TOGS 1.3.7: Analytical Detectability and Quantitation Guidelines for Environmental Parameters. (Revised)
- TOGS 1.3.13: Permitting Strategy for Implementing Guidance Values for PFOA, PFOS, and 1,4-D. (New)[1]

The TOGS were publicly noticed in the Environmental Notice Bulletin and on the NYSDEC website on October 6, 2021. The public comment period was originally set to close on November 5, 2021, but was extended to December 6, 2021.

Timely comments were received from:

Affiliation	Name	Commentor Number	Date
n/a	Diana Stahl	1	10/05/21
WeLoveOutdoors.org	Rich Davenport	2	10/13/21
Ken W. Kloeber Consulting Engineers	Ken Kloeber	3	10/11/21
Development Authority of the North Country	Christina Fout	4	10/15/21
Riverkeeper	Victoria Leung	5	12/06/21
Erie County Fisheries Advisory Board	Robert King	6	11/01/21
DOE, Brookhaven National Laboratory	Robert Gordon	7	11/19/21
n/a	Wendy Dwyer	8	12/04/21
Rensselaer Environmental Coalition	Robert Welton	9	12/04/21
Arcadis	Norman Forsberg	10	12/05/21
American Chemistry Council	Stephen Risotto	11	12/06/21
Integral Consulting	Kristain Fried	12	12/06/21
NYC Law Department	Antonia Pereira	13	12/06/21
Tetra Tech	Tyler Brown	14	12/06/21
National Waste & Recycling Association	Steve Changaris	15	12/06/21
Beveridge & Diamond for 3M	Matthew Schneider	16	12/06/21
Westchester County	David Chen	17	12/06/21

[1] The title of the final version of this document was changed to "TOGS 1.3.13: Industrial Permitting Strategy for Implementing Guidance Values for PFOA, PFOS, and 1,4-Dioxane."

NYSDEC has prepared this Assessment of Public Comments to address the comments that were received on the TOGS documents. The comments on the TOGS documents, and NYSDEC's responses, have been organized into sections corresponding to each TOGS. Frequently raised comments are summarized and presented as one general comment and are not repeated as specific comments under the Assessment of Public Comments. Responses to all comments on the TOGS documents are addressed below with commenter(s) referenced at the end of each comment.

A. GENERAL COMMENTS

A.1 **Comment:** Comments of general support for the guidance value (GV) package. (Commentors 1 and 2)

Response: The New York State Department of Environmental Conservation (DEC) acknowledges these comments.

A.2 **Comment:** The concentration levels of contaminants allowed in drinking waters to protect public health versus those allowed in non-drinking waters to protect aquatic life do not make sense/seem out of balance. (Commenters 2 and 8)

Response: Ambient water quality GVs of three different types (Health (Water Source), Aquatic (Chronic), and Aquatic (Acute)), set to protect two different best uses (source of potable water supply and fishing), were included in the proposed TOGS.

Health (Water Source), or H(WS), GVs are set exclusively for the protection of human consumers of Class A, AA, A-Special, AA-Special and GA waters. Within the PFOA, PFOS, and 1,4-Dioxane (1,4-D) proposed TOGS, the H(WS) GVs are the most stringent and apply whenever discharges occur to waters that are classified as drinking water sources, which could include discharges to waters that flow into a Class A, AA, A-Special, or AA-Special water. These GVs apply to surface waters independent of any other GV, including those used to protect aquatic life.

The Aquatic (Chronic), or A(C), GVs are set to protect the best use of 'fishing' through supporting propagation (reproduction) of aquatic life. The A(C) GVs apply to all Classes of surface waters except D and SD.

The Aquatic (Acute), or A(A), GVs are also set to protect the best use of 'fishing," but through supporting survival of aquatic life only and not propagation. The A(A) GVs apply to all Classes of surface waters including D and SD.

All GVs are set based on standardized methods defined in Title 6 New York Codes, Rules, and Regulations (6 NYCRR) Part 702 (Derivation and Use of Standards and Guidance Values). The methods used in derivation are dependent upon the best use to be protected and the type of water quality standard or guidance value being developed. In this case, both the A(C) and A(A) GVs are set using research on the toxic effects observed in various types of aquatic organisms. Sometimes marine organisms and freshwater organisms are affected differently by the same contaminant which can result is different GVs for freshwater versus marine Classes. If a water

is used as a drinking water source, the freshwater A(C) and A(A) GVs do not need to be more stringent, because drinking water is protected under its own H(WS) GVs.

A.3 **Comment:** Commentors requested a thirty (30) day extension of the public comment period. (Commentor 5)

Response: This request was fulfilled on October 27, 2021. The deadline was extended from November 5, 2021, to December 6, 2021.

A.4 **Comment:** "Strict adherence to this proposed guidance values for 1,4-dioxane could result in multiple treatment system shut-downs, loss of hydraulic control of existing groundwater plumes, renegotiation of multiple Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) Records of Decision, and remedial system redesigns." (Commenter 7)

"…New Guidance creates standards that may be duplicative of, and at worse may conflict with, the requirements set forth by our current BCA [Brownfield Cleanup Agreement]. …We should be able to rely on DEC's representations that we are doing what is required under the BCA with respect to PFOA, PFOS, and 1,4-Dixoane without having to worry that we may nevertheless unwittingly run afoul of separate, statewide DEC guidance relating to SPDES permits with respect to those same pollutants." (Commenter 17)

Response: Most regulatory vehicles used by DEC, such as cleanup agreements and SPDES permits, are not opened immediately for modification upon adoption of new WQSs or GVs. If a permit, permit equivalent, or agreement was opened for renewal, renegotiated for noncompliance, or required modification for other reasons, DEC would consider any new WQSs or GVs that may have been adopted since the issuance of that permit or agreement. As SPDES permits or permit equivalents are reopened, compliance with the PFOA, PFOS, and 1,4-D GVs will be evaluated and incorporated into permits as outlined in TOGS 1.3.13. Regulated parties should continue to act in good faith to meet previously agreed upon limits and goals for PFOA, PFOS, and 1,4-D.

The Brownfield Cleanup Program (BCP) and the SPDES program are separate and distinct regulatory programs. They are consistent in their requirement to prevent discharge/migration of contaminants from a site/facility at concentrations above regulatory limits. The BCP requires prevention of migration of contamination from a site and relies upon existing standards, criteria, and guidance to determine compliance with this objective.

In the interim, prior to renegotiation or renewal of a permit, permit equivalent, or agreement, regulated parties must follow their currently permitted discharge limits and plan for the addition of PFOA, PFOS, and 1,4-D limits in the future. This could include:

A. Regulated parties under an existing permit or permit equivalent are expected to make a good faith effort to modify their systems to address PFOA, PFOS, and/or 1,4-D to meet new requirements under the expectation they will be added in a future renewal.

B. Any permits or permit equivalents that are in the process of being renewed or about to be renewed will be provided additional time to modify the existing system to meet new PFOA, PFOS, and/or 1,4-D discharge limits.

C. Regulated parties with permit equivalents that do not specify a renewal date should evaluate their discharges for PFOA, PFOS, and/or 1,4-D concentrations and consider upgrades to treatment systems to treat for these compounds if found.

Under all the above scenarios, regulated parties must consult with DEC on modifications to their current treatment systems to ensure current discharge limits are met and the discharge complies with the new PFOA, PFOS, and/or 1,4-D GVs.

A.5 **Comment:** Separation and/or concentration technologies appear to have the highest potential for success in managing PFAS in wastewater. However concentrated PFAS liquid is produced with no clear or economical disposal remedy. (Commenter 15) Product bans or source control efforts for PFOA, PFOS, and 1,4-D would be a more effective way to regulate contaminants and environmental impacts. (Commenters 8, 13, 14, and 15)

Response: The proposed GVs are part of a comprehensive strategy that will complement DEC's source control efforts for PFOA, PFOS, and 1,4-D. As part of this comprehensive strategy, and to specifically address the issue of PFAS in leachate from landfills, the Department is developing a regulatory mechanism to require all solid waste landfills to treat leachate onsite to reduce PFAS content prior to discharge, either to a POTW or directly.

In 2016, New York became the first state in the nation to regulate PFOA and PFOS as hazardous substances. The regulation requires the proper storage of PFOA and PFOS and limited releases to the environment and enabled the state to use its legal authority and resources of the State Superfund program to advance investigations and cleanups of impacted sites.

In 2019, the NYS Legislature enacted amendments to Environmental Conservation Law (ECL) Article 35 and Article 37 to establish limits on the amount of 1,4-D that can be present in household cleansing, personal care, and cosmetic products sold or offered for sale in New York State. The law establishes a maximum allowable concentration in certain products that will be phased in from December 2022 through December 2023.

Finally, the NYS Legislature enacted the Hazardous Packaging Act, Title II of Article 37 of the ECL to prohibit any person from distributing, selling, or offering for sale in NYS, any food packaging containing PFAS substances as intentionally added chemicals on or after December 31, 2022.

B. COMMENTS ON TOGS 1.1.1

B.1 **Comment:** Why are the proposed guidance values for the protection of human health inconsistent with NYSDOH MCLs? (Commentors 7, 11, 12, 13, 15, and 17)

Responses: DEC's proposed H(WS) GVs for PFOA, PFOS, and 1,4-D to protect drinking water sources are required to be established using procedures defined in 6 NYCRR Part 702.

Ambient water quality GVs are more stringent than DOH's Maximum Contaminant Levels (MCLs) because different procedures are used to derive each Agency's target values. Per 6 NYCRR 702.3, DEC ambient water quality standards and GVs must be at least as stringent as the DOH drinking water MCL. But beyond that minimum requirement, the risk-based calculation in 6 NYCRR 702.4-702.7, based on principal organic contaminant classes, oncogenic effects, nononcogenic effects, and chemical correlation, exclusively drive the value of the ambient GV.

Furthermore, water quality standards (WQS) and GVs are set to prevent contaminants from entering the water at levels that would prevent that water from meeting its best uses. Having a more stringent GV to protect a source water against contamination provides an extra margin of safety and helps to ensure that the drinking water MCLs are not exceeded, which could result in costly treatment for drinking water providers.

B.2 **Comment:** "PFAS should be regulated as a class …total organic fluorine (TOF) should be measured to capture all PFAS." (Commenter 9)

Response: DEC acknowledges that the universe of PFAS chemicals is continually expanding and regulating these chemicals as a class would have certain advantages, but there are key obstacles to this approach.

WQSs and GVs are set based on careful examination of the toxicological research and the results of calculations found in 6 NYCRR Part 702. Currently available toxicological research on PFAS chemicals focuses on dosing with a single compound and the effects observed after that dosing. To regulate PFAS as a class, new research would need to be performed using a PFAS mixture to dose, and that mixture would need to be consistent across multiple studies. For similar reasons related to a lack of toxicological research, it is not practical to regulate PFAS using the measurement of TOF. Multiple dosing studies with a specific mixture of PFAS chemicals with a known TOF value would need to be performed and validated before a TOF WQS or GV could be considered.

B.3 **Comment:** "Your document completely ignores EPA's recent (2021) risk assessments on PFOA and PFOS…" (Commenter 9)

Response: USEPA released new risk assessment studies for PFOA and PFOS to their Science Advisory Board for peer review in November 2021. USEPA used the new risk assessment studies to set new health advisory levels for PFOA and PFOS in June 2022. The new health advisory levels are not MCLs or Clean Water Act (CWA) 304(a) criteria recommendations, therefore there is no requirement to set WQS or GV to align with the health advisory levels. Also, DEC's GV package was released in October 2021 using values calculated in April 2021, before both USEPA actions detailed above occurred.

B.4 **Comment:** "Your document also completely ignores EPA's (2021) GenX risk assessment which says GenX is more toxic than PFOA or PFOS." (Commenter 9)

Response: The current GV package is specific to PFOA, PFOS, and 1,4-D. It is the first step in DOW's efforts to control PFAS contamination but will likely not be the last. DOW will continue to evaluate other PFAS chemicals, including GenX, for future GVs as data becomes available.

B.5 **Comment:** "These are not health protective." (Commenter 9)

Response: The H(WS) GVs are protective of human health in waters designated as drinking water sources and were finalized using procedures in 6 NYCRR Part 702 considering all data available at that time. It is acknowledged that toxicological data on these chemicals is continually evolving and to wait for this information to be 'settled' prior to setting GVs is counterproductive and a poor strategy for environmental protection. The GVs for PFOA and PFOS will be reevaluated as new risk data and USEPA criteria recommendations are finalized.

B.6 **Comment:** DEC should set PFOA and PFOS limits to protect human consumers of fish (type H(FC)) and human consumers of wildlife, primary white-tail deer. (Commenters 5 and 9)

Response: DEC is currently gathering data on PFOA and PFOS concentrations in fish and wildlife tissue. Once statewide baseline tissue concentration levels and bioaccumulation patterns are understood, DOW plans to work with NYS DOH and DEC's Division of Fish and Wildlife to set H(FC) GVs and/or WQSs in the future.

B.7 **Comment:** "…the chronic levels for fresh and salt water (160 ppb and 41 ppb, respectively) are too high." (Commenter 9)

Response: The proposed GVs were set using procedures specified in 6 NYCRR 702.9 using the most current research on aquatic toxicity.

B.8 **Comment:** "It is possible that, like lead, there is no safe level of PFOA. These numbers should be lower." (Commenter 9)

Response: The proposed GVs were set using procedures specified in 6 NYCRR Part 702 using the most current peer-reviewed toxicological research. The PFOA GVs will be reviewed as more data on PFOA toxicity becomes available.

B.9 **Comment:** The derivation of the ambient water quality value for 1,4-D relies on outdated scientific information that does not reflect the current state of scientific knowledge on the chemical's mode of action (MOA) for causing cancer. Several studies provide convincing scientific evidence that 1,4-D causes liver tumors through a threshold mechanism and therefore the ambient water quality value should have been derived under this assumption, rather than by the default linear low dose mechanism that assumes no threshold. 6 NYCRR 702.4(d)(3) requires the NYS DEC to derive guidance values for oncogenic substances using threshold dose-response models when supported by sufficient MOA information. (Commenters 10 & 15)

Response: *The following comment response was provided to DEC by NYS DOH who derived the PFOA/PFOS/1,4-D GV and authored the supporting fact sheet* - The NYS DOH is aware of and has reviewed the recent assessments done by Health Canada (2018), Dourson et al (2014, 2017) as well as the recent toxicological literature on 1,4-D, including studies on the MOA for carcinogenesis. The available information on the MOA for 1,4-D liver carcinogenicity in mice is

not sufficient to justify departure from the default assumption of low dose linearity used by the USEPA to derive their estimate of 1,4-D cancer potency (USEPA 2013), which in turn was used by the NYS DOH to derive the ambient water quality value based on oncogenic effects. 6 NYCRR 702.4(d)(3) applies "if a mode-of-action analysis provides no evidence for linearity at low doses and provides unequivocal evidence of nonlinearity at low doses". Based on the NYS DOH evaluation, neither of these conditions has been met. The NYS DOH also notes that the MOA for other types of tumors caused by 1,4-D in animals (e.g., kidney, nasal cavity, mammary gland tumors) is not definitively known. The NYS DOH position on the 1,4-D cancer mechanism is consistent with the USEPA's most recent evaluation of 1,4-D (USEPA 2020) in which the agency concluded:

- There is insufficient information to support a specific MOA for any of the tumor types associated with 1,4-D exposure
- There is uncertainty on whether the toxic moiety is 1,4-D or one or more metabolites
- There is uncertainty about whether cytotoxicity is a necessary key event in the progression to observed liver tumors
- In the absence of information to indicate otherwise, nasal, liver, renal, peritoneal, mammary gland, Zymbal gland, and subcutis tumors reported in animal studies are all considered relevant to humans.

The NYS DOH will consider new information on the cancer MOA for 1,4-D as it becomes available in the future and will evaluate if it is appropriate and feasible to update/revise the ambient water quality value based on oncogenic effects.

B.10 **Comment:** "In establishing effluent limitations, Section 702.16 advises the Department to consider analytical detectability and treatability. The current proposal does not evaluate the detectability and treatability aspects of complying with the proposed limits…" (Commenter 11)

Response: The regulations referenced in 6 NYCRR 702.16 are specific to calculating effluent limitations for a SPDES permit, not the derivation of the WQS or GV. Section 702.16 does not require DEC to adjust the WQS or GV in anticipation of higher analytical reporting limits or insufficient available treatment technology.

B.11 **Comment:** DEC's approach to assume PFOS is carcinogenic is not common practice within the current state of understanding of the carcinogenicity of perfluoroalkyl substances and has no precedent. The comparisons with PFOA do not materially contribute to a "read across" approach to carcinogenesis. (Commenters 12 & 16)

Response: *The following comment response was provided to DEC by NYS DOH who derived the PFOA/PFOS/1,4-D GVs and authored the supporting fact sheets* - PFOS has oncogenic effects as defined in 6 NYCRR 700.1 based on its induction of tumors in "one mammalian species, supported by positive results for another substance for which similar oncogenic effects are anticipated because of similarity of functional groups or metabolic or toxicologic pathways."

While toxicological similarity to PFOA was used qualitatively to support the weight of evidence for PFOS carcinogenicity, the quantitative dose response assessment of oncogenic effects is based on PFOS induction of tumors in rodents. Derivation of an ambient water quality value for PFOS based on oncogenic effects is consistent with the procedures outlined in 6 NYCRR 702.2 through 702.7.

B.12 **Comment:** The NYS DEC's preference for outside data over New York State and federal data is unconventional. The points of departure for the derivation of the oncogenic-based ambient water quality values for PFOS and PFOA were based on single studies and outside third-party interpretations and manipulation of data, which did not include insights from the in-state NYS DOH on the same compounds. It remains unclear why the NYS DEC relied on these third parties instead of relying on the NYS DOH and adopting New York MCLs by applying 6 NYCRR Section 702.3 (Procedures for Deriving Standards and Guidance Values Based on Specific MCLs and Principal Organic Contaminant Classes). The NYS DOH also relied on the point of departure (a benchmark internal concentration for a 10% response) from a single study (Tardiff et al. 2009) but did not note that this study also says that 7,700 ppt (ng/L) is a protective drinking water equivalence level for cancer effects. This value is much higher than the ambient water quality value for PFOA based on oncogenic effects. (Commenter 12)

Response: *The following comment response was provided to DEC by NYS DOH who derived the PFOA/PFOS/1,4-D GVs and authored the supporting fact sheets* - The ambient water quality values were derived by the NYS DOH for the NYS DEC, which is the regulating agency in New York for implementing guidelines and standards for the protection of ambient water quality. The values are derived in accordance with the procedures outlined in 6 NYCRR 702. The derivation of ambient water quality values based on nononcogenic or oncogenic effects requires a review of the toxicological literature for studies on the chemical that provide the best basis for deriving toxicity values which can be used to develop the water values. It is typical risk assessment practice to use data from a single study to derive toxicity values. Alternatively, the NYS DOH also uses assessments and toxicity values on the chemicals from other authoritative bodies (state and national health agencies) as the basis for ambient water quality values. Decisions on which studies, toxicity values or assessments to use to derive an ambient water quality value for a specific chemical are made on a case-by-case basis and consider study quality issues, the nature and sensitivity of the effect caused by the chemical, and whether existing assessments from authoritative bodies are scientifically defensible and follow generally accepted risk assessment practice.

For PFOA and PFOS, the NYS DOH is required to derive ambient water quality values based on oncogenic effects because the definition for oncogenic effects for a chemical in 6 NYCRR 700.1 has been met. PFOA has oncogenic effects under 6 NYCRR 700.1 based on induction of tumors in one mammalian species, reported in two independent studies. PFOS has oncogenic effects under 6 NYCRR 700.1 because it induces tumors in one mammalian species, supported by positive results for another substance (PFOA) for which similar oncogenic effects are anticipated because of similarity of functional groups or metabolic or toxicologic pathways.

Tardiff et al. (2009) reported a PFOA drinking water equivalence level of 7700 ppt (ng/L) for protection against cancer. This value was derived under the assumption that PFOA causes cancer by a nonlinear threshold mechanism. The derivation applied uncertainty factors to a benchmark PFOA serum level in a manner similar to the derivation of a noncancer reference dose. This approach is reserved for carcinogens for which a nonlinear threshold mechanism has been firmly established. However, there is insufficient evidence from the scientific literature to definitively conclude that PFOA causes cancer by this mechanism, and in such cases the USEPA recommends using the default assumption of low dose linearity for the derivation of cancer-based toxicity values (USEPA 2005a). In addition, 6 NYCRR 702.4(d)(2) states that "if the mode-of-action analysis provides evidence of linearity at low doses or does not provide unequivocal evidence of nonlinearity at low doses, the standard or GV shall be based on the 95 percent lower confidence limit on the human dose corresponding to an excess lifetime cancer risk of one-in-one million". Since information on the cancer mechanism for PFOA does not provide unequivocal evidence for nonlinearity at low doses, the NYS DOH derived the PFOA ambient water quality value assuming low dose linearity, and the value was set at an excess lifetime cancer risk of one-in-one million, in accordance with the regulations.

B.13 **Comment:** The determination and application of Klimisch scores for study selection is unclear and inconsistent. (RE PFOS, Commenter 12)

Response: The literature review and the derivation of the GVs were done following established methodology requiring review of original publications to independently assess data quality. The assignment of the Klimisch scores may not always agree with the decisions in Organization for Economic Co-operation and Development (OECD 2002) guidance. For example, the *Artemia sp. (Brine Shrimp)* study was likely excluded because of uncertainty in the concentrations of the chemical during the experiment. The purity of the material was not specified, and the nominal concentrations were not verified by measurement. Furthermore, it is not clear whether additional data would have provided higher levels of confidence in the GVs derived. Uncertainties in actual concentrations used in the study would have resulted in unreliable estimate of the toxicity threshold, decreasing the level of confidence in the GVs derived.

B.14 **Comment:** The derivation of the aquatic life GVs relied on an incomplete data set. (RE PFOS, Commenter 12)

Response: DEC is confident the literature research conducted was adequate at the time the factsheet was first drafted. DEC acknowledges that the science on PFOS continues to grow and will so into the future. The GVs will be reviewed as more data on PFOS toxicity becomes available.

B.15 **Comment:** The reporting of study results is inconsistent between publicly available sources. (RE PFOS, Commenter 12)

Response: DEC has always been vigilant in verifying study results to ensure accuracy of the data used for the derivation of WQSs and GVs. It appeared that the commenter was referring to the results from the early life-stage toxicity test with the fathead minnow (*Pimephales promelas,* 3M Company 2000) as the example of inconsistency between the publicly available sources. The LOEC of 650 µg/L from that study cited by the commenter, was included in a summary of data from other previously released studies and did not include any supporting data. The fathead minnow data points (NOEC = 300 µg/L, LOEC of 600 µg/L, MATC = 424.3 µg/L) used by DEC to set the PFOS A(C) GV from OECD (2002) originate from Drottar et al. (2000), which did include all supporting data. DEC concluded that LOEC reported in OECD (2002) was more reliable and more appropriate for deriving the GVs. The LOEC data point also goes through two geometric mean calculations before arriving at the final acute: chronic ratio (FACR) used to set the A(C) GV, therefore the difference between using a LOEC of 600 µg/L and 650 µg/L is likely insignificant.

B.16 **Comment:** The use of a secondary acute factor (SAF) from a source other than New York State guidelines is likely unnecessary. (RE PFOS, Commenter 12)

Response: DEC believes the use of a secondary acute factor (SAF) from a source other than New York State guidelines was justified. The "greater than" value for saltwater fish was from a single-dose acute exposure study using sheepshead minnow. Another saltwater fish study was discussed in OECD (2002), but the test concentrations were not confirmed by measured concentrations in that study. Considering significant differences between nominal concentrations and measured concentrations in available saltwater studies, the fish lowest genus mean acute value (GMAV) could be within a wide range of 2.5 to 20 mg/L. Therefore, DEC considered both results unreliable and did not include them in the calculation of the GVs.

The "lowest GMAV" referred to by the commenter was based on another "greater than" value reported in Eastern Oyster. The value was based on the mean measured concentrations on three samples from 0 hours and two samples each from 48 and 96 hours. There were considerable variations in the test concentrations during the exposure and the highest measured concentrations were greater than the GMAV of the *Mysidae* (3,600 µg/L). Therefore, there is high uncertainty in the GMAV of *Ostreidae* and DEC deemed it unreliable.

Based on the above considerations, the DEC believes that the use of a secondary acute factor (SAF) from a source other than New York State guidelines was justified.

B.17 **Comment:** "These Values Should Be Adopted as Numeric Water Quality Criteria, Not Guidance Values… The law requires numeric water quality criteria where feasible… Water quality standards are critical to ensure effective cleanups when water sources have been contaminated with PFOS or PFOA." (Commenter 5)

Response: GVs and WQSs provide equal authority for setting effluent limits and cleanup levels for contaminated sites. 6 NYCRR Part 750 considers WQSs and GVs equivalent for the purpose of setting effluent limits. 6 NYCRR Part 375 also requires consideration of GVs when setting

cleanup specifications. DEC Division of Environmental Remediation's "Index of Standards, Criteria and Guidance (SCGs) for Investigation and Remediation of Inactive Hazardous Waste Disposal Sites" (https://www.dec.ny.gov/regulations/61794.html) also requires adherence to GVs found in TOGS 1.1.1.

Acknowledging that new data on the toxicity of these chemicals is constantly being developed and published, DEC believes the GV approach, using the narrative WQS for 'no toxics' (6 NYCRR 703.2) as a basis, affords the ability to revise criteria as new data warrants and to ensure the highest levels of protection for NYS waters.

In addition, there are no federal laws or regulations that prevent DEC from using GVs to define compliance with a narrative WQS.

B.18 **Comment:** "When a state proposes new numeric water quality criteria, it must submit the revisions to EPA for review and approval." (Commenter 5)

Response: The above statement is true for WQSs but not applicable to GVs used to define compliance with an existing narrative WQS.

B.19 **Comment:** DEC Should Create Aquatic Life Criteria for PFOA (Commenter 5)

Response: At this time, DEC feels that there is insufficient data available to set PFOA GVs for aquatic life protection. Going forward, DEC will continue to monitor the study of PFOA aquatic toxicity and release a WQS or GV if appropriate.

B.20 **Comment:** "To the extent remediation of PFOA, PFOS, and 1,4-Dioxane in groundwater is required by NYSDEC, the City [of New York] encourages NYSDEC to focus on the end use of the groundwater in determining whether and to what extent remediation is necessary." (Commenter 13)

Response: DEC WQSs and GVs are applied to waters based on their assigned Classification to protect the best uses assigned to that Classification. The current, or future, use of the water is irrelevant. The classification dictates what best uses must be protected within the water and the WQSs and GVs are set specific to protecting those uses.

B.21 **Comment:** "The City [of New York] is concerned about the adequacy of the data used to support the development of the ambient water quality criteria (AWQC) for two compounds--PFOS and 1,4 Dioxane." (Commenter 13)

Response: The data used to set the A(A) and A(C) GVs for PFOS and 1,4-D meets the 'Tier II' requirements established in 6 NYCRR 706.1 for setting WQSs and GVs protective of aquatic life. The lack of data available to satisfy 'Tier I' requirements was one of the key reasons these criteria are being proposed as GVs and not WQSs.

B.22 **Comment:** Before finalizing the guidance values, DEC should provide greater transparency on the source data used for derivation including but not limited to Host, et al (1995). (Commenter 13)

Response: The information used to derive the GVs was largely from peer reviewed literature readily available to the public. The factsheets provide the appropriate citations to those references. Full text of Host, et al (1995) is freely available for download by the public by visiting National Service Center for Environmental Publications (NSCEP).

B.23 **Comment:** The Butenhoff et al. (2012) study showing increases in liver tumors in rats should not be used to derive an ambient water quality value for PFOS because it is well established that PFOS is a peroxisome proliferator-receptor alpha (PPAR-*alpha*) activator, and the effects observed in rodent livers occur via a mode of action (MOA) that is of questionable relevance to humans. The established mechanistic data do not lead to the conclusion that PFOS is likely to cause liver cancer in humans because of the differences between humans and rodents in the susceptibility of nuclear receptor activation. There is also no epidemiological evidence for liver tumors in humans exposed to PFOS, and PFOS is neither genotoxic nor mutagenic. In addition, deriving a PFOS ambient water value using PFOA data a surrogate for PFOS-specific data is inappropriate because it too has limited relevance to humans given the PPAR-*alpha* MOA operative in rodents. (Commenter 16)

Response: *The following comment response was provided to DEC by NYS DOH who derived the PFOA/PFOS/1,4-D GVs and authored the supporting fact sheets* - The statement that PFOA cancer data were used as a surrogate for PFOS-specific data is not accurate. PFOS has oncogenic effects under 6 NYCRR 700.1 based on its induction of tumors in "one mammalian species, supported by positive results for another substance for which similar oncogenic effects are anticipated because of similarity of functional groups or metabolic or toxicologic pathways." Therefore, while toxicological similarity to PFOA was used qualitatively to support the weight of evidence for evaluating PFOS oncogenicity, the quantitative dose-response assessment of its oncogenic effects is based on PFOS-specific data for induction of tumors in rodents. The procedures used to derive an ambient water quality value for PFOS based on oncogenic effects are consistent with 6 NYCRR 702.2 through 702.7. In addition, USEPA (2016a) evaluated human and animal studies on the carcinogenicity of PFOS and concluded that there is "suggestive evidence" of carcinogenic potential in humans based on evidence in rodents. PFOS was also recently added to California EPA's Proposition 65 based on cancer effects (CA EPA, 2021). In addition, animal carcinogenicity studies of PFOS have been used by other agencies to evaluate the health risks to humans and to support health-based values for drinking water (NJ DEP, 2019a).

While it has been hypothesized that the health effects of PFOS are PPAR-alpha mediated, studies in mice demonstrate that PFOS can exert effects on the liver independent of PPAR-alpha (Qazi et al. 2009) and can upregulate genes for lipid metabolism, inflammation, and xenobiotic metabolism in PPAR-alpha-null mice (Rosen et al. 2010). In addition, PFOS alters the expression of other nuclear receptors such as PPAR-gamma, estrogen receptor alpha, constitutive androstane receptor and pregnane X receptor, which could play a role in PPAR-alpha independent modes-of-action (NJ DEP, 2019a). Overall, the possible modes of action for PFOS toxicity are not well elucidated and the specific mode of action for the carcinogenic effects of PFOS is currently not known. Thus, linear low-dose extrapolation of PFOS

carcinogenicity data in rodents is appropriate and consistent with the procedures outlined in the ambient water quality regulations (6 NYCRR 702.4).

B.24 **Comment:** The Dong et al. (2009) should not be used to derive a nononcogenic-based PFOS ambient water quality value because this study has several technical deficiencies, such as incomplete antibody isotyping, partial assessments in some primary immune organs, and no second challenge to elicit permanent antibody response. As a result, Dong et al. (2009) fails to provide compelling scientific evidence to support the claim that PFOS causes immune suppression in mice. (Commenter 16)

Response: *The following comment response was provided to DEC by NYS DOH who derived the PFOA/PFOS/1,4-D GVs and authored the supporting fact sheets* - The Dong et al. (2009) study reported immune effects (decreased plaque forming cell response) in adult male mice exposed to PFOS for 60 days. The New Jersey Department of Environmental Protection (NJ DEP) used this study to derive a PFOS reference dose and maximum contaminant level (NJ DWQI 2018). The NYS DOH based its nononcogenic ambient water quality value on the NJ DEP reference dose and considers Dong et al. (2009) to be of sufficient quality to serve as the principal study for this purpose. The study used well-established methods as evaluated by the National Toxicology Program (NTP 2016) and produced a clear dose-response with a no-observed effect level and a lowest observed effect level (i.e., a NOEL and a LOEL). The study reported measured serum PFOS concentrations (the preferred dose metric) at each administered dose and employed an adequate number of animals and exposure levels. Of the available animal studies investigating the effects of PFOS on the plaque forming cell response, the Dong et al. (2009) study reports effects at one of the lowest serum PFOS levels. Dong et al. (2009) also measured corticosterone levels to assess stress, which is known to decrease immune function. Corticosterone levels were not elevated at the LOEL, and this finding increases confidence that the effects were PFOS-related. Thus, in evaluating the overall strengths and weaknesses of the study, the NYS DOH does not consider the study limitations raised in the comment sufficient to reject the study as the basis for deriving a PFOS ambient water quality value.

Four other studies (Peden Adams et al. 2008; Zheng et al. 2009; Keil et al. 2008; and Qazi et al. 2010) investigated the plaque-forming cell response in animals exposed to PFOS, and a statistically significant decrease was observed in three of these studies. In addition, the immune effects in animals are supported by several epidemiological studies that associate decreased vaccine response with PFOS exposures in the general population (Grandjean et al. 2012, 2017a, 2017b; Granum 2013; Stein et al. 2016). The NTP (2016) concluded that PFOS is presumed to be an immune hazard to humans based on a high level of evidence from animal studies that PFOS suppressed the antibody response, and a moderate level of evidence from studies in humans. The Agency for Toxic Substances and Disease Registry's Toxicological Profile for Perfluoroalkyls (ASTDR 2021) notes that the database of human studies provides convincing evidence of an association between serum PFOS levels and immunosuppression, and that animal studies provide strong evidence of immunotoxicity. Furthermore, multiple health agencies have derived or proposed PFOS reference doses, health-based water values,

or other limits based on immune effects reported in animal studies or associations between PFOS exposure and immune effects in human studies. These agencies include the NJ DEP (NJ DWQI 2018), the Minnesota Department of Health (MN DOH 2020), the European Food Safety Authority (EFSA 2020), and the USEPA (US EPA 2021a). Thus, a large body of scientific evidence and risk assessment analysis support the conclusion that PFOS immune toxicity is a sensitive, well-established toxicity endpoint in animals, is an important health concern for human exposure, and is an appropriate basis for derivation of a reference dose and nononcogenic health-based value.

B.25 **Comment:** Studies that demonstrate a lack of association between PFOA and excess kidney and testicular cancer were inappropriately dismissed. Epidemiology studies show no consistent evidence to support the conclusion that PFOA poses an increased cancer risk in humans. (Commenter 16)

Response: *The following comment response was provided to DEC by NYS DOH who derived the PFOA/PFOS/1,4-D GVs and authored the supporting fact sheets* - Based on the induction of tumors at multiple sites in rats (i.e., liver, mammary gland, testicular Leydig cell, and pancreatic acinar cell tumors) in at least two independent studies, PFOA meets the definition for having oncogenic effects under 6 NYCRR 700.1. In deriving an ambient water quality value for PFOA based on oncogenic effects, the NYS DOH applied the procedures specified in the New York State ambient water quality regulations (6 NYCRR 702.2 through 702.7). Relevant toxicity studies in humans and animals as well as authoritative body assessments on the carcinogenicity of PFOA were evaluated. Some of the evaluated human studies include Barry et al. (2013), Vieira et al. (2013), Steenland and Woskie (2012) and Raleigh et al. (2014). The assessments from authoritative bodies that were reviewed and evaluated include IARC (2016), EC/HC (2012), USEPA, (2005b, 2006, 2016b), NJ DWQI, (2017) and NJ DEP (2019b). No human studies were dismissed from the evaluation of PFOA carcinogenicity. However, lack of positive findings in one study does not negate positive findings in other studies. Moreover, recent human epidemiological studies (such as Shearer et al. [2021], which showed an association between exposure to PFOA and increased risk of kidney cancer) provide additional support for the carcinogenicity of PFOA. As described in the ambient water quality fact sheet for PFOA, IARC (2016) classifies PFOA as possibly carcinogenic to humans (Group 2B) and the USEPA (2016b) classifies PFOA as having suggestive evidence for carcinogenicity.

B.26 **Comment:** The ambient water quality value for PFOA should not be based on a rat study showing a relationship between Leydig cell (testicular) tumors and PFOA exposure in rats because there is no evidence of PFOA-induced increase in this specific and very rare tumor type in humans. The results of these studies therefore have little relevance to cancer risk in humans. The Department should also reevaluate its assessment of PFOA cancer risk in light of recent publications by C8 Science Panel coauthors (Steenland et al. [2020, 2021]), who "re-examined the literature and revised their assessment." (Commenter 16)

Response: *The following comment response was provided to DEC by NYS DOH who derived the PFOA/PFOS/1,4-D GVs and authored the supporting fact sheets* - Human and animal studies

both contribute to the weight-of-evidence on the carcinogenic potential of chemicals. However, due to controlled study designs, animal studies often provide the most robust quantitative estimates of carcinogenicity, and thus are commonly used by many health agencies to derive toxicity values for evaluating cancer risks in humans. The use of animal or human data to evaluate carcinogenicity and to perform quantitative dose response assessment is permitted by the ambient water quality regulations under the definitions and procedures for deriving standards and GVs based on oncogenic effects (6 NYCRR 700.1 and 700.4). While strong evidence of carcinogenicity from animal studies is sufficient for deriving an ambient water quality value based on oncogenic effects even in the absence of supporting human data, it should be noted that there is supporting evidence of PFOA carcinogenicity in several human studies (Barry et al. 2013; Vieira et al. 2013; Steenland and Woskie 2012; Raleigh et al. 2014; Shearer et al. 2021). For example, Shearer et al (2021) demonstrated an association between prediagnostic PFOA serum concentrations and renal cell carcinoma in a nested case-control study of an adult cohort within the general population.

Steenland et al. (2020) and Steenland and Winquist (2021) reviewed the evidence for the health effects of PFOA in human epidemiological studies. There is general agreement between the two review articles that there is evidence for cancer effects from exposure to PFOA in human studies. Regarding conclusions on carcinogenicity, Steenland et al. (2020) stated that the epidemiological evidence remains supportive for kidney and testicular cancers, and that for testicular cancer, the literature review revealed little additional research to confirm or refute the original C8 assessment. However, for kidney cancer, the authors concluded that the evidence has been strengthened by the Shearer et al. (2021) case control study. In addition, the Steenland and Winquist (2021) review article discussed a variety of limitations of human epidemiological studies (e.g., ability to control confounding factors, demonstrate temporality of associations, and have precise estimates of exposure) and noted that the strength of evidence for health effects across studies varies based on these and other factors. However, the authors indicated that human studies provide some evidence for testicular and kidney cancer, and that the evidence for an association between kidney cancer and exposure to PFOA is strengthened by the Shearer et al. (2021) case control study. The human and animal scientific literature support the appropriateness of performing quantitative dose-response assessment to evaluate the carcinogenicity of PFOA using animal studies, and this approach has been used by other agencies to evaluate the human health risks of PFOA (NJ DEP, 2019b; NJ DWQI, 2017; USEPA, 2016b).

B.27 **Comment:** Changes in relative liver weights reported in the Macon et al. (2011) study should not be used to derive a nononcogenic-based ambient water quality value for PFOA because they represent adaptive, not adverse effects. In addition, the effects in rodent livers are the result of PFOA activation of nuclear receptors (e.g., PPAR-*alpha*), and this MOA has little relevance in humans. (Commenter 16)

Response: *The following comment response was provided to DEC by NYS DOH who derived the PFOA/PFOS/1,4-D GVs and authored the supporting fact sheets* - There is considerable evidence in the scientific literature that liver effects are a well-established and sensitive

toxicological endpoint for PFOA exposure. Numerous studies (Cui et al. 2009; Elcombe et al. 2010; Yahia et al. 2010; Tan et al. 2013; Butenhoff et al. 2002, 2004) have reported liver toxicity in animals after exposure to PFOA, and several studies have demonstrated increased liver weights and other liver effects at relatively low levels of PFOA exposure (e.g., 0.3 to 1 mg/kg/day) (Loveless et al. 2006; Macon et al. 2011; Quist et al., 2015; Son et al., 2008). In humans, several epidemiological studies have found associations between PFOA exposure and indicators of liver toxicity, such as changes in alanine aminotransferase (ALT) activity (Gleason et al., 2015, Lin et al., 2010, Yamaguchi et al., 2013, Gallo et al., 2012). Overall, the weight of evidence indicates that exposure to PFOA is likely to increase the risk for liver effects in humans.

DOH is aware that there is not a clear scientific consensus about whether increased liver weights in the absence of liver damage should be considered an adaptive response or an adverse effect. While the increased liver weights in the Macon et al. (2011) study were not accompanied by liver damage, higher PFOA exposures and/or PFOA exposures of longer duration are known to cause liver damage, including histopathological changes, severe edema, vacuolar degeneration, and cellular necrosis (Loveless et al. 2008; Yang et al., 2014; NJ DWQI 2017). In addition, there is some evidence that PFOA-induced hepatocellular hypertrophy, a liver effect also considered by some to be adaptive, may not always be reversible. Gestational exposure to a low dose of PFOA caused hepatocellular hypertrophy that persisted until adulthood (Quist et al., 2015). Thus, based on an overall evaluation of the available information on PFOA and liver toxicity, the NYS DOH considered increased liver weights the first and most sensitive indicator of liver toxicity, and this toxicological endpoint was used as the basis for deriving a reference dose and nononcogenic based ambient water quality value.

Other health agencies have evaluated the toxicity of PFOA and recognized liver toxicity as an important and relevant endpoint. The NJ DEP (2019b) and the New Hampshire Department of Environmental Services (NH DES, 2019) have established reference doses and health-based water values based on increased liver weights reported in animal studies. The ATSDR (2021), the USEPA (2021b), and the Massachusetts Department of Environmental Protection (MA DEP, 2019) have all recognized that the results of animal studies investigating liver effects after PFOA exposure provide strong evidence that the liver is a sensitive toxicological endpoint for PFOA.

The comment also asserts that a proposed mechanism of PFOA-induced liver toxicity in rodents (i.e., involvement of the activation of peroxisome proliferator-activated receptor-alpha (PPAR-alpha)) is not relevant to humans. In general, the mechanisms of PFOA toxicity have not been fully elucidated and there is not enough evidence to definitively conclude that the PPAR-alpha mechanism is not applicable to humans. The findings of non-human primate studies support that PPAR-alpha activation is a mode of action that may not be limited to rodents. For example, studies involving cynomolgus monkeys reported that PFOA caused increased liver weights and peroxisomal proliferating activity, demonstrating that PPAR-alpha

activity is functional in a species that has known relevance to humans (Thomford 2001; Butenhoff et al. 2002).

There is also evidence from studies comparing wild type mice (having normal PPAR-alpha) with PPAR-alpha null mice (lacking PPAR-alpha) that liver effects most likely occur through both PPAR-alpha dependent and independent pathways (NJ DWQI 2017; ATSDR 2021). In these studies, PFOA caused similar increases in liver weights in wild type and PPAR-alpha null mice (Yang et al. 2002; Wolf et al. 2008; Minata et al. 2010). In addition, gestational exposures of PFOA to PPAR-alpha null mice caused hepatocellular hypertrophy and bile duct hyperplasia in offspring (Filgo et al. 2015).

PFOA has also been shown to activate other nuclear receptors including PPAR-gamma, CAR (constitutive activated receptor), PXR (pregnane X receptor) and estrogen receptor-alpha in addition to PPAR-alpha (NJ DWQI 2018; Peters and Gonzalez, 2011). Thus, while PFOA has been shown to cause some liver toxicity through the PPAR-alpha activation mode of action, other modes of action are possible. Overall, is not sufficient information to conclude that liver effects in rodents following PFOA exposure is not relevant to humans.

C. COMMENTS ON TOGS 1.3.7

C.1 Comment: Which laboratory method will wastewater testing for 1-4-D require, 522 or 8270 SIM? (Commentor 4)

Response: Currently, testing will require the use of SW-846 8270 SIM. Section V of TOGS 1.3.7 - Analytical Detectability and Quantitation Guidelines for Environmental Parameters details the Division of Water's (DOW) selection process for environmental testing methods for 1,4-D and any other parameter that may be monitored under the DOW's regulatory programs. In the case of 1,4-D, where no methods are currently approved under 40 CFR Part 136, Section V.1.2 of the TOGS directs the user to consult NYS Department of Health (DOH) Environmental Laboratory Approval Program's (ELAP) list of methods certified for use in non-potable water (ELAP Certification Manual, Item 180.2). From the ELAP list, DOW would select a method that is sufficiently sensitive to measure down to the permit limit. Current versions of SW-846 8270 and 8260 (SIM and non-SIM) are presently certified by ELAP for 1,4-D, but EPA Method 522 is not. Currently, SW-846 8270 SIM is the only method ELAP offers certification in that is sufficiently sensitive to measure at or below the proposed 1,4-D GV.

D. COMMENTS ON TOGS 1.3.13

D.1 **Comment:** "The NYSDEC should be consistent and migrate from the use of SIC to NAICS on all documents, forms, and reporting." (Commentor 3)

Response: No changes were made to the draft TOGS 1.3.13 in response to this comment. Although DEC has begun to migrate over to the use of the North American Industry Classification System (NAICS) instead of Standard Industrial Classification (SIC) codes, the background research to establish the SPDES implementation guidance utilized historical data still tied to SIC Codes.

D.2 **Comment:** DEC should act quickly to integrate these limits into all SPDES permits rather than relying on the EBPS. (Commenter 5)

Response: The implementation strategy outlined in TOGS 1.3.13 focuses DEC's efforts on discharges most likely to impact human health. The Department relies on EBPS to ensure that those permits whose discharges pose the greatest potential risk to the environment, are significantly overdue for modification, or are otherwise in substantial need of modification, receive the most expedient attention.

EBPS was developed to focus staff time on full technical review of the most deficient permits based upon environmental need and the need to better reflect current standards and regulations in the permit, with the results being permits which provide better protection for the environment. EBPS includes Water Quality Enhancement Multipliers that consider the environmental benefit of modification of the permit.

DEC has utilized the EBPS, pursuant to the authority in ECL §17-0817(4), since the statute became effective on August 2, 1994, to help achieve the objectives of the SPDES program and efficiently manage and prioritize SPDES permitting with the resources available. This allows DEC to identify and prioritize permits that have the greatest potential for causing significant environmental harm. Thus, the EBPS is a program designed for maximizing the efficiency of developing and managing permits in accordance with the Department's SPDES program, while attaining the highest levels of environmental protection.

D.3 **Comment:** DEC should apply the guidance values to all facilities, including sewage treatment plants (Commenter 5)

Response: Changes were made to TOGS 1.3.13 to clarify that TOGS 1.3.13 applies to SPDES permits for industrial discharges. Rather than delay finalization of the guidance values and implementation of a permitting strategy that addresses the most significant industrial sources, the Department is developing and will soon release for public comment, a new TOGS detailing our publicly owned treatment works (POTW) permitting strategy.

D.4 **Comment:** DEC should work with EPA to set pretreatment standards for PFOA, PFOS, and 1,4-D for indirect discharges to POTWs. (Commenter 5)

Response: Changes have been made to TOGS 1.3.13 to clarify that TOGS 1.3.13 outlines the Department's permitting strategy for industrial discharges. Since the release of draft TOGS 1.3.13, EPA released guidance recommending monitoring of influent, effluent and biosolids to enable EPA to obtain comprehensive information on the sources and quantities of PFAS discharges and will use these data to inform the agency's Effluent Limitation Guidelines (ELG) actions. A separate guidance document is being developed to detail the permitting strategy for POTWs and establishing pretreatment standards.

D.5 **Comment:** Does DEC use MCLs directly to set effluent limits? (Commentors 7, 11, 12, 13, 15, and 17)

Response: 6 NYCRR 702.3 does not grant DEC any default authority to use the MCL as a WQS, GV, or effluent limit. If the MCL is to be used to calculate a water-quality based effluent limitation, it must be formally adopted as a WQS or GV.

D.6 **Comment:** The proposed guidance value package for PFOA, PFOS, and 1,4-D lacks a cost-benefit analysis and could cause undue financial burden on POTWs. (Commenter 14)

Response: 6 NYCRR Part 702 does not require DEC to perform a cost-benefit analysis prior to setting GVs. Changes were made to TOGS 1.3.13 to clarify that the SPDES permitting strategy applies to industrial discharges. A separate guidance document is being developed to detail the permitting strategy for POTWs.

D.7 **Comment:** The commenter believes the following two statements in the 'V. Procedure' section of TOGS 1.3.13 are at odds and seeks clarification of the difference between guidance values and effluent limits:

- *"The Department will prioritize incorporation of the GVs for PFOA, PFOS and 1,4-D into SPDES permits for discharges of industrial wastewaters from facilities identified as 'priority facilities.'"*
- *"Based on this information, the Department will establish effluent limitations and incorporate them into the SPDES permit in accordance with established procedures and guidance."* (Commenter 14)

Response: Changes were made to clarify that the GVs would be incorporated into SPDES permits in the form of water quality based effluent limits (WQBELs). Pursuant to 6 NYCRR 750-1.11, DEC uses WQSs and GVs as a basis to set WQBELs. The Department considers a mixing zone analysis, critical flows, and reasonable potential analysis when developing a WQBEL. In certain cases, the WQS or GV may be applied directly as an end of pipe limit, or it may be subject to dilution calculations. The process for developing WQBELs is described in TOGS 1.3.1. The fact sheet that accompanies a SPDES permit provides the details of the site-specific factors used to develop a discharge specific WQBEL.

D.8 **Comment:** The commenter seeks clarification on the Request for Information (RFI) program described in TOGS 1.3.13. Based on the codes in Appendix A and B of TOGS 1.3.13, landfills are a known source of PFOA, PFOS, and 1,4-dioxane. It is unclear what values would be used for stormwater run-off, or surface water at a given facility. Additional clarification and how these values would be determined if they are going to differ from the GV. (Commenter 14)

Response: TOGS 1.3.13 was developed to focus regulatory efforts on facilities that are most likely to contribute to a human health hazard (i.e., drinking water) and are considered to be primary sources of PFOA, PFOS, and 1,4-D to NY waters. Secondary sources of PFOA, PFOS, and 1,4-D will not be an initial focus for implementation. DEC will rely on the established permit writing guidance in TOGS 1.3.1 to establish applicable effluent limitations for industrial dischargers. Once finalized, the GVs will be used to assess discharges and/or ambient water quality and the need for additional action. As noted in draft TOGS 1.3.13 and continued in the final TOGS, in cases where a release of PFOA, PFOS, or 1,4-D is the result of an emergency and/or spill, the clean-up effort will be handled through the Department's Division of

Environmental Remediation spill clean-up protocols and will not be handled through the SPDES permitting program.

The Department will utilize the provisions of 6 NYCRR § 750-2.1(i) as an RFI to request information to make appropriate assessments for priority facilities.

D.9 **Comment:** TOGS 1.3.13 indicates facilities will receive a Request for Information letter from the department based on their SIC codes and the location of the site within the HUC 12 watershed. The required sampling for PFAS and 1,4-dioxane are not outlined clearly. Is this just added on to any required analytical sampling already being conducted? It is unclear if it means all samples such as surface water, groundwater, pond sampling etc. would require the additional analytical data to be collected. An explanation about how, and when a response is required is needed. (Commenter 14)

Response: Sampling directions, including where to sample and the appropriate analytical method that will be required, and submission timelines will be provided in the Request for Information letter sent to each permittee.

D.10 **Comment:** For existing facilities additional explanation about the scoring system with the Environmental Benefit Permit Strategy (EBPS) that would move a facility to the priority status is required. It is unclear if this priority system is based on volume of discharge, water body that is being discharged to, concentration, etc. Additional clarification on the priority determination is required. (Commenter 14)

Response: No changes were made in response to this comment. Prioritization of full technical review of SPDES permits is based on 13 priority ranking factors as detailed in DOW 1.2.2 – Administrative Procedures and the Environmental Benefit Permit Strategy for Individual SPDES Permits. DOW 1.2.2 provides the background for the scoring system to rank SPDES permits. The scoring includes those factors, and their water quality enhancement multiplier.

D.11 **Comment:** The commenters seek clarification on the following statement from TOGS 1.3.13:

> *This guidance does not preclude the use of the PFOA, PFOS and 1,4-D GVs at sources other than the industrial categories identified as potential sources in Appendices A and B. If further analysis determines a significant source of concern and/contamination exists elsewhere, this guidance may be applied.*

Is this a catch-all for any type of SPDES permit? How will DEC expand the use of PFOA, PFOS, and 1,4-D GVs beyond the industrial facilities with the listed SIC codes? (Commenter 14 and 15)

Response: The statement is included to acknowledge that the science is evolving and provides flexibility to apply the GVs to other permitted discharges as new information on sources and priority categories becomes available.

D.12 **Comment:** Data from the states of Vermont, Michigan, and North Carolina indicate that PFAS is present in non-industrial discharges above the proposed GVs. Within this dataset, the influent concentration is "inconsistent," the effluent concentration is sometimes higher, and

the ambient conditions exceed the proposed GVs. In conclusion, the GVs are unnecessarily low. (Commenter 15)

Response: The GVs for PFOA, PFOS, and 1,4-D were set using toxicological derivation procedures defined in 6 NYCRR Part 702. These procedures are established solely for the protection of human health and/or aquatic life and do not need to account for background concentrations or treatment plant loadings. If needed, relief from effluent limits calculated from the proposed GVs through compliance schedules and/or variances can be granted to permittees where appropriate.

D.13 **Comment:** It is recommended that NYSDEC provide a statement confirming the applicability of aquatic criteria where a receiving water body is not used for drinking water in lieu of a much more conservative human health-based criteria. (Commenter 15)

Response: WQBELs are established to protect the receiving waters best use as identified by the assigned classification regardless of current uses. When more than one applicable standard or GV exists for aquatic or human health protection for a specific pollutant, a reasonable potential analysis is conducted for each applicable standard and GV and corresponding critical flow to ensure effluent limitations are sufficiently stringent to ensure all applicable water quality standards and GVs are met as required by 40 CFR 122.44(d)(1)(i). For brevity, the pollutant summary table included in the SPDES permit fact sheet reports the results of the most conservative scenario. This holds true even when a water is not being used for all its currently assigned best uses.

D.14 **Comment:** Priority facilities with existing SPDES permits may be required to amend the permit to include PFOS, PFOA, and 1,4-D at levels up to three times levels lower than the drinking water standard, even when no one would drink the water at the end of the pipe leaving the facility (Commenter 17)

Response: DEC's proposed H(WS) GVs for PFOA, PFOS, and 1,4-D to protect drinking water sources are established using procedures defined in 6 NYCRR Part 702. The resulting ambient water quality GVs are more stringent than DOH's MCLs because different procedures are used to derive each Agency's target values. See response to Comment B.1.

As discussed in the response to Comment D.13 above, the WQBELs must be sufficiently stringent to protect the designated best uses of the water, even when those uses are not currently practiced.

D.15 **Comment:** "…recommends the SPDES permit owners have the ability to provide a site-specific PFOS, PFOA, and 1,4 Dioxane guidance value protective of human health. This specific number could be defined through modeling and/or monitoring the mixing zones and concentrations before reaching the water supply source." (Commenter 17)

Response: Site specific considerations in establishing WQBELs are detailed in TOGS 1.3.1 and described in the SPDES permit fact sheet for the specific SPDES permit.

D.16 **Comment:** The proposed GVs are set at or near applicable method detection limits for these compounds. The applicable treatment technology may also fail to remove PFOA, PFOS, or 1,4-D down to the concentrations of the GVs. (Commenter 7 and 16)

Response: WQS and GVs are set using procedures in 6 NYCRR Part 702 based on toxicological endpoints without consideration for analytical or treatment technology.

Pursuant to 40 CFR 122.44(i)(1)(iv) and 6 NYCRR 750-2.5(d), SPDES permits must contain monitoring requirements using sufficiently sensitive test procedures approved under 40 CFR Part 136 or as selected by the NYSDEC Quality Assurance Officer following procedures detailed in TOGS 1.3.7 - Analytical Detectability and Quantitation Guidelines for Environmental Parameters. A method is "sufficiently sensitive" when the method's minimum level (ML) is at or below the level of the effluent limitation established in the permit for the measured pollutant parameter; or the lowest ML of the analytical methods approved under 40 CFR Part 136. The ML represents the lowest level that can be measured within specified limitations of precision and accuracy during routine laboratory operations on most effluent matrices. When establishing effluent limitations for a specific parameter (based on technology or water quality requirements), it is possible that the calculated limitation will fall below the ML established by the approved analytical method(s). In these instances, the calculated limitation is included in the permit with a compliance level set equal to the ML of the most sensitive method.

D.17 **Comment:** "In establishing effluent limitations, Section 702.16 advises the Department to consider analytical detectability and treatability. The current proposal does not evaluate the detectability and treatability aspects of complying with the proposed limits…" (Commenter 11)

Response: No changes were made to TOGS 1.3.13 in response to this comment. As stated in draft TOGS 1.3.13 and continued in the final TOGS, there are treatment technologies capable of meeting the expected limitations to be derived from the GVs that can be implemented by industrial facilities. The Department will establish effluent limitations and permit conditions in accordance with established procedures and guidance.

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