ENVIRONMENTAL PROTECTION

WATER RESOURCE MANAGEMENT

DIVISION OF WATER SUPPLY AND GEOSCIENCE

Private Well Testing Act Rules; Safe Drinking Water Act Rules; Regulations Governing the Certification of Laboratories and Environmental Measurements

Maximum Contaminant Levels (MCLs) for Perfluorononanoic Acid and 1,2,3-Trichloropropane; Private Well Testing for Arsenic, Gross Alpha Particle Activity, and Certain Synthetic Organic Compounds

Adopted Amendments: N.J.A.C. 7:9E-2.1; 7:10-5.2, 5.3, and 12.30; and 7:18-6.4

Proposed: August 7, 2017, at 49 N.J.R. 2361(a).

Adopted: July 31, 2018, by Catherine R. McCabe, Commissioner, Department of Environmental Protection.

Filed: August 2, 2018, as R.2018 d.165 **with non-substantial changes** not requiring addition public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 13:1D-1 et seq., 58:11-9.1 et seq., 58:11-23 et seq., 58:11-64 et seq., 58:12A-1 et seq., and 58:12A-26 et seq.

DEP Docket Number: 13-17-06.

Effective Date: September 4, 2018.

Expiration Dates: January 23, 2022, N.J.A.C. 7:9E;

March 29, 2024, N.J.A.C. 7:10; and

October 23, 2020, N.J.A.C. 7:18.

This rule adoption may be viewed or downloaded from the Department's website at

http://www.nj.gov/dep/rules/adoptions.html

The Department is adopting amendments to the New Jersey Safe Drinking Water Act (SDWA) rules at N.J.A.C. 7:10 to establish, as recommended by the New Jersey Drinking Water Quality Institute (Institute), a maximum contaminant level (MCL) for perfluorononanoic acid (PFNA) of 0.013 micrograms per liter (µg/l) and an MCL for 1,2,3-trichloropropane (1,2,3-TCP) of 0.030 µg/l. The adopted rule requires public community and public nontransient noncommunity water systems to monitor for these contaminants beginning in first quarter of 2019. In addition, the adopted amendments set forth requirements regarding information to be included in the consumer confidence report (CCR) that public community water systems issue each year regarding the quality of the water delivered to their customers. Currently, there are no Federal drinking water standards for these contaminants, which have been detected in drinking water supplies in New Jersey and which are associated with adverse health effects.

The Department is also adopting amendments to the SDWA rules to require public nontransient noncommunity water systems to begin monitoring for radionuclides in 2019, and to update the monitoring and analytical requirements applicable to public water systems for other contaminants.

Further, the Department is adopting amendments to the Private Well Testing Act (PWTA) rules at N.J.A.C. 7:9E, and the SDWA rules, respectively, to require testing of private wells subject to sale or lease and of newly constructed wells for public noncommunity water systems and nonpublic water systems for 1,2,3-TCP as well as ethylene dibromide (EDB) and 1,2 dibromo-3-chloropropane (DBCP). EDB and DBCP have existing Federal MCLs, which are applicable in New Jersey. These contaminants are synthetic organic compounds that, like 1,2,3-TCP, are potent carcinogens. Other amendments to the PWTA rules and the SDWA rules expand the geographical extent of testing for gross alpha particle activity and arsenic, such that testing will be required Statewide. The amendments also establish a requirement to test for uranium in the northern counties of New Jersey.

Lastly, the Department is adopting amendments to the Regulations Governing the Certification of Laboratories and Environmental Measurements at N.J.A.C. 7:18 to clarify the procedure to be used by the laboratories to test for gross alpha particle activity for drinking water samples.

Summary of Hearing Officer's Recommendation and Agency Response:

The Department held a public hearing on the notice of proposal on Tuesday, August 29, 2017, at 1:00 P.M., in the Department's Public Hearing Room, 401 East State Street, Trenton, New Jersey. Kristin Tedesco, an Environmental Engineer for the Division of Water Supply and Geoscience, was the hearing officer. Four persons commented at the public hearing. After considering the testimony at the public hearing and the written comments received, the hearing officer recommended that the Department adopt the amendments. The Department accepts the recommendation. A record of the public hearing is available for inspection in accordance with applicable law by contacting:

Department of Environmental Protection

Office of Legal Affairs

ATTN: DEP Docket No. 13-17-06

401 East State Street, 7th Floor

Mail Code 401-04L

PO Box 402

Trenton, NJ 08625-0402

Summary of Public Comments and Agency Responses:

The following persons timely submitted comments on the notice of proposal:

1. Carroll Arkema

2. Kevin Avery

3. Diane and Mel Baiada

4. Diane Barrett, The Academy of Nutrition and Dietetics

5. Deborah Baumann

6. Hannelore Baumann

7. Tom Beatini

8. David Bendich

9. Richard Bizub, Pinelands Preservation Alliance

10. Bryan Bonfiglio

11. Jane Books

12. Jennifer Books

13. Marinus Broekman

14. Tracy Carluccio, Deputy Director, Delaware Riverkeeper Network

15. Tracy Carluccio and Maya van Rossum, Delaware Riverkeeper Network

16. Monica Carsky, Weill Cornell Medical Center

17. Holly Cullen

18. Suzanne Curry

19. Ryan Dodson

20. Carolyn Enger

21. Hugh Evans

22. Karen Ferriday

23. Marilynn Formica

24. Michael Gochfeld, M.D., Ph.D., Rutgers Biomedical and Health Sciences, Robert Wood Johnson Medical School, Environmental and Occupational Health Sciences Institute

25. Aud Gold

26. Francie Goldstein

27. Mark Harris

28. Dennis Hart, on behalf of the Chemistry Council of New Jersey and the Site Remediation Industry Network

29. Jeanne Jordan

30. Ronald Joyner, Department of Defense

31. Catherine Kaiser, Action Together Gloucester County

32. Birgitta Karlen

33. Carla Kelly-Mackey

34. Marilyn King

35. Harvey Klein, Laboratory Director, Garden State Laboratories, Inc.

36. Robert Laumbach, Rutgers University

37. Denise L. Lytle

38. Gloria Machnowski

39. Patches Magarro

40. Marie Mannino

41. Richard McNutt, Tidewaters Gateway Partnership Inc.

42. David Miller

43. Anthony Montapert

44. P Naprstek

45. Paul Netusil

46. Doug O'Malley, Director, Environment New Jersey

47. Carol Parker

48. Dorothy Plaza

49. Ed Potosnak, Executive Director, New Jersey League of Conservation Voters, providing a petition with 782 signatures

50. Vincent Prudente

51. Jean Public

52. Christopher M. Roe, Fox Rothschild LLP, on behalf of Solvay Specialty Polymers USA, LLC

53. Joseph Russell

54. Bruce S. Shapiro, on behalf of New Jersey Realtors®

55. Meg Sleeper

56. Jeff Tittle, Director, New Jersey Sierra Club

57. Laura Tracey-Coll, New Jersey Sierra Club

58. Adam Wall

59. Donna Yavorsky

60. Nicole Zanetakos

The comments received and the Department's responses are summarized below. The number(s) in parentheses after each comment identify the respective commenter(s) listed above.

Comments in support of the amendments

1. COMMENT: The proposed amendments are supported. (2, 3, 4, 5, 6, 9, 11, 12, 15, 18, 20, 21, 23, 24, 26, 32, 34, 37, 38, 39, 40, 43, 46, 47, 48, 49, and 60)

2. COMMENT: The Institute recommended new limits for PFNA of 0.013 µg/l and an MCL for 1,2,3-TCP years ago and putting these into place is long overdue. New Jersey can no longer let our toxic history poison our families. (1, 7, 8, 13, 14, 15, 16, 17, 22, 25, 29, 42, 44, 45, 49, 53, and 57)

3. COMMENT: Stringent rules to regulate levels of PFNA in drinking water are urgently needed given the discovery of these substances in a number of water supplies and finished water samples in New Jersey. Potential health effects are manifold and serious, and epidemiological studies, as well as animal models suggest health effects at levels found in drinking water in New Jersey. The rule should be adopted as written, because it is time to take

reasonable action to reduce exposures and the drinking water standard is an important and necessary first step. (36)

RESPONSE TO COMMENTS 1 THROUGH 3: The Department acknowledges the comments in support of the amended rules. The Department is charged with the protection of the environment and public health and continues to ensure that there is clean and safe drinking water for all of New Jersey's citizens. The Department agrees that promulgation of MCLs is an important part of protecting public health and, therefore, has prioritized this adoption accordingly.

Compliance with the SDWA and Administrative Procedure Act (APA)

4. COMMENT: The Department has failed to comply with the SDWA as to the proposed MCLs for PFNA and 1,2,3-TCP, which charges the Department with considering the recommendations of the Institute. (28, 30, and 52)

RESPONSE: The MCLs were developed in conformance with the SDWA at N.J.S.A. 58:12A-13.b. The Institute evaluates health effects, the availability of analytical methods, and the ability to install treatment to remove contaminants from drinking water. The Institute is composed of experts in scientific and technical fields relevant to development of MCLs. The Institute reviews the most current science prior to finalizing a recommendation. The Department considers and reviews the Institute's recommendations and performs additional research to determine whether new information is available. During its review of the Institute's recommendation, the

Department determines whether it agrees with the Institute's findings regarding testing, treatment, and health effects. In this way, the Department has complied with the SDWA in adopting MCLs for PFNA and 1,2,3-TCP.

5. COMMENT: The Department has not presented an adequate regulatory flexibility analysis, jobs impact statement (including an assessment of the number of jobs generated or lost), agriculture industry impact statement, housing affordability impact analysis, or smart growth development impact analysis, as required by the APA. (28 and 52)

RESPONSE: The Department disagrees with the commenter regarding the sufficiency of the analyses and statements required by the APA.

As stated in the notice of proposal, the economic impacts of the amendments will depend on various factors, such as the type of treatment being implemented, site conditions, background quality of the source water, the size of the installation, and the concentration of the target contaminant in source water. Consequently, there may be some job growth in industries related to the design and installation of treatment systems, and for certified laboratories related to sampling and the analysis of water sources. The amendments are not anticipated to have any impacts on the agriculture industry in New Jersey because the water used for agricultural purposes is typically sourced from private irrigation wells that are not subject to the SDWA rules.

As noted in the Department's regulatory flexibility analysis in the notice of proposal, the safe drinking water requirements applicable to small businesses that serve customers potable water on a regular basis generally do not vary from those applicable to any other public water suppliers because relaxation of these standards would not be protective of public health. As to its housing affordability impact and smart growth development impact analyses, the Department made the statutorily required findings, specifically, that the establishment of two new MCLs, expansion and new testing for private and nonpublic wells and monitoring and treatment for radionuclides for public nontransient noncommunity water systems, are extremely unlikely to evoke either a major change in the average costs of housing in the State or in housing production in Planning Areas 1 and 2 or designated centers. The commenter did not provide information that would support different findings.

6. COMMENT: The Department did not provide an analysis of why the proposed rule requirements exceed the standards and requirements imposed by Federal law, specifically regarding setting an unprecedentedly low, trace-level MCLs and practical quantitation levels (PQLs) for PFNA and 1,2,3-TCP, and listing PFNA as a hazardous substance. Federal agencies, including the U.S. Environmental Protection Agency (USEPA) and the Agency for Toxic Substances and Disease Registry (ATSDR), have set no regulatory standards for PFNA in drinking water and do not list it as a Federally recognized hazardous substance. The proposed rule acknowledges the applicability of this APA requirement by including a "Federal Standards

Statement." That acknowledgement is wholly inadequate, however, in that it fails to include the required "cost-benefit analysis" with respect to the proposal concerning PFNA and 1,2,3-TCP. The USEPA has clear guidelines on how a cost-benefit analysis must be performed for an MCL. (28 and 52)

7. COMMENT: It is important to remember that neither the Federal government nor any state in the United States has acted to set an MCL for PFNA or for any other perfluorinated compound (PFC). This is not because PFCs, including PFNA, are unique to New Jersey. To the contrary, four PFCs, including PFNA, are present at trace levels in the blood of nearly all Americans. Several states, for example, Minnesota and West Virginia, have been investigating and responding to PFCs in drinking water for years. Yet, the Department seems intent on being the first agency in the country to set an MCL for any PFC and to do so at the unprecedented, trace level of 0.013 micrograms per liter. (28 and 52)

RESPONSE TO COMMENTS 6 AND 7: As explained in the Department's Federal standards statement in the notice of proposal, the SDWA rules at N.J.A.C. 7:10 incorporate by reference the National Primary Drinking Water Regulations (National Regulations) at 40 CFR 141. There are some areas for which the Department has determined, as authorized by the SDWA and allowed by the National Regulations, to establish New Jersey-specific requirements. Pursuant to the SDWA, the Department is authorized to promulgate MCLs after considering the recommendation of the Institute if there are adverse health effects associated with the contaminant and the contaminant may be found in public water supplies in New Jersey. Both

PFNA and 1,2,3-TCP were detected in public water systems in New Jersey through sampling conducted during the third iteration of the Federal Unregulated Contaminant Monitoring Rule (UCMR3) and Department-initiated sampling.

As New Jersey-specific requirements promulgated under State law, Federal cost benefit analysis guidelines are not applicable in the development of the State MCLs. As required by the APA, the notice of proposal includes an economic impact statement, as well as a Federal standards statement, which explain the difference between the State and Federal processes for developing MCLs and the need for a State-specific MCL for PFNA and 1,2,3-TCP. The SDWA sets forth what the Department may consider in establishing an MCL. The MCLs were proposed and are being adopted after considering the Institute's recommendations, in accordance with the SDWA. The Institute's studies upon which its recommendations were based included an evaluation of the necessary health-based level, limits of testing methodology in achieving those levels, and best available treatment technologies to remove the contaminants from drinking water to achieve the health-based levels.

The Department notes that the ATSDR does not set regulatory limits but has recently published notice in the Federal Register (see 83 Fed. Reg. 28849 at https://www.federalregister.gov/documents/2018/06/21/2018-13385/availability-of-draft-toxicological-profile-perfluoroalkyls) of the availability for comment of its Draft Toxicological Profile for Perfluoroalkyls (Draft Toxicological Profile). PFNA is a perfluoroalkyl compound and is discussed in the Draft Toxicological Profile (see

https://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=1117&tid=237). While the Department is developing comments on the Draft Toxicological Profile, it believes that the ATSDR's evaluation of PFNA lends further support to the Department's adoption of an MCL for PFNA.

In the Draft Toxicological Profile, the ATSDR concluded that there is sufficient information for risk assessment of PFNA. Like the Institute, the ATSDR concludes that human epidemiology studies provide evidence that exposure to PFNA may be associated with human health effects, including increases in serum lipids and decreased antibody response to vaccines. Both the Institute and the ATSDR also conclude that although human data are useful for identification of health effects of PFNA, uncertainties about these data preclude their use in the dose-response component of the risk assessment. Therefore, both the Institute and the ATSDR based their quantitative risk assessments on animal toxicology data. ATSDR's general approach to PFNA risk assessment is consistent with and provides support to the risk assessment approach used by the Institute for PFNA.

8. COMMENT: The notice of proposal does not identify the specific legal authority under which the proposed amendments are authorized, for example, the Industrial Site Recovery Act (ISRA), N.J.S.A. 13:1K-6 et seq., and the Brownfield and Contaminated Site Remediation Act (Brownfield Act), N.J.S.A. 58:10B-1 et seq., pursuant to which the proposed MCLs will become ground water quality criteria and immediately be enforced as "minimum remediation standards for groundwater." The Department does not acknowledge or explain the consequences of this

rulemaking under those statutes and does not evaluate the proposed ground water quality criteria in compliance with the requirements of those laws. Failure to identify clearly, the authority under which the Department is acting and the implications for the regulated community under those statutes is a violation of the APA that must be cured before this rulemaking can be completed. (28 and 52)

RESPONSE: The notice of proposal caption identifies the statutory authority for the rules as the Safe Drinking Water Act, N.J.S.A. 58:12A-1 et seq., under which the Department establishes New Jersey-specific maximum contaminant levels. Action to modify or add new specific ground water quality standards (GWQS) is authorized pursuant to the Water Pollution Control Act, N.J.S.A. 58:10A-1 et seq., and the Water Quality Planning Act, N.J.S.A. 58:11A-1 et seq. The GWQS provide the basis for protection of ground water quality through the establishment of constituent standards for ground water pollutants. The constituent standards of the GWQS rules become the minimum remediation standards to which ground water must be remediated in accordance with the Department's Remediation Standards rules at N.J.A.C. 7:26D-2.2 promulgated pursuant to the Brownfield and Contaminated Site Remediation Act, N.J.S.A. 58:10B-1 et seq., and the Industrial Site Recovery Act, N.J.S.A. 13:1K-6 et seq. The SDWA rules are not promulgated under the authority of those acts.

9. COMMENT: The Department did not provide a meaningful description of the expected socio-economic impact of the imposition of the proposed MCL for PFNA. The Department fails

to acknowledge or evaluate that it is suggesting with its proposed MCL that every water resource in the State is not "potable" if the barely detectable, trace level of 13 parts per trillion of PFNA is exceeded. This relative concentration is almost 100 times lower than the level that is consistently detected in the blood samples from Americans nationwide. As many as 18 water supply wells have already been shut down and millions of dollars are already being spent to remove this trace level of PFNA from municipal wells. This has led to significant social disruption in towns where PFNA has been detected. This disruption has included fear of using the water, the shutting down of water resources, and the expenditure of millions of dollars on treatment systems. No discussion of these very real social and economic effects, known to the Department, is included as part of the rulemaking package. (52)

10. COMMENT: At such extremely low concentrations, it would be overly burdensome for water systems to attain the MCL for PFNA, which would deplete monetary resources currently used for other health-based programs. (30)

11. COMMENT: The Department completely ignores the intense focus on requiring water suppliers to detect and treat trace levels of PFNA will divert scarce public resources and attention from substances that science shows cause harm, such as lead. As a result of the proposed MCL for PFNA, there will be a diversion of limited resources of water suppliers towards PFNA and away from other substances that are far more problematic from a public health perspective. The opportunity costs resulting from this diversion of resources are not accounted for in the Department's economic analysis. For example, if the proposed rule is

adopted, water purveyors would be sampling for (and possibly remediating) PFNA and expending resources to do so, when those resources could be used more effectively in repairing water infrastructure or remediating known and well-studied hazardous substances in water.

(52)

RESPONSE TO COMMENTS 9 THROUGH 11: The Department is charged with the protection of public health. Public water systems are responsible for providing safe drinking water. All contaminants with MCLs are associated with adverse health effects, including the proposed MCLs.

The commenter seems to suggest that there is an adverse social impact, or "disruption," that arises from the new MCLs for PFNA or 1,2,3-TCP, but does not clearly identify what that disruptive social impact might be. As explained in the social and economic impact statements in the notice of proposal, public water systems routinely make decisions regarding the operation of their sources and budgeting for maintenance and water system improvements to deliver safe drinking water to the consumers. The Department disagrees that monitoring and treatment of drinking water will cause the public to fear consumption of the water supply. Rather, the Department believes that failure to regulate these contaminants will have the negative social impact of eroding consumer confidence in drinking water.

The commenter also seems to imply that because the MCLs are low levels, that the contaminants must not pose a threat to public health. In fact, the Department is regulating these contaminants at low levels because these compounds are associated with health effects

at low levels. With ongoing exposure, PFNA concentrates approximately 200-fold from drinking water to blood serum on average, as described in the Response to Comment 30. Hence, the Department's concern with low levels of the contaminant in drinking water.

Compliance with the Common-Sense Principles in Executive Order No. 2 (2010)

12. COMMENT: The proposed amendments do not comply with the Common Sense Principles set forth in Executive Order No. 2 (2010). The Department did not engage in the "advance notice of rules" by soliciting the advice and views of knowledgeable persons from outside government, including the private sector and academia. The Department promised an open stakeholder process that was to include the advice and views of knowledgeable persons, including the private sector and licensed site remediation professionals from outside the Department and other State government agencies. Numerous meetings were scheduled and canceled, however, and ultimately no substantive discussion of the proposed rulemaking changes for PFNA and 1,2,3-TCP occurred with stakeholders before the publication of the proposed rule. The Department did not use cost-benefit analyses and scientific and economic research from other jurisdictions, including the Federal government; did not detail or justify why elements of the proposed amendments exceed the requirements of Federal law; did not establish that the proposed amendments will lead to results that are based on the best scientific and technical information that can be reasonably obtained; and did not draft the

rulemaking in a way that imposes the least burden and costs to business, including paperwork and other compliance costs. (28 and 52)

13. COMMENT: The proposed MCL does not set a standard for the highest quality and best available science. Standards based on poor scientific methodologies are often the subject of litigation because they are arbitrary. (30)

RESPONSE TO COMMENTS 12 AND 13: The Department's amended rules are promulgated in accordance with the APA. Though Executive Order No. 2 (2010) does not confer any legal rights and cannot be used as a basis for legal challenge to New Jersey agency rules, the amended rules nevertheless reflect the principles of Executive Order No. 2 (2010).

In addition to the Institute's two solicitations of public input, the Department initiated a stakeholder process in November 2016, to solicit advice and views from various stakeholders. The Department invited stakeholders to attend discussions regarding potential amendments to the SDWA and PWTA rules, including this rulemaking. The stakeholders included public water systems; county health departments; New Jersey-certified laboratories; business, industry, and consulting firms; business associations; and environmental groups. The Department held two stakeholder meetings at the U.S. Geological Survey (USGS) New Jersey Water Science Center in Lawrenceville, New Jersey on November 10 and 15, 2016. Stakeholders were provided, by e-mail on August 7, 2017, advance notice of the amendments to the rules.

The amendments reflect the Department's determination that the costs of implementing the MCLs do not outweigh the benefits of protecting public health. The impacts

associated with the MCLs are system-specific and will depend on many factors, such as the number of sampling points, the volume and characteristics of water being treated, site conditions and the level of PFNA or 1,2,3-TCP in the source water (see also the Response to Comments 77 through 82 and the Response to Comment 83).

As stated above in the Response to Comments 9, 10, and 11, the development of New Jersey-specific MCLs for PFNA and 1,2,3-TCP is necessary to protect public health. Further, the SDWA provides that an MCL may be established if there are adverse health effects associated with the contaminant, which may be found in drinking water. Both contaminants were detected in public water systems in New Jersey through sampling conducted during UCMR3 and Department-initiated sampling. Without State MCLs for these contaminants, water systems are under no obligation to monitor and install treatment to reduce exposure to them and ensure the protection of public health.

The MCLs were developed based on recommendations from the Institute. The Institute reviews the most current science prior to finalizing a recommendation. The Department considers the Institute's recommendations and performs additional research, as necessary, to determine whether new information is available. Therefore, the MCLs are developed using the best available science. As stated in the regulatory flexibility analysis, the amendments to the rules apply to water systems that are also considered small businesses but that also serve many customers potable water on a regular basis. A relaxation of these standards would not be protective of public health and would be inconsistent with the existing application of the

requirements of the New Jersey Safe Drinking Water Program, which have been effective for decades.

14. COMMENT: The Department's reliance on the Institute is flawed because the Institute has failed to follow the statutory mandate that the public be represented in its actions. Since April 2014, the Institute has been operating without two of the three statutorily required members having backgrounds in environmental health issues, as those two positions have remained vacant and unfulfilled. The role of these individuals under the statute is that they "shall represent the public." The absence of two of the three required non-agency environmental health experts is contrary to the stated statutory purposes underlying the composition of the Institute's membership, which are expressly designed to bring multiple stakeholders into the process. The absence of the public's statutorily required representatives from the subcommittees exacerbated the significant flaws in the Institute's recommendations. This contradicts the animating purpose behind the formation of the Institute, and undermines the transparency of the process, in contravention of the Common Sense Principles, Executive Order No. 2. (28 and 52)

RESPONSE: Pursuant to N.J.S.A. 58:12A-20.c, a majority of the Institute membership constitutes a quorum for the transaction of business and action may be taken at any meeting by the affirmative vote of a majority of the full membership of the Institute. The votes recommending MCLs for 1,2,3-TCP and PFNA were made by the required majority with a

quorum present (see http://www.nj.gov/dep/watersupply/pdf/minutes160922.pdf; http://www.nj.gov/dep/watersupply/pdf/minutes150604.pdf). Additionally, though the Institute is composed of three subcommittees, members sit on only one committee. When the recommendations for PFNA and 1,2,3-TCP were under development, there was an environmental health expert on the Health Effects Subcommittee, as is the case today. Each subcommittee recommendation is shared with the other members of the Institute and the public is invited to provide comments at all meetings. A recommendation becomes final only after a majority vote by the full membership.

Derivation of the MCLs Should be Subject to Formal Peer Review

15. COMMENT: The Institute and the Department are closely allied and Institute involvement alone does not represent meaningful consideration of a broad range of scientific views. As noted by many commenters, real peer review, that is a rigorous, independent, and external review of the unusual and unprecedented methodologies used by the Institute in deriving the MCL and PQL that is recommended to the Department is needed but has been absent from the proposed rule with respect to PFNA and 1,2,3-TCP. (28 and 52)

16. COMMENT: There is concern about the scientific basis supporting the proposed MCL, including the need for a transparent and scientific peer review process. The technical assessment of PFNA toxicity was not independently reviewed by experts. (30)

17. COMMENT: Per the U.S. Office of Management and Budget (OMB) (USOMB, 2004) and numerous USEPA policies and guidance (USEPA 2003, 2006, 2013a, and 2015), the recommended MCL for PFNA must undergo external peer review by independent experts to ensure the derivation is consistent with standard scientific principles. Both the USEPA and OMB state that the peer reviewers must not be involved in producing the draft product and must be external to the agency; therefore, the Institute's work on PFNA does not qualify as an independent peer review. Moreover, individuals with public health experience from the New Jersey Department of Health are stakeholders in the results of the PFNA toxicology analysis and are not completely independent from the Department. They are also not "peers" who routinely conduct toxicity assessments for environmental contaminants. Both the USEPA and OMB are clear that public comment and other stakeholder processes, although important, do not qualify as the intended peer review (USEPA, 2015). (28 and 52)

18. COMMENT: The Department and the Institute used a methodology for calculating a drinking water standard based on internal serum level rather than administered reference dose that has not been peer reviewed. The Department is relying on a unique approach to the calculation of a drinking water standard starting from a target human serum level, rather than from an administered dose. This approach has not been subject to peer review and is not consistent with standard USEPA approaches to risk assessment and the calculation of drinking water standards, nor is it consistent with the Department's own standard approach for calculating the level of a substance in drinking water that is protective of human health, which

is embodied in the Department's groundwater rules at N.J.A.C. 7:9C-1.7(c)3 and 4. This PFNA-specific, unique approach is not even consistent with the administered dose-based approach that the Institute recently used to calculate a recommended MCL for PFOA. (28 and 52)

RESPONSE TO COMMENTS 15 THROUGH 18: The Department does not agree with the commenters' assertion that the Institute recommendation for an MCL and PQL for 1,2,3-TCP and PFNA does not represent meaningful consideration of a broad range of scientific views.

The Institute was established by the SDWA, which specifies the Institute's role as an advisory body that evaluates scientific information and make recommendations to the Commissioner of the Department for the implementation of the Department's drinking water quality program, including MCLs. The members of the Institute include academics, water purveyors, members of the public, as well as representatives of the Department and the New Jersey Department of Health (NJDOH). The Department notes that the Institute sought public comment on the draft subcommittee reports for both PFNA and 1,2,3-TCP. In developing the recommended MCLs, the Institute considered any comments and information developed by scientists and experts that the commenters submitted.

The Department acknowledges that several peer-reviewed publications whose authors included one or more Institute members were cited in the Health Effects Subcommittee reports as part of the final recommendation on PFNA. However, the information cited in these publications includes background information about PFNA and other PFCs that does not impact the development of the MCL, data on occurrence of PFNA and other PFCs in New Jersey

drinking water, and summaries of information from the scientific literature related to toxicokinetics, toxicology, epidemiology, and mode of action. The fact that these publications were peer-reviewed and published in highly respected journals only strengthens the basis for the MCL.

Peer review involves the evaluation of a draft document by qualified individuals selected to conduct the review based on their expertise in the subject matter. The OMB and USEPA guidance the commenters cite is directed to Federal agency staff, not to the states, and is intended to inform and improve the management of peer review by Federal agencies and the USEPA when they do conduct peer review; the guidance does not require that peer review be conducted.

As described in more detail in the Department's responses below, the approach and assumptions used to develop the MCLs for 1,2,3-TCP and PFNA were appropriately based on relevant scientific information. Contaminants vary considerably in their toxicity, mode of action, exposure pathways, and fate in the environment and human body. Due to this complexity, the most appropriate values and equations must be used to adequately protect public health.

Occurrence of PFNA and 1,2,3-TCP

19. COMMENT: The Department should have prevented the contamination of the drinking water to begin with, and it is unfair that the cost has been shifted from the polluters to the public. (51)

RESPONSE: As stated in the notice of proposal Summary, PFNA and 1,2,3-TCP were detected in New Jersey drinking water supplies through sampling conducted during UCMR3 and Department-initiated sampling. PFNA has been historically used in New Jersey as a processing aid in the manufacturing of high-performance plastics, while 1,2,3-TCP was primarily a contaminant of nematocides and fumigants applied to soil. The use of PFNA and 1,2,3-TCP in major manufacturing and agriculture activities has been discontinued due to concerns about their health effects and awareness of their presence and persistence in the environment.

PFNA and 1,2,3-TCP are both listed as hazardous substances on the Discharges of Petroleum and Other Hazardous Substances rules at N.J.A.C. 7:1E Appendix A. N.J.A.C. 7:1E Appendix A lists all substances that, in addition to petroleum and petroleum products, are considered hazardous substances under the Spill Compensation and Control Act (Spill Act), N.J.S.A. 58:10-23.11 et seq. The Spill Act provides strict liability for cleanup and removal costs resulting from any discharge of a hazardous substance and provides a fund for compensating businesses and other persons damaged by a discharge. Therefore, Spill Fund monies may be available upon adoption for water systems contaminated with PFNA and 1,2,3-TCP.

20. COMMENT: The Department should take steps to educate the public on the dangers present in their drinking water, what they can do to protect public health, how they got in the water and how to get them out. (33 and 41)

RESPONSE: All water systems are required to provide information regarding regulated contaminants and those unregulated contaminants that are sampled for pursuant to the Federal Unregulated Contaminant Monitoring Rule in their annual Consumer Confidence Report (CCR). CCRs must be provided to consumers annually and made publicly available. In addition, the Department provides information regarding regulated contaminants at all public water systems via Drinking Water Watch (see https://www9.state.nj.us/DEP_WaterWatch_public/NJMap.jsp).

21. COMMENT: The Department makes the following statement in the proposed rule: "[t]he Department does not anticipate that more than the 11 systems already identified with levels above the recommended MCL will be required to treat for PFNA." This statement is a fundamental assumption underlying the Department's socio-economic analysis of the impact of the proposed MCL for PFNA. The Department has no reasonable basis for its illogical assumption that all PFNA in the State has been found when most water systems have never been tested to the level that the Department is proposing. (28)

22. COMMENT: The rule proposal fails to analyze its practicability, feasibility, and real cost because it relies on an unfounded assumption instead of actual information about the

occurrence of PFNA in New Jersey water supplies. Very limited sampling has been done for PFNA at any level within New Jersey water supplies. Even that cursory sampling has identified 18 water supplies with levels above the proposed MCL. However, the Department ignores both the overall lack of information and specific information already available. Instead, it assumes that PFNA will be "localized near responsible parties." This assumption is not based on any comprehensive data or any explained fate and transport characteristics of PFNA, or explained in any other way and is, thus, unfounded. It, therefore, sheds no light on how many water suppliers will be burdened, not only with the testing required of all providers, but with the regular monitoring above 0.002 µg/L and/or treatment of their water supplies below the trace level of 0.013 µg/L. (52)

RESPONSE TO COMMENTS 21 AND 22: Pursuant to the SDWA, the Department, after considering recommendations of the Institute, adopts MCLs for chemical compounds that "may be found in drinking water" and, at levels above the recommended MCL, may "cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunction (including malfunctions in reproduction), or physical deformity ..." (see N.J.S.A. 58:12A-13.b). The SDWA does not require the Department to evaluate all water supplies prior to adoption of an MCL.

In addition to the sampling required pursuant to UCMR3, approximately 50 public community water systems in New Jersey have conducted sampling for PFNA as part of a study by conducted the Department in 2009 and 2010, as well as sampling of raw water in Gloucester

and Salem counties as part of the remediation of PFNA-contaminated groundwater. As a result, the Department is aware of 13 public water systems in New Jersey with levels of PFNA above the MCL. As stated in the notice of proposal Summary, the majority of these public water systems are located in Gloucester and Camden counties. Therefore, the Department has investigated PFNA use in New Jersey and believes it has identified the sources associated with the detections at public water systems.

23. COMMENT: The Department has incomplete information on how many groundwater aquifers in New Jersey may be impacted by PFNA and would be required to implement groundwater remediation to the MCL. (30)

RESPONSE: The SDWA rules at N.J.A.C. 7:10 implement New Jersey's Safe Drinking Water Program to ensure the provision of safe drinking water to consumers and apply to the State's public water systems. The amendments establish an MCL, not a ground water remediation standard. Thus, this rule does not compel remediation. Rather, it requires treatment of the source water utilized by public water systems.

24. COMMENT: Of the 1,134 New Jersey data points for 1,2,3-TCP, the most recently published USEPA UCMR3 database (USEPA, June 2015) indicates that the compound has been detected only four times at two facilities. Therefore, it appears that widespread exposure through New Jersey drinking water systems is not a concern and measurable human health

protection would not be significantly realized despite the significant expense associated with 1,2,3-TCP MCL requirements. (28)

RESPONSE: As stated in the notice of proposal Summary, the occurrence of 1,2,3-TCP in drinking water in New Jersey has been documented through Department-conducted sampling for synthetic organic compounds in public water systems in addition to UCMR3. Since 2000, the Department has identified 19 public water systems that have had detections of 1,2,3-TCP. These systems have taken steps to address the detections including follow-up monitoring or the installation of treatment. As stated by the commenter, two of these systems had detections in the USEPA UCMR3 monitoring program, which had a minimum reporting level of 0.030 µg/L. However, 1,2,3-TCP is classified as likely to be carcinogenic to humans. Thus, the Department believes that monitoring at all public community and nontransient noncommunity water systems and the application of treatment where the MCL is exceeded is necessary to protect public health.

Maximum Contaminant Level for PFNA

Development of the MCL for PFNA

25. COMMENT: The Department notice of proposal fails to provide a scientific basis for the proposed health effects of PFNA. For example, the Department does not discuss why the adverse health effects of exposure to PFNA are significantly different than other similar compounds. On May 25, 2016, the USEPA issued health advisories of 0.07 µg/L for PFOA and

perfluorooctane sulfonate (PFOS). The health advisories were established to provide a margin of protection, including the most sensitive populations, from a life-time of exposure to PFOS and PFOA in drinking water. The Department-proposed MCL of 0.013 µg/L for PFNA is significantly below the USEPA's health advisory for these related compounds. (30)

RESPONSE: The health-based MCL for PFNA is based on evaluation of scientific information relevant to PFNA. As discussed in the Institute's Health-based MCL Support Document for PFNA, the available scientific information indicates that PFNA is more persistent in the body and more toxic than PFOA, an analogue with one less fluorinated carbon. The USEPA health advisories for PFOA and PFOS cited by the commenter are not relevant to the MCL for PFNA, as they are based on information for PFOA and PFOS, not PFNA.

26. COMMENT: The MCL for PFNA should be set to a single significant digit. In other words, instead of setting the MCL at 0.013 µg/L, it should set at 0.010 or 0.020 µg/L. When a public water system has a result of 0.011 µg/L or 0.014 µg/L, one system may be in exceedance and the other may not be. (35)

RESPONSE: The Institute determined to recommend the MCL for PFNA in two significant figures. Therefore, the Department is adopting the MCL for PFNA as it was recommended by the Institute, that is, with two significant digits. In the past, the Department has followed the USEPA convention when adopting new State MCLs, including the use of significant figures. However, the USEPA has not consistently promulgated MCLs with a single significant digit for

Federally regulated contaminants nor has it adopted requirements or provided consistent guidance regarding the number of significant digits.

The Department determines compliance with the MCL using two significant figures. For example, a detection of 0.0135 µg/L for PFNA is reported as 0.014 µg/L and, thus, is considered an exceedance of the MCL of 0.013 µg/L. If the MCL were expressed as one significant figure, it would be 0.01 µg/L. In that case, a detection of 0.0135 µg/L would be reported as 0.01 µg/L and would not be considered an exceedance.

27. COMMENT: PFNA should be added to the parameters that must be tested for in newly constructed public noncommunity and nonpublic water systems under N.J.A.C. 7:10-12.30(b). To leave PFNA out of testing requirements allows newly constructed wells to "fall between the cracks," potentially delivering drinking water contaminated with PFNA to unaware water users. (15)

RESPONSE: The occurrence of PFNA in New Jersey is low and localized near known dischargers. In New Jersey, two areas of contamination are being actively investigated by the Department, and private well owners with contaminated supplies are also being identified. As the Department considers the regulation of more ubiquitous perfluorinated compounds, such as PFOA, which are analyzed using the same method as used for PFNA, the Department may consider requiring broader testing.

28. COMMENT: The Department should adopt even stricter standards for PFNA to provide more effective protection. Independent toxicologists conclude that the MCL for PFNA should be between 0.003 to 0.005 µg/L to better protect vulnerable fetuses and young children whose development can be permanently marred by PFNA exposure. (14, 15, 19, 50, 58, 59, 56, 27, and 33)

29. COMMENT: Regulation should be put into effect for having no more than 0.006 µg/L for PFNA. (31)

RESPONSE TO COMMENTS 28 AND 29: The Institute makes MCL recommendations to the Department based on the health effects of the targeted contaminant, as well as the certified laboratories' ability to test for the contaminant, and the availability of treatment removal technologies. For PFNA, the recommended MCL is the health-based level, which was developed using accepted methods of risk assessment and current scientific data. As stated by the Institute (2015), the health-based level is based on lifetime exposure and is expected to be protective of all age groups.

30. COMMENT: PFNA has not been detected to date in any New Jersey public water supply above even one µg/L, the regulatory level that the Department has established and allows even for well-studied and known human carcinogens, such as benzene (one µg/L) and vinyl chloride (two µg/L), in drinking water. Lead, known to cause developmental effects in children, has an action level in drinking water of 15 µg/L. (28 and 52)

RESPONSE: PFNA has been detected in New Jersey water supplies at concentrations exceeding the MCL of 0.013 µg/L. The MCLs of two µg/L for vinyl chloride and one µg/L for benzene, and the action level for lead of 15 µg/L, are not relevant to the levels of PFNA detected in New Jersey public water systems for several reasons. The MCLs for PFNA, vinyl chloride, and benzene are based on the evaluation of the health effects, and analytical and treatment removal data specific to each contaminant. The USEPA MCLGs (health-based goals) for vinyl chloride, benzene, and lead in drinking water are zero. The New Jersey health-based levels, based on one-in-one million lifetime cancer risk, for vinyl chloride and benzene are below the MCLs, which are set at their respective PQLs because the PQL for each is higher than the health-based level. The action level for lead is not an MCL or health-based goal. Under the National Regulations at 40 CFR 141.2, an action level is the concentration of lead in water that determines, in some cases, the treatment requirements that a water system is required to implement. In contrast, the MCL for PFNA is set at the health-based level.

31. COMMENT: The proposed PFNA MCL of 0.013 µg/L is an extraordinarily trace level and is even far below the relative concentration of PFNA that exists in the blood serum of the general United States population. (28 and 52)

RESPONSE: There is no basis for comparison of drinking water levels and blood serum levels of PFNA. PFNA and the other long-chain perfluorinated chemicals bioaccumulate from drinking water in the blood serum in humans. The Department expects that, with continuous exposure

to PFNA in drinking water, the average blood serum levels will increase by about 200 times the drinking water concentration. For this reason, concentrations of PFNA in drinking water below the concentrations found in blood serum are of public health concern.

32. COMMENT: The best information and available scientific evidence on PFNA is not sufficient to characterize PFNA's potential human toxicity. The methods utilized by the State to overcome the gaps in the scientific knowledge are not technically supportable and lead to extreme overestimates of potential toxicity. (30)

33. COMMENT: The Department did not establish that an MCL for PFNA is justified based on the best information available within the limits of medical, scientific, and technological feasibility because there is insufficient science to support the identification of human health effects from PFNA at environmentally relevant levels. (28)

34. COMMENT: There is insufficient information to identify a human health hazard at environmentally relevant exposures to PFNA. The available scientific information clearly establishes that rodents are not appropriate species from which to evaluate human health risks from exposure to PFNA and that the available human data do not suggest risks at the low environmentally relevant levels. The weight of the generally accepted and peer reviewed scientific evidence simply does not support a conclusion that PFNA is hazardous to human health or poses a threat to public health and safety at environmentally relevant concentrations. (52)

RESPONSE TO COMMENTS 32, 33, AND 34: As explained in the notice of proposal Summary, PFNA accumulates in the human body. Exposure to low drinking water concentrations of PFNA results in increased concentrations in human blood serum that persist for many years after exposure ends. The toxicological effects of PFNA in mice include weight loss and toxicity to the liver, immune system, kidney, and testes. Effects on a developing mouse fetus or offspring include premature death, persistent decreased body weight, and delays in reaching developmental milestones. Most human health risk assessments are based on toxicological data from animal studies based on the default assumption that toxicological effects observed in animals are relevant to humans. Additional studies in rats (for example, Stump et al., 2008; Mertens et al., 2010) indicate more severe toxicity at much lower doses and serum levels than in the mouse study used to develop the health-based MCL. However, these studies could not be used because the numerical serum PFNA data needed for dose-response modeling were not available to the Department. It is highly likely that the health-based MCL based on these additional rat studies would be lower than 0.013 µg/L. In human studies that evaluated associations of PFNA concentrations in blood serum with health endpoints, evidence of associations was strongest for increases in serum cholesterol and the liver enzyme alanine transaminase (ALT), an indicator of liver damage. As explained in the notice of proposal Summary, PFNA in drinking water is of particular concern for infants because they receive higher exposures than older individuals and they are susceptible to PFNA's developmental effects. Detailed information about PFNA's adverse impacts on human health was previously

published by the Department (NJDEP, 2016), which referenced the European Chemical Agency Risk Assessment Committee's conclusion (ECHA, 2014) that "PFNA is a presumed human reproductive toxicant for damage to the unborn child, a suspected human reproductive toxicant for fertility effects, a suspected human carcinogen, causes specific target organ toxicity to liver, thymus, and spleen after prolonged or repeated exposure, and causes harm to the breast-fed child through effects on or via lactation." As discussed in the Responses to Comments 44 and 45, the Department concludes that mode of action data for PFNA indicate that the toxicological effects of PFNA in rodents are relevant for evaluation of human health risks of PFNA.

35. COMMENT: The Basis and Background Document selectively presents positive associations from epidemiology studies only, does not accurately present the entire weight of evidence for both laboratory animal and epidemiology studies, nor provides a critical analysis of study methods and results. (30)

RESPONSE: The Department presumes that the commenter is referring to the Institute's Health-based MCL Support Document (Institute, 2015) by referencing the Basis and Background Document. The Department does not agree that positive epidemiology associations were selectively highlighted. A concerted effort was made to present a comprehensive, consistent, and transparent review of the human health studies and findings, which is shown in the individual study tables presented in Appendix 2 of Institute (2015). In order to integrate and

interpret the overall body of epidemiology literature, summary tables were provided for the reader to compare findings across studies evaluating the same endpoints. Because human epidemiology data were not used as the primary basis for risk assessment, a formal weight of evidence evaluation of causality for the human studies was not conducted. For animal data, all available toxicology studies were evaluated and described. The design and results of studies of each toxicology endpoint are presented in the text and/or tables, and the body evidence for each type of toxicity is synthesized in summary sections.

Uncertainty Factors

36. COMMENT: The uncertainty factors (UFs) used in the health-based MCL calculation are misapplied and overly conservative, thereby rendering the health-based MCL overly stringent and technically unsupportable. The Department characterized the total uncertainty factor (UF) as 1,000 in its calculation of the PFNA health-based MCL, which included a factor of 10 to account for variation in human susceptibility, a factor of three to account for toxicodynamic differences between humans and mice, a factor of 10 to account for the shorter duration of exposure, and finally, a factor of three to account for an incomplete PFNA database. This characterization ignores the uncertainty inherent in the unproven equation the Department used based on internal dose and liver enlargement in mice, which, when compared to the traditional and standard approach based on administered dose, makes the Department's real total uncertainty extrapolation orders of magnitude higher than 1,000. Combined, this total

uncertainty is at a level that is not generally accepted in scientific risk assessment and is overly conservative and results in a final PFNA MCL that is overly stringent. (52)

37. COMMENT: The uncertainty factors are not justified or technically supported. (30)

38. COMMENT: The Department and the Institute's Health Effects Subcommittee did not establish that an MCL of 0.013 µg/L for PFNA is justified based on the best information available within the limits of medical, scientific, and technological feasibility because the Institute and the Department applied an unprecedented series of uncertainty factors and unprecedented overall level of uncertainty to the limited information a mouse study provided.

In addition, in order to use a single mouse study as the basis for an MCL for human health effects, the Health Effects Subcommittee employs an unprecedented series of "uncertainty factors" to convert increased liver size in mice to what it calls a health protective level in humans. The uncertainty factors applied are unprecedented for a proposed MCL, with total uncertainty extrapolation of more than 300,000, when the unique way that this proposed MCL was calculated is fairly considered. The Health Effects Subcommittee's path to an MCL is one based on supposition and cumulative uncertainties, and not on the best information available as required by law. The Department only got to a proposed MCL of 0.013 µg/L because of the lack of science on health effects associated with PFNA, not on the basis of existing information. (52)

RESPONSE TO COMMENTS 36, 37, AND 38: The uncertainty factors used by the Department in development of the MCL for PFNA were applied in accordance with the USEPA (2012a)

Integrated Risk Information System (IRIS). The uncertainty factor of 10 for variation in human susceptibility is the default used in almost all risk assessments. The default uncertainty factor of three for toxicodynamic differences between humans and animals is used because there are no data to support a chemical-specific value for PFNA. The default uncertainty factor of 10 for shorter duration of exposure was used because the study used as the basis for quantitative risk assessment for PFNA (Das et al., 2015) used an exposure duration of 17 days and, as stated in the Institute (2015), "[n]o chronic toxicology studies of cancer or other effects that may occur after longer exposures and/or in old age have been conducted ... Results of the subchronic (Mertens et al., 2010) and the two-generation study (Stump et al., 2008) suggest that additional and/or more severe effects may occur as exposure duration increases." The factor of three accounts for an incomplete PFNA database (see also Response to Comment 39).

It is generally agreed that interspecies comparisons for perfluorinated compounds, such as PFNA should be based on serum levels (a measure of internal dose) rather than administered dose (for example, Butenhoff et al., 2004; Post et al., 2009; Tardiff et al., 2009; NCDENR, 2012; USEPA, 2016a). The internal dose is most relevant to toxicity because it reflects the dose reaching target tissues. Because of large interspecies pharmacokinetic differences, a given administered dose (mg/kg/day) results in a much higher internal dose (serum level) in humans than in experimental animals. Internal dose is the relevant measure in regard to toxicity, as it is relevant to the dose reaching target organ(s). A dose-response assessment based on administered dose would not consider these important differences in internal exposure.

Because exposures to humans and animal species are compared on the basis of serum levels, the point of departure (POD) is based on serum concentrations and an uncertainty factor to account for interspecies kinetic differences is not used. Uncertainty factors are applied to this POD. The total uncertainty factor was 1,000, and the commenter's statement that the total uncertainty factor was greater than 300,000 is incorrect. The ratio of the internal doses in humans and experimental animals from the same administered dose is not part of the "uncertainty extrapolation," and it is not appropriate to include it when calculating the total magnitude of the total uncertainty associated with the criterion. The commenter also mentions additional uncertainty regarding the use of increased liver weight in mice as the basis for the risk assessment. However, as explained in the Responses to Comments 44 and 45, the Department concludes that this effect is relevant for human risk assessment and does not agree that its use adds uncertainty that is not otherwise accounted for.

39. COMMENT: When deriving a chemical-specific toxicity factor, the database uncertainty factor (UF) is applied in the absence of chemical toxicity data for basic critical endpoints (for example, genotoxicity, developmental, and/or reproductive toxicity). In its revised Reference Dose (RfD) derivation for PFNA, the Institute applies a database uncertainty factor of three. The Institute's nearly 200-page 2015 Support Document for its recommended PFNA MCL illustrates that the toxicology database for PFNA is robust, especially for the endpoint that the Institute identified as critical (hepatic effects in rodents). As described in the 2015 PFNA MCL

Support Document, the peer-reviewed literature database consists of acute, subacute, and subchronic toxicity studies, toxicokinetic studies, genotoxicity studies, and developmental and reproductive toxicity studies (in two animal species). This is in addition to several published epidemiology studies.

Aside from the lack of a chronic study in animals, the rationale provided in the 2015 Institute PFNA MCL Support Document for a database uncertainty factor of three does not justify the application of such a factor for the PFNA RfD. First, while there are no chronic exposure studies in the PFNA literature, the Institute already accounted for this data gap by applying a 10-fold less-than-chronic uncertainty factor to their modeled point of departure. Therefore, applying an additional database uncertainty based on the absence of a chronic study unnecessarily multiplies another point of uncertainty. Second, while there are no liver histopathology data in PFNA-exposed mice that can explain the cause of the increased maternal liver weight during pregnancy (again, the effect the Institute identified as critical for its PFNA RfD), citing a rat study that reported increased liver necrosis at lower PFNA doses does not constitute a data gap. The observations in rats are not relevant to the increased liver weights in pregnant female mice for two reasons: 1) the effect is sex-specific, as the three rat studies that reported liver necrosis only observed such in male rats, whereas necrosis was largely absent in female rats in all dose groups in these studies; 2) the kinetics of PFNA in mice and rats are different, so much so that the Institute discounted certain rat data that contradicted effects observed in mice (for example, the largely negative effects data reported in rat developmental

toxicity studies). Finally, noting the absence of PFNA studies on effects of a related compound (PFOA) highlights an interesting area of research to pursue, but does not indicate a major data gap for PFNA for the purposes of risk assessment.

In its original PFNA risk assessment, in fact, the Institute did not consider the database uncertainty factor to be of consequence, only adding it later in a subsequent iteration of its PFNA risk assessment. Given the database summarized by the Institute in the PFNA health assessment and the other uncertainty factors, the application of a UF greater than one is unjustified. Furthermore, the record shows that the incorporation of this UF into the derivation of the Institute's RfD for PFNA was an afterthought and gives the appearance of an arbitrary process as opposed to one based on best science. (28)

RESPONSE: The commenter refers to the use of a Reference Dose in the derivation of the health-based MCL. However, a Reference Dose was not part of derivation of the health-based MCL for PFNA. In deriving the health-based MCL, uncertainty factors were applied to a benchmark dose (BMD) based on serum PFNA levels to derive a target human serum level, which is analogous to a Reference Dose but in terms of serum level rather than administered dose. The USEPA (2012a) Integrated Risk Information System (IRIS) states that an uncertainty factor for database deficiencies should be applied "if there is concern that future studies may identify a more sensitive effect, target organ, population, or lifestage." As explained in NJDEP (2016) and Institute (2015), the toxicological effects of PFNA are generally similar to those of the closely related compound, PFOA, although PFNA is more biologically persistent and more

toxicologically potent than PFOA. PFOA and other persistent PFCs cause developmental effects at low doses that have not been evaluated for PFNA. Specifically, developmental exposure to low doses of PFOA causes delayed mammary gland development and persistent hepatic damage. Additionally, neonatal mice exposed to a single low dose of PFOA, PFOS, or perfluorohexane sulfonate (PFHxS) exhibit permanent neurobehavioral effects accompanied by changes in critical brain proteins. The Department is concerned that the lack of data on the potential for PFNA to cause these effects indicates that more sensitive endpoints have not yet been identified and justifies use of an uncertainty factor for database deficiencies. Additionally, there is evidence that PFNA causes liver toxicity at lower doses than those used for the dose-response modeling in Das et al. (2015).

Effects in both female mice and male rats are relevant to human health risk assessment of PFNA, and the database uncertainty factor is not based on the relationship of the more sensitive liver toxicity in male rats to increased liver weight in female mice. Rather, it is used, in part, because there is evidence that there is a more sensitive endpoint than the one used as the critical effect, but that the data for the sensitive effect do not permit dose-response modeling. While more severe effects occur in male rats at lower doses than those used in the Das et al. (2015) study in female mice, the liver toxicity in male rats, a much more sensitive endpoint, could not be used as the basis for quantitative risk assessment because the required serum data were not published or provided to the Department. Furthermore, there is no evidence that the hepatic effects of PFNA are “sex specific.” The greater susceptibility to hepatic toxicity

in male rats as compared to female rats is due to the much more rapid excretion of PFNA (and several other perfluorinated chemicals) by female rats, resulting in much lower internal doses (serum levels) from the same administered doses. It is well established that female rats are not a suitable model for humans because they rapidly excrete these compounds. In contrast to female rats, PFNA and the other perfluorinated compounds mentioned above are excreted slowly by male rats and both male and female mice. The Institute conducted only one risk assessment of PFNA and it included a database uncertainty factor of three. The inclusion of this uncertainty factor in the Institute's risk assessment was not arbitrary or an afterthought. The Institute's Health Effects Subcommittee conducted an in-depth review of the application of the database uncertainty factor in previous USEPA, Department, and Institute risk assessments. The Subcommittee concluded that an additional uncertainty factor of three is appropriate, which is consistent with USEPA guidance and previous USEPA, Institute, and Department risk assessments. The Department reviewed the Subcommittee's evaluation of the choice of uncertainty factors for development of a health-based value for chronic exposure to PFNA in drinking water and concurs with the Subcommittee's conclusions on this issue.

Benchmark Dose Modeling

40. COMMENT: The benchmark dose (BMDL) used to derive the point of departure is not based on standard best practices for dose-response analysis or the USEPA's guidance. (30)

RESPONSE: The USEPA guidance (USEPA, 2012b) cited by the commenter is considered best practice and was followed with regard to all aspects of the benchmark dose modeling. This can be confirmed from the information presented in Institute (2015), as all input and output information for the models, as generated by the USEPA modeling software, are presented in Appendix 4 of Institute (2015).

41. COMMENT: The Department's use of internal dose rather than administered (external) dose is technically flawed and does not decrease the uncertainty compared to the standard approach. The Department's use of internal dose, rather than administered (external) is an unproven approach for PFNA that lacks transparency and introduces significant uncertainty. However, these deficiencies are not fully acknowledged, disclosed, or justified in the notice of proposal. According to the NJDEP documents describing the technical basis for the proposed MCL, the use of internal dose was necessary to account for differences in the kinetics of PFNA in the human body compared to animals. While relative kinetics may be an important uncertainty, a more substantial dataset is required to support the assumptions used and approach taken by the Department. The Department has not established that there are compelling lines of evidence that the assumptions underlying the internal dosimetry methods provide greater certainty in the estimated relationship between chronic exposure via drinking water and adverse health effects in humans. The Department's position appears to rely on an unsupported assumption that the uncertainty in its unproven methodology is less than, and

somehow more acceptable than, the uncertainty associated with using the traditional administered dose-based toxicity value in mg/kg-day, consistent with standard risk assessment practice. (52)

RESPONSE: It is generally agreed that interspecies comparisons for perfluorinated compounds such as PFNA should be based on serum levels (a measure of internal dose) rather than administered dose (for example, Butenhoff et al., 2004; Post et al., 2009; Tardiff et al., 2009; USEPA, 2009; MDH, 2017; NCDENR, 2012; USEPA, 2016a). The internal dose is most relevant to toxicity because it reflects the dose reaching target tissues. Because of large interspecies pharmacokinetic differences, a given administered dose (mg/kg/day) results in a much higher internal dose (serum level) in humans than in experimental animals. Internal dose is the relevant measure in regard to toxicity, as it is relevant to the dose reaching target organ(s). A dose-response assessment based on administered dose would not consider these important differences in internal exposure. This approach, using internal dose for interspecies extrapolation, adds a degree of certainty because it is based on chemical-specific data for PFNA rather than a default uncertainty factor. This approach is in accordance with accepted risk assessment methodology in which chemical-specific data are used, when available, instead of default uncertainty factors.

42. COMMENT: The Department should present a comparative analysis of dose modeling for the Das et al. (2015) data. When deriving a toxicity value for regulatory use, it is imperative

that the risk assessor present a clear, transparent, and comparative analysis of all available dose-response relationships in the critical study. In using maternal serum levels from Das et al. (2015) as the dose metric to derive an MCL for PFNA, the Department, and the Institute ignored the dose response assessment presented by the USEPA scientists within the paper itself. Das et al. (2015) presented a benchmark dose (BMD) analysis on several endpoints associated with PFNA administered via oral gavage to pregnant mice. When compared with the RfD for PFNA that the Department back-calculated from the Institute's analysis of the maternal serum data (0.74 ng PFNA/kg/d), an RfD based on BMD estimates reported by USEPA scientists (using standard allometric scaling and USEPA uncertainty factors) is greater by more than three orders of magnitude (900 ng PFNA/kg/d). Applying uncertainties [three for interspecies difference; 10 for intraspecies differences; one for exposure duration (per USEPA since exposure throughout gestation is considered chronic duration for fetus); and one for database deficiencies] results in an RfD based on applied dose of 0.0009 mg/kg/day (or 900 ng/kg/day). This alternative RfD represents a standard USEPA approach to deriving an RfD based on applied dose, and clearly indicates that the selection of dose metric has a profound impact on the RfD value for PFNA.

In addition to ignoring the applied dose-response relationships, the Department did not consider the liver PFNA data in its dose-response assessment. This is a significant technical oversight given that the argument for using serum levels is based on using a dose metric relevant to the target tissue. However, the Department never evaluated the relationship between the PFNA levels reported in liver and the observed responses (in any life stage group –

maternal, fetal, or pup). Given that the Department identifies liver as the most sensitive target organ for PFNA toxicity, and that PFNA liver levels are reported by Das et al. (2015), this is a third dose metric that the Department must evaluate and include in a comparative analysis to ensure transparency and scientific defensibility of its risk assessment. It is imperative, therefore, that the Institute and the Department model and reevaluate the dose-response data for all dose metrics presented by Das et al. (2015), report the BMD results for all dose metrics, and present scientific justification for the dose metric selection. In the absence of such complete analyses, the Institute and the Department dose-response assessment for PFNA is deficient and inadequate for serving as the basis of MCL for PFNA. (28)

RESPONSE: The Department's approach for risk assessment of PFNA was explained in Institute (2015), and the same approach was used for development of a health-based drinking water value for PFOA that was published in a peer-reviewed paper (Post et al., 2009). The part of the comment referring to back-calculation of a Reference Dose is not relevant because a Reference Dose was not presented in the health-based MCL calculation in Institute (2015). The health-based MCL was calculated from the target human serum level, which is equivalent to a Reference Dose but in terms of serum PFNA level rather than administered dose. The target human serum level is derived by applying uncertainty factors to the serum level at the point of departure from the animal study used as the basis for the health-based MCL. It is well accepted that the much longer (estimated to be about 50- to more than 100-fold for PFNA) half-life in humans than experimental animals must be taken into account in developing human health-

based drinking water values, such as health-based MCLs, for biologically persistent perfluorinated chemicals such as PFNA. Additionally, the comparison of the approach suggested by the commenter to the approach used as the basis for the health-based MCL is not valid because several uncertainty factors used for the health-based MCL were omitted. The commenter's suggested approach is based on a developmental endpoint and, therefore, does not include a duration of exposure uncertainty factor, while the health-based MCL is based on a systemic endpoint from short-term exposure and, therefore, includes a duration of exposure uncertainty factor. Additionally, the commenter's suggested approach does not include a database duration uncertainty factor that is needed for reasons explained in the Department's Response to Comments 36, 37, and 38; and the Response to Comment 39, regarding uncertainty factors. As is the case for almost all other contaminants, including those which cause hepatic toxicity, data are not available to derive a health-based MCL for PFNA based on PFNA concentrations in liver.

Critical Effect

43. COMMENT: Some of the information from the key study utilized by the Department (Das et al. 2015) is not publicly available and cannot be reproduced or verified. (30)

RESPONSE: The data from Das et al. (2015) that was used in the PFNA risk assessment are publicly available. The study was published in a peer-reviewed scientific journal. The risk assessment is based on data on PFNA serum levels and liver weight in pregnant mice from Das

et al. (2015). The benchmark dose used in the health-based MCL is based on serum concentration data for pregnant mice that are shown in Figure 3A and for liver weight that are shown in Figure 2A of Das et al. (2015). In these figures, the data for mean and standard error are shown in bar graphs. The numerical data that were input into software programs to generate these published graphs are available upon request from the primary author of the paper. These data are identical to those used in construction of the figures.

44. COMMENT: The Department/Institute's choice of adaptive effect in liver from the Das study as the critical effect is not consistent with generally accepted science and methodology. As described by the International European Society of Toxicologic Pathology (ESTP) Expert Workshop, liver hypertrophy and increased liver-to-body weight ratios are considered adverse, only if accompanied by necrosis, fibrosis, inflammation, and steatosis. If liver hypertrophy and increased weight are present with concomitant evidence of PPARa activation, or without any of the additional histopathological examination and/or findings, these effects are to be deemed as adaptive (that is, not adverse) and not relevant to human health hazard identification. Such findings are useful as indicators of exposure, not as indicators of adverse health effects. Consistent with the USEPA's current assessment of PFOA, summarized in the final Office of Water 2016 Health Effects Support Document for PFOA released in May 2016, the Department and the Institute should reevaluate all studies with liver endpoints to ensure that the criteria

from the ESTP experts are correctly applied, and that non-adverse and/or non-human relevant liver endpoints are not utilized in the derivation of MCLs for PFOA or PFNA. (28)

45. COMMENT: The critical effect selected by the Department (change in rodent absolute or relative liver weight) is not indicative of adverse effects in humans and is an inappropriate basis for establishing a health-based level in humans. (28, 30, and 52)

RESPONSE TO COMMENTS 44 AND 45: The Department is aware of the recommendations of Hall et al. (2012), which find that increased liver weight or hepatocellular hypertrophy are adverse when they co-occur with, or progress to, other types of hepatic toxicity. It should be noted that the primary focus of Hall et al. (2012) is pre-clinical toxicity studies for drug development. Hall et al. (2012) emphasize that the expected duration of exposure must be considered in determining the adversity of hepatic effects, such as increased liver weight and hepatocellular hypertrophy. These effects may be reversible if the anticipated duration of exposure is short, while progression to more severe hepatic effects may occur from longer exposures to the same dose. These duration of exposure considerations are relevant to safety evaluation of drugs, since the drugs are normally only taken for a limited period of time. However, because the health-based MCL is intended to protect human health for lifetime exposure, reversibility of effects when exposure ends is not a relevant consideration. Numerous other risk assessments of PFOA (for example, Health Canada, 2016; enHealth, 2016) are based on increased liver weight and/or hepatocellular hypertrophy. Health Canada (2016) cites the conclusions of Hall et al. (2012), but concludes that increased liver weight and

hepatocellular hypertrophy in rats should be used as the basis for its PFOA risk assessment. Health Canada (2016) notes that these effects can progress to more serious hepatic toxicity with continued exposure and reviews the data to support this conclusion. EnHealth (2016) relies on the Tolerable Daily Intake (TDI) developed by EFSA (2008) which is based on increased liver weight in rodents. EFSA (2008) states that, while hepatocellular hypertrophy and increased liver weight are often classified as adaptive and reversible, these effects are possibly related to "effects such as tumor promotion and/or changes in drug-metabolizing enzyme activities, and that reversibility is of limited importance when assessing compounds with high persistence and long biological half-life," such as PFOA and PFNA. Increased liver weight is used as a key endpoint in risk assessments of chemicals unrelated to perfluorinated chemicals by USEPA IRIS and other organizations without histopathological changes necessarily occurring concurrently. In some instances where increased liver weight is the basis for risk assessment, the effect occurred in the absence of histopathological changes in the liver. In other cases, histopathological changes occurred at higher doses than the Lowest Observed Adverse Effect Level (LOAEL) for increased liver weight that was used as the basis for risk assessment.

An issue related to relevance to humans of increased liver weight in rodents is whether the effect occurs through activation of the peroxisome proliferator activated receptor-alpha (PPAR-alpha), which may be more active in rodent liver than in human liver. As discussed in the NJDEP (2016), No Observed Adverse Effect Levels (NOAELs) and LOAELs for increased liver weight, when based on serum levels (internal dose), are consistent in the wild type mice and

PPAR-alpha null mice, suggesting that this effect is not related PPAR-alpha status. Additionally, a more recent paper (Das et al., 2017) provides further support for the human relevance of increased liver weight and other hepatic effects of PFNA. In this study, perfluorinated chemicals, including PFNA and PFOA, increased liver weight in both wild type and PPAR-alpha null mice. However, the specific PPAR-alpha activator (identified as WY-14643) did not increase liver weight in PPAR-alpha null mice. These results indicate that the increased liver weight caused by these perfluorinated chemicals is not dependent on PPAR-alpha. Furthermore, while both PFOA and PFNA increased hepatic lipid and triglyceride accumulation in wild type mice, only PFNA caused these effects in PPAR-alpha null mice. These findings provide further evidence that PFNA causes PPAR-alpha independent hepatic effects.

Relative Source Contribution (RSC)

46. COMMENT: The MCL for PFNA recommended by Institute was derived using a RSC factor based on the 95th percentile of serum PFNA from the 2011-2012 NHANES cohort dataset. In July 2016, the Centers for Disease Control and Prevention (CDC) released the PFNA serum data from the 2013-2014 NHANES cohort, which represent the most recent background serum level data for PFNA. Statistical analysis of the 2013-2014 NHANES weighted serum data for PFNA illustrates that the background levels have further decreased in the U.S. population since the 2011-2012 NHANES sampling. The Department should use an RSC of 0.8 for PFNA based on the most recent NHANES dataset (published in July 2016). Using the latest NHANES

dataset, an updated RSC can be calculated. Following the decision tree presented in the USEPA guidelines (USEPA, 2000) for selecting the most appropriate RSC, the subtraction approach is deemed most relevant for PFNA (USEPA, 2000; Krishnan and Carrier, 2013). Using a serum-based approach, the RSC is equivalent to the serum level associated with drinking water ingestion divided by the health effect-derived target serum level. The serum level attributable to drinking water is estimated by subtracting the background serum levels (that is, attributable to all non-drinking water exposure pathways) from the target serum level. PFNA serum levels in 2013-2014 NHANES, consisting of approximately 2,300 serum PFNA sample measurements, reflect the most current background exposures to PFNA throughout the U.S. from all exposure sources (for example, food, water, air, dust, and consumer products). USEPA guidance indicates that the RSC terms should represent the average contribution of the drinking water pathway (USEPA, 2000). Applying Institute's target serum level of 4.9 nanograms per milliliter (ng/ml) and the geometric mean of the 2013-2014 NHANES PFNA serum dataset (0.67 ng/ml) to the RSC subtraction formula results in an RSC 0.86. Since this exceeds the USEPA's RSC ceiling value of 0.8, the recommended RSC based on the 2013-2014 NHANES serum data for PFNA is 0.8 (USEPA, 2000; Krishnan and Carrier, 2013). (28 and 30)

RESPONSE: The Department used the subtraction approach from the USEPA (2000) recommended by the commenter to derive the RSC for PFNA. USEPA (2000) recommends the use of a combination of central tendency and upper percentile values in its exposure assumptions for deriving ambient water quality criteria for the protection of human health. For

national ambient water quality criteria, USEPA uses a mean value for RSC in combination with upper percentile values for drinking water and fish consumption. When populations within a state could have higher exposures than the general U.S. population, USEPA (2000) recommends that the state use alternative (that is, more protective) assumptions. NHANES does not provide a geographical breakdown of its exposure data, and the mean NHANES serum concentration for the United States may not be representative of exposures in New Jersey. Non-drinking water exposures in New Jersey may reflect multiple overlapping sources of PFNA, including background exposures that are influenced by air transport within the State. This may be particularly true in communities where ground water has been impacted by past industrial use and discharge of PFNA. Mean national estimates of exposure, as indicated by the mean serum levels identified in NHANES, reflect exposures in large parts of the U.S. where there are few or no sources of PFNA manufacture or use. Also, relevant to this issue, the Maine Department of Health and Human Services (2014) developed a health-based drinking water value for PFOA using an RSC based on the subtraction approach and using the 95th percentile NHANES serum data. Based on these considerations, the Department concluded that an RSC based on the 95th percentile of NHANES data was appropriate for use in development of the MCL for PFNA. Use of the 95th percentile serum PFNA in NHANES data from 2013-14, which became available after the health-based MCL was developed, instead of the data from 2011-12, would result in only a small change in the RSC.

Blood Serum Data

47. COMMENT: The Department and the Institute's Health Effects Subcommittee upon which it relied, did not establish that an MCL of 0.013 µg/L for PFNA is justified based on the best information available within the limits of medical, scientific, and technological feasibility because the empirical data shows that the Department's and the Institute's assumptions are incorrect. The Paulsboro human blood serum data from 25 residents and blood serum data gathered by Rutgers shows that: (a) for 25 of 26 residents, including many long-term users of the Paulsboro water supply, PFNA levels in blood serum are well below the 17 µg/L that as recently as 2014, the Department determined was expected to be protective; (b) the median level of PFNA in blood serum of the 194 Paulsboro residents tested is 3.5 µg/L, below even the Department's revised protective target serum level of 4.9 µg/L; and (c) the equation relied on by the Department and the Institute for converting a target serum level to a drinking water standard is incorrect and greatly overstates the amount of PFNA expected to be found in human blood.

Using the measured concentrations of PFNA in drinking water, the Department's model and assumptions would predict a median blood serum concentration for Paulsboro residents of 40 µg/L. By contrast, the initial 26 results from Paulsboro had a measured median PFNA level of 5.6 µg/L and the 194 residents in the Rutgers study had a median PFNA of 3.5 µg/L. Therefore, it is clear that the Department's model and assumptions are in error and

overestimate the median by as much as an order of magnitude. That error greatly affects the calculated safe drinking water concentration.

The Department simply could not calculate an MCL as low as 0.013 µg/L, unless it affirmatively chooses to ignore the actual human blood serum data from Paulsboro. This is contrary to both common sense and to New Jersey law requiring that a proposed MCL be justified by the best medical, scientific, and technological information available. (28 and 52)

48. COMMENT: In crafting an MCL proposal on a stated lack of direct information on the relationship between PFNA in drinking water and PFNA in human blood serum, the Institute's Health Effects Subcommittee and the Department ignored actual empirical data that, when considered, show that the calculations and assumptions employed by the Subcommittee and the Department are wrong.

The relevance of these data to the MCL process cannot be disputed. The water supply results from Paulsboro for PFNA were noted as justification for the Institute's consideration of, and development of, an MCL for PFNA. In addition, the Health Effects Subcommittee Report acknowledges the crucial importance of human blood serum data and yet inexplicably states: "[t]o our knowledge, there have been no studies of populations exposed to PFNA through contaminated drinking water or other environmental media." It defies logic and reason for the Department to derive and propose an MCL for PFNA by explicitly considering the Paulsboro water supply sampling results, while ignoring the Paulsboro blood serum sampling results.

In fact, the Paulsboro blood serum data was the only new scientifically relevant

information that became available between the Department's issuance of the proposed interim specific ground water quality criterion (ISGWQC) in March 2014 and the issuance of the Health Effects Subcommittee Report in April 2015. The Das, et al. mouse study was not new information to the Department in that period; it was formally published in 2015, but its unpublished, draft findings were used by the Department in the 2014 ISGWQC analysis. (28 and 52)

RESPONSE TO COMMENTS 47 AND 48: The data submitted for the report cited by the commenter (Integral, 2015b; 2015c) were collected from a small number (25) of Paulsboro residents and were not collected in a scientifically valid manner, that is, with a statistical sampling design, quality assurance plans and controls, or other components of a valid scientific study. Therefore, the Department determined it was not appropriate to use such data in the derivation of a regulatory environmental standard. In addition, the relevant exposures to PFNA in drinking water is not known for these 25 individuals. The Department reviewed the analyses of the data in the report, which attempted to reconstruct drinking water concentrations that contributed to the observed serum PFNA concentrations. These analyses are not reliable because multiple wells with different PFNA levels over time supplied drinking water to different parts of Paulsboro, and the mixture of wells supplying water to any given location varied over time. Further, the full history of the PFNA concentration in individual wells and the time at which different individuals began to receive PFNA-contaminated water are not known. Once contamination was known to the public, individuals may have switched partly or entirely to

bottled sources of drinking water. Thus, the individual characteristics of historical drinking water consumption among Paulsboro residents is not known. Additionally, the Department notes other flaws in the analysis of the Paulsboro serum data in the report, including inappropriate exclusion of data for the subject with the highest serum level and unsupported conclusions about the age and gender distribution of the PFNA serum data.

49. COMMENT: In 2016, more than 1,300 residents of Paulsboro had their blood serum analyzed for PFCs, including PFNA. Of those tested, 194 provided their individual results to Rutgers and reported the period of time they have resided in Paulsboro. In addition, 116 of those residents completed long form surveys designed by Rutgers to capture information on key parameters related to exposure, such as drinking water source, uses, and home filter systems, as well as health status. Despite the existence and availability of this directly relevant information, the Department steadfastly refuses, to this day, to even consider the information from Paulsboro residents and Rutgers in calculation of the MCL and the specific groundwater criterion. This failure to consider Paulsboro human blood serum data is in direct contravention of the statute's call for a determination "on the basis of the best information available" (N.J.S.A. 58:12A-13.b), which is echoed in the mandate of Governor Christie's Common Sense Principles that proposed rules be "based on the best scientific and technical information that can be reasonably obtained." (28 and 52)

RESPONSE: According to a preliminary report (see https://eohsi.rutgers.edu/wp-content/uploads/Paulsboro_Report_LONG_ver9.14.2017.pdf), Rutgers conducted a statistical analysis of the serum concentration of several perfluoroalkylated substances (PFAS), including PFNA, from 194 residents of Paulsboro, New Jersey. The residents voluntarily agreed to share their serum PFNA results with Rutgers in addition to providing residential history, drinking water consumption, and potential occupational exposure to PFNA. One hundred and sixteen residents also completed a longer survey regarding health history. Rutgers has yet to publish its final report on the study.

The preliminary report presents information on the frequency of detection of perfluorinated compounds, including PFNA, in the participants' blood serum, comparison of median concentration of perfluorinated compounds in the study subjects with the general U.S. population, and PFNA levels in the participants by age group and sex. Rutgers has not indicated whether the study will provide information on the quantitative relationship between drinking water exposure and PFNA serum levels. Further, the report does not indicate whether drinking water consumption was surveyed during the study nor does it discuss the relationship of drinking water consumption to serum PFNA levels.

The data used in the Rutgers study are a non-random sample from the Paulsboro population, which the Department does not consider as statistically valid. A non-random and self-selecting study of this size and nature will not provide data about associations of human health effects and PFNA exposure that is useful for MCL development. Additionally, as

discussed with respect to the Paulsboro serum data in Response to Comments 46 and 47, the participants' historical exposure to PFNA in drinking water will remain undetermined.

50. COMMENT: Additional PFNA biomonitoring data collected from residents of New Jersey are currently being compiled and analyzed by the New Jersey Department of Health (NJDOH). Important goals of the Statewide biomonitoring program are to evaluate PFNA body burdens relative to national levels and to quantify the change in serum levels following drinking water exposure mitigation. NJDOH notes that these data can be used to estimate the human half-life of PFNA and to obtain a distribution of serum:drinking water ratios. (52)

RESPONSE: For the reasons provided in NJDEP (2016), the key estimates of the risk assessment parameters relating to the ratio of PFNA in drinking water to the concentration of PFNA are reliable and scientifically defensible. The NJDOH is currently in the process of collecting serial samples of serum for analysis for perfluoroalkylated substances (PFAS), including PFNA. The primary goal of the study is to determine if, with the reduction of PFNA concentrations in drinking water, serum levels of PFNA will decrease over time. Depending on the quality and quantity of the data collected and depending on the presence or absence of non-drinking water sources of PFAS exposure in Paulsboro, a secondary outcome of the study may be an estimate of the rate of decrease of the several PFAS in serum over time (that is, the half-life of PFAS in the serum). There is no way to reliably know in advance whether the nature of the data and the conditions of exposure will be adequate to provide a reliable estimate of this parameter.

The NJDOH study is designed to determine whether the anticipated decrease in serum PFNA levels occurs after the study participants have stopped consuming water containing PFNA and was initiated after they stopped consuming the water. In order to estimate the drinking water:serum ratio using data from these study participants, it would have been necessary to have information that is not available and will not be able to be obtained, namely, the concentration of PFNA in the drinking water over the time period extending across several half-lives of PFNA in the body; the PFNA concentration in the study participants' blood serum prior to their stopping consumption of the drinking water containing PFNA; and the extent to which any particular study participant relied on the contaminated water source since some study participants may have consumed bottled water for part or all of their water consumption and this may have changed over time. Thus, the NJDOH study will not provide data on the quantitative relationship between PFNA in drinking water and the resulting PFNA in serum.

Serum:Drinking Water Ratio

51. COMMENT: PFNA internal and external exposure assumptions are incorrect and are not based on reasonable, validated assumptions of exposure, and data-driven factual information. The Department's conversion method from internal to external dose is incorrect – it is not based on correct interpretation of available data nor does it utilize available human empirical data on PFNA. To extrapolate from internal to external (administered) dose, the Department relies largely on two key assumptions: (1) the 100:1 serum-to-drinking water ratio developed

for PFOA (Emmett et al. 2006) is reasonable and can be used to estimate a ratio for PFNA; and (2) steady-state serum levels are approximately proportional to the ratio of half-lives between PFOA and PFNA, which are well-defined. Both assumptions are significantly flawed.

First, the available data on paired serum and water measurements supports a serum:water ratio for PFOA that is lower than the 100:1 that is assumed by the Department. The Department attributed this serum:water ratio for PFOA to Emmett et al. 2006, who reported a ratio of summary statistics (median serum and mean water) of 105:1. Although Emmett et al. 2006 also use the term "serum:water," it is clear that they are intentionally including all non-water exposures. Their research answers the question – what would we expect for the median serum PFOA concentration in a community if the average water concentration is X? It makes sense in this context to include all potential sources in addition to the drinking water ingestion pathway. It would be more accurate to refer to their ratio as a "serum:exposure" ratio. However, it is possible to isolate the drinking water pathway because Emmett et al. 2006 also provide summary statistics for a subset of n=20 individuals who reported not drinking tap water. Tables 4 and 5 from Emmett et al. (2006) shows that the median serum PFOA for the "0 drinks per day" group is 301 ng/mL. Therefore, 301 ng/mL is the median serum PFOA from non-drinking water sources from this study cohort. This can be subtracted from the serum measurements for the drinking water exposure groups to yield estimates of serum levels attributed to water alone, and the corresponding serum:water ratios based on these values. When the tabular information is put in graphical format – the error bars

represent the interquartile range (25th to 75th percentiles) – the results indicate that across all exposure groups, the median serum:water ratio is closer to 20:1, and for the highest exposure group (more than eight drinks per day, n=55), the median serum:water ratio is closer to 50:1.

Second, the scientific evaluations conducted to date have not directly measured PFNA half-life in humans. Therefore, the Department made assumptions about the relative PFNA clearance, based on the PFOA clearance factor instead; however, this factor has been shown to be extremely variable (see Tardiff and Carson (2010)), and to relate to total exposure to PFOA, not just drinking water (see Emmett et al. 2006, Tables 4 and 5). (52)

52. COMMENT: No kinetic models for PFNA exist to support the difference in clearance that the Department estimated for PFOA and PFNA; there is no generally accepted or peer-reviewed scientific evidence supporting the factor-of-two multiplier on which the Department relies. To support its assumptions about relative kinetics of PFNA and PFOA, the Department relied on one study in humans by Zhang et al. (2013) despite the high variability in half-life estimates based on urinary clearance for both PFNA and PFOA. The summary statistics from the Zhang et al. (2013) study provide only marginal support for the assumption. The study demonstrates that the ratio of the summary statistics on half-lives of PFNA and PFOA are highly variable and depend on the gender/age category and the particular summary statistic that is selected. For example, among females 21 to 50 years, the ratio of the median half-lives (PFNA:PFOA) reported by the Department is 0.8. In other words, this particular selection indicates that, for half of adult women ages 21 to 50 years, PFNA is 20 percent less persistent than PFOA, rather

than twice as persistent. For all men plus women older than 50 years, the ratio is roughly 2.1. (52)

53. COMMENT: The serum to drinking water ratio factor of 200:1 is highly uncertain. (30)

54. COMMENT: The assumption that PFNA is twice as persistent as PFOA in humans is contradicted by empirical data, including biomonitoring data. (30)

RESPONSE TO COMMENTS 51, 52, 53, AND 54: The Department reviewed the extensive literature supporting a central tendency (mean or median) serum:drinking water ratio of greater than 100:1 for PFOA. A peer-reviewed publication presenting the basis for this ratio was published in Environmental Science & Technology (Post et al., 2009). Post et al. (2009) includes an analysis of the serum:drinking water ratios in a large population from six communities with a wide range of PFOA concentrations in their drinking water, showing that a ratio of 100:1 is supported over a range of PFOA drinking water concentrations. A ratio of greater than 100:1 for PFOA has subsequently been supported by additional peer-reviewed publications reporting both empirical data from multiple locations and several toxicokinetic modeling efforts. A peer-reviewed publication of individual paired serum:drinking water data from users of private wells with a wide range of PFOA concentrations (Hoffman et al., 2011) is among the studies on this topic reviewed by the Department. As stated in NJDEP (2016), "[i]n 108 users of contaminated private wells with mean and maximum PFOA levels of 200 ng/L and 13,300 ng/L (Hoffman et al., 2011), the estimated ratio was 141:1 (95% CI: 135:1–148:1) based on regression modeling, and 114:1 based on a one-compartment toxicokinetics model." It is

well established that the central tendency value for the serum:drinking water ratio after ongoing exposure to PFOA is greater than 100:1 based on data from several locations and toxicokinetic modeling. Additionally, an online calculator that predicts the steady-state serum PFOA concentration after ongoing exposure to a given drinking water concentration, based on a serum:drinking water ratio of 114:1, has recently been published the highly respected peer-reviewed journal Environmental Health Perspectives (Bartell, 2017). Any unpublished individual-level data from Hoffman et al., 2011 that may exist will not alter this conclusion.

Although upper percentile exposure factors are typically used in risk assessment, 100:1 represents a central tendency estimate (or lower than central tendency estimate, since, as discussed above, current data support a higher value for the ratio) for the serum:drinking water PFOA ratio in exposed populations. This ratio can be higher or lower among individuals due to differences in daily water consumption rates and physiological parameters related to excretion rate, and use of a central tendency value for the ratio results in a less stringent criterion than if an upper percentile value were used. The inter-individual range of the serum:drinking water ratio for PFOA, and the fact that the ratio represents a central tendency, rather than an upper percentile value, are discussed in NJDEP (2016), as well as Institute (2015) and Institute (2017). As discussed in NJDEP (2016) and Institute (2015), it is reasonable and not overly conservative to assume a 200:1 ratio for PFNA based on toxicokinetic data from rats, mice, and humans. The toxicokinetic studies summarized in these documents indicate that PFOA and PFNA follow a similar toxicokinetic pattern (slow excretion in male rats and both genders of mice), but that

half-lives for PFNA in rodents are two- to 30-fold longer than for PFOA. Data presented by Zhang et al. (2013) indicate the median and geometric mean half-life of PFNA in humans (except in women of childbearing age) is at least twice that of PFOA. Half-life estimates for perfluorinated compounds in women of childbearing age in this study include a modeling component to account for excretion through menstrual blood loss in women of childbearing age and are, therefore, more uncertain than the estimates for other age groups. Although children were not included in the Zhang et al. (2013) study, the increased excretion rate due to menstrual blood loss is not applicable to children or pregnant women, and children's pattern of excretion is expected to be similar to adults other than women of childbearing age. Additionally, as discussed in NJDEP (2016) and Institute (2015), data presented by Fromme et al. (2010) indicate that PFNA serum levels in breast-fed infants increase after birth to levels higher than in maternal serum. Exposures of pregnant women, infants, and children are of particular concern because developmental effects are sensitive endpoints for PFNA toxicity. These animal and human data collectively support use of an estimated half-life of PFNA at least twice that of PFOA. Post et al. (2009; excerpt below) considered the contributions of non-water exposures when developing the 100:1 serum:drinking water ratio for PFOA.

As discussed above, the 100:1 serum:drinking water ratio for PFOA is not based only on the Emmett et al. (2006) study of a community with very high (greater than three µg/L) levels of PFOA in their drinking water, but also considered data from communities with a range of drinking water concentrations (0.06 to 4.3 µg/L) in Ohio and West Virginia:

For lower drinking water concentrations, nonwater sources are likely to contribute a greater proportion of the PFOA in the blood than in those using highly contaminated water. To find a lower bound on the ratio of serum to water PFOA concentrations, it can be assumed that none of the U.S. background serum concentration of about 4 μg/L results from drinking water. If this serum concentration of 4 μg/L is subtracted from the median serum concentration for Village of Pomeroy, Ohio (12 μg/L), the ratio of the remaining serum concentration (8 μg/L) to the drinking water concentration (0.065 μg/L) is 123:1. Therefore, PFOA appears to concentrate in serum of people exposed to lower drinking water concentrations in a similar ratio to that reported in a highly exposed community.

Additionally, as explained in the Health-based MCL Support Document for PFNA (Institute, 2015), the ratio of greater than 100:1 developed by Post et al. (2009) was subsequently supported by additional peer-reviewed publications regarding individuals with a wide range of drinking water exposures from several locations, as well as multiple pharmacokinetic modeling studies. The mean or median serum:drinking water ratio of greater than 100:1 is further confirmed by additional studies reviewed in the Institute (2017) Health-based Maximum Contaminant Level Support Document for PFOA, including a peer-reviewed pharmacokinetic model relating exposure to serum levels for PFOA developed by the USEPA that predicts an average serum:drinking water ratio of 114:1 (Lorber and Egeghy, 2011).

As confirmed by information from Emmett (personal communication, August 2017), data from Emmett et al. (2006) represent only consumption of plain tap water and do not include any other water consumption, including cold or hot drinks made with tap water (for example, powdered drink mixes added to water, iced tea, hot tea, or coffee) and do not include consumption of water used to prepare food (for example, soup, stew, rice, hot cereal). Additionally, these data represent tap water consumption at the time of the survey, when participants were aware that their drinking water was contaminated, and do not represent potentially higher tap water consumption during earlier time periods. Therefore, these data do not provide information on the relevant exposures to PFOA from contaminated drinking water and are not informative in the determination of the serum:drinking water ratio used in the derivation of the health-based MCL for PFNA.

PQL for PFNA

55. COMMENT: At present, no certified laboratory in New Jersey can conduct the analysis required by the Proposed Rule. This fact is ignored by the Department in the Proposed Rule as are the implications of a limited availability of laboratories, nationally. (28 and 52)

56. COMMENT: The Department has not considered the impracticality of measuring PFNA throughout the State's water supplies, given the few commercial laboratories currently certified by the State for PFNA analysis in drinking water, and none located in New Jersey. (30)

RESPONSE TO COMMENTS 55 AND 56: The Department is phasing in the monitoring

requirements PFNA to allow laboratories time to purchase equipment, train staff, and obtain certification in New Jersey. All public community water systems using a groundwater source(s) serving a population 10,000 or less and public nontransient noncommunity water systems will begin monitoring within the first quarter of 2019. All public community water systems using a surface water source(s) and all public community water systems serving a population greater than 10,000 will begin monitoring within the first quarter of 2020. At the time that the Institute's Testing Subcommittee developed and recommended the PQL for PFNA, six laboratories were certified to analyze PFNA in drinking water. Currently, there are 14 laboratories with New Jersey laboratory certification for PFNA analysis, one of which is located in New Jersey.

57. COMMENT: New Jersey needs to confirm reporting limit and PQL variability after the initial demonstration of capability. (30)

RESPONSE: To date, nearly all PFNA samples in New Jersey have been analyzed using USEPA Method 537 (see USEPA Document #: EPA/600/R-08/092). The procedure for establishing the minimum reporting level (MRL) at or lower than the PQL of 0.005 µg/L is verified during a laboratory certification audit. In addition, USEPA Method 537 requires a laboratory to meet quality control procedures included in the method, such as the requirement that the low level continuing calibration check meet the quality control criteria for the analysis to proceed. If a laboratory requests certification by the Department for use of a proprietary analysis method,

the Department's Office of Quality Assurance requires a MRL study and conformance with the USEPA Method 537 quality control requirements as a condition of approval to ensure that all laboratories and methods meet the reporting limit of equal to or less than 0.005 µg/L.

58. COMMENT: The Department should explain how eight minimum reporting limits were chosen to develop the PQL of 0.005 µg/L for PFNA and if any MRLs were dropped from consideration. (30)

RESPONSE: Table 6 of the Institute's Testing Subcommittee PFNA PQL document includes nine sets of performance data. In the basic calculation of the mean (and the median), the reporting limit of a proprietary method was not included because this method did not require verification of the low continuing calibration check standard prior to the analytical run and instead allows the initial calibration verification standard to be a midrange concentration standard. Therefore, eight minimum reporting limits were used to calculate the basic statistical mean of 0.0049 µg/L.

59. COMMENT: The Department notes that the method detection limit (MDL) has historically been used to derive the PQL, but has not adequately justified the departure from this approach in developing the PQL for PFNA. Further, the New Jersey Ground Water Quality Standards require that preference be given to setting the PQL at five times the MDL (N.J.A.C. 7:9C-l.9(c)3ii(l)). Given that the PQL is the groundwater remediation standard in the Pinelands National Reserve, it is critical that a consistent, defensible method be used for developing PQLs.

Per N.J.A.C. 7:9C-l.7(c)3i, if the Department promulgates an MCL for a constituent, the health-based level used to establish the MCL shall be the specific ground water quality criterion for the constituent. However, in the Pinelands National Reserve, the groundwater remediation standard is set at the PQL (N.J.A.C. 7:26D-2.2(2) and 7:9C-l.7(b) and 1.9(c)). The Department has not considered the economic burden or the technical impracticability associated with cleaning up groundwater within the Pinelands National Reserve to the proposed PQL of 0.005 µg/L. (30)

RESPONSE: In 1993, the Department conducted a study (Eaton, 1993) that determined that a factor of five applied to an interlaboratory MDL could yield a supportable PQL value. Starting in 1994, the Institute's Testing Subcommittee used this procedure when tasked with determining PQLs. In more recent USEPA regulations, such as the disinfection by product rules and the UCMR3 and UCMR4, the USEPA has used the MRL. The MRL is a reporting limit that requires a study for accuracy in addition to a precision study. In order for a laboratory to report data to their clients at an MRL, the accuracy and precision criteria of the method must be met. The MRL used for reporting data analyzed using USEPA Method 537 is described as the lowest analyte concentration that meets the data quality objectives of the intended use of the method. For the Institute's Testing Subcommittee, the data quality objective is to determine a PQL for PFNA that is as close to the health-based MCL as possible. The Testing Subcommittee, in addition to using the traditional approach of multiplying the median interlaboratory MDLs by five to determine the PQL, evaluated the MRL approach developed by the USEPA in

recommending a PQL.

The commenter is incorrect regarding the PQL and the groundwater remediation standard in the Pinelands National Reserve. The provision in question, N.J.A.C. 7:9C-l.7(c)3i, applies only to ground water quality criteria for constituents in Class II-A ground waters, which are designated for use as potable water supplies. Ground water quality criteria for Class II-A ground waters are designed to protect public health from exposure to contaminants in drinking water. Ground waters in the Pinelands are Class I-PL ground waters, not Class II-A ground waters. Ground water quality criteria for Class I-PL ground waters are not health-based; they are designed to protect the unique ecological resources of the Pinelands. Therefore, PQLs are not a consideration for ground water in the Pinelands and there is no relationship between PQLs, MCLs, and GWQS for ground waters in the Pinelands. The cleanup standard for PFNA in ground water in the Pinelands is not PQL driven, nor is it health-based; it is either natural water quality or background water quality as established at N.J.A.C. 7:9C-1.6(b)1 and 2. Thus, it is not impacted at all by the proposed MCL for PFNA nor the recently adopted GWQS for PFNA in Class II-A ground water (see 50 N.J.R. 334(a)).

60. COMMENT: The Department and the Institute failed to consider the economic burden or conduct a proper analysis of whether water purveyors in New Jersey could reliably and reasonably test their water supplies for PFNA to the Institute-recommended PQL of 0.005 µg/L or the proposed trigger for quarterly sampling of 0.002 µg/L, and have not evaluated the

presence of PFNA for more than 75 percent of State water supplies that would need to be tested under the proposed MCL. (28, 30, and 52) If the Department adopts the Institute's recommendations, testing requirements will result in more than 16,000 samples over a three-year period, potentially costing municipalities more than $6.5 million in chemical analysis alone. (52)

RESPONSE: At the time of the Institute Testing Subcommittee PQL determination, five of the six laboratories that are certified by the Department's Office of Quality Assurance reported MDLs of 0.002 µg/L or less and reporting limits of 0.005 µg/L or less. Approximately 50 public community water system have conducted voluntary PFNA monitoring and have shared this data with the Department. This data includes results from over 60 water distribution system points of entry. The reporting limits for the majority of these results was 0.0025 µg/L.

The initial quarterly monitoring is phased in. Systems may reduce monitoring frequency to annual or once every three years depending on sample results. The Department estimated sampling costs per sampling point in the Economic Impact statement of the notice of proposal. At the time of the Institute's Testing Subcommittee PQL development, the typical cost of the USEPA Method 537 analysis was $400.00. A recent survey of the New Jersey certified laboratories indicates that this analysis can be conducted for as low as $250.00 per analysis. The price of analysis often decreases as the analysis becoming more routine.

The Department acknowledged these costs in the Economic Impact statement, but determined, given the health effects associated with exposure to PFNA, that the costs were

outweighed by the benefits provided by protection of public health.

Maximum Contaminant Level for 1,2,3-TCP

Development of the MCL for 1,2,3-TCP

61. COMMENT: The Department should adopt a stricter standard for 1,2,3-TCP than the 0.030 µg/L proposed by this rule. The California Department of Public Health has adopted a standard of 0.005 µg/L based on the most current science, after years of study due to extensive water contamination there, primarily related to agricultural practices. There is ample evidence that the more protective standard of 0.005 µg/L is justified and would provide the necessary level of protection. The Department should adopt the more protective MCL of 0.005 µg/L to protect people more fully from the risk of developing cancer. (14, 15, 19, 27, 33, 50, 56, 58, and 59)

RESPONSE: As stated in the notice of proposal Summary, the Institute recommended to the Department an MCL for 1,2,3-TCP of 0.030 µg/L, which is the PQL developed by the Institute's Testing Subcommittee. Although higher than the health-based level of 0.005 µg/L recommended by the Institute's Health Effects Subcommittee, 0.030 µg/L is the level to which 1,2,3-TCP can be reliably measured at this time.

The Department is aware that the California Department of Public Health adopted an MCL of 0.005 µg/L in December 2017. At this time, the Department is evaluating additional

analytical methods for detection of 1,2,3-TCP at levels closer to the Institute's recommended health-based level.

Health-based Level for 1,2,3-TCP

62. COMMENT: The Department and the Institute did not appropriately take into account an Integral Consulting, Inc. and Environmental Standards, Inc. document containing relevant information related to 1,2,3-TCP that was submitted following the Institute's request for post-2009 data. A number of toxicology experts have published new (post-2009) studies and agency documents with a reevaluation of the key study, NTP (1993), upon which the recommended MCL for 1,2,3-TCP is based and have identified extensive technical limitations in the key study work. This new information affirms that the recommended MCL is overly stringent. For example, comparing New Jersey to another state, the health-based standard that the Institute is proposing is over 1,000 times higher than the limit Hawaii's Department of Health uses. (28)

RESPONSE: As mentioned by the commenter, the document submitted to the Institute on October 16, 2015, by Integral and Environmental Standards was in response to a request by the Institute for information relevant to development of an MCL for 1,2,3-TCP that had become available since 2009. The studies referenced by the commenter (Tardiff and Carson, 2010; TetraTech, 2012; Meek et al., 2014) were also identified in the literature search for information relevant to the Institute's development of the health-based MCL for 1,2,3-TCP that have been available since 2009. These studies were considered by the Institute and are discussed in the

Institute Addendum to Health-based Maximum Contaminant Level Support Document for 1,2,3-Trichloropropane (Institute, 2009) dated October 27, 2015 (see http://www.nj.gov/dep/watersupply/pdf/123-tcp-appendixa.pdf). The studies do not support the conclusion that NTP (1993) has extensive technical limitations. The information presented in the Institute document demonstrates that the health-based MCL and the MCL are scientifically valid and are not overly stringent.

The basis for Hawaii's MCL for 1,2,3-TCP of 0.6 µg/L (600 ng/L) is discussed in the Institute (2015) document mentioned above. As discussed in the document, Hawaii's MCL was adopted in 2005 and its basis was reviewed by TetraTech (2012). It is based on a different endpoint and different risk assessment approaches than those used in the Institute risk assessment for 1,2,3-TCP. The approach used by Hawaii also did not follow USEPA guidance regarding adjustments for extrapolation of doses in animals to humans, or age-dependent adjustment factors (ADAFs) to account for the greater susceptibility to mutagenic carcinogens early in life, resulting in a less stringent MCL than if USEPA guidance had been followed. In contrast, the health-based MCL developed by the Institute adjusted for animal-to-human extrapolation and used ADAFs, as recommended in current USEPA risk assessment guidance. Based on the above factors, the Department has determined that the health-based MCL recommended by the Institute is scientifically valid and health-protective.

PQL for 1,2,3-TCP

63. COMMENT: The Department should not promulgate an MCL for 1,2,3-TCP unless and until such time as a reliable analytical method can be demonstrated by eligible laboratories and certified by the Department. (28)

RESPONSE: 1,2,3-TCP is a target analyte in at least five USEPA analytical methods for drinking water: EPA Methods 502.2, 504.1, 524.2, 524.3, and 551.1. The Department's Office of Quality Assurance offers certification for drinking water analysis of 1,2,3-TCP by EPA Methods 502.2, 504.1, 524.2, and 524.3. If a laboratory requests the use of EPA Method 551.1, the Department's Office of Quality Assurance will include it on its list of certified methods. Three methods, EPA Methods 504.1, 524.3, and 551.1, can detect 1,2,3-TCP to an MDL of 0.010 µg/L. Currently, 12 laboratories are certified by the Department to analyze drinking water samples using EPA Method 504.1.

64. COMMENT: The Department is currently basing the proposed MCL for 1,2,3-TCP by mandating use of EPA Method 504.1 as being the most sensitive drinking water method for analysis of 1,2,3-TCP. Section 2.3 of EPA Method 504.1 states that confirmation of tentatively positive results should be obtained as follows: "[c]onfirmatory evidence should be obtained for all positive results. This data may be obtained by using retention data from a dissimilar column, or when concentrations are sufficiently high by GC/MS [gas chromatography/ mass spectroscopy]." It is noteworthy that under current Federal Safe Drinking Water Regulations, the analytical method, EPA Method 504.1, is not an approved drinking water method, unlike

EPA Method 524.3. Using a better analytical method, such as a GC/MS technique is prudent and responsible with regard to proposing and ultimately promulgating an MCL for 1,2,3-TCP. The Institute acknowledges this issue and states EPA Method 524.3 is an analytical method currently under development with certification not offered by the Office of Quality Assurance. In that regard, we note that the Department currently does not accredit laboratories using drinking water EPA Method 524.3 for 1,2,3-TCP. Finally, during a recent survey of 18 Department accredited laboratories, it was observed that 15 laboratories are accredited to perform 1,2,3-TCP using approved drinking water GC/MS EPA Method 524.2. (28)

RESPONSE: EPA Methods 504.1 and 524.3 are approved EPA analytical methods. Laboratories are not required to utilize EPA Method 504.1 for 1,2,3-TCP analysis. The USEPA does not provide a list of its approved analytical methods for contaminants without a Federal MCL, such as 1,2,3-TCP. EPA Method 524.3 is considered a "promulgated" method only because USEPA required the use of EPA Method 524.3 for the UCMR3.

For New Jersey-specific MCLs, certified laboratories are required to use methods approved by the Department. A laboratory may request certification using EPA Method 524.3 as an option for the analysis of 1,2,3-TCP in drinking water from the Department's Office of Quality Assurance. Although the Department offers certification for the analysis of 1,2,3-TCP by EPA Method 524.3, no laboratories have requested to use this method for 1,2,3-TCP. There are additional USEPA drinking water testing methods for which 1,2,3-TCP is a target analyte.

EPA Methods 504.1, 524.3 (SIM), and 551.1 can reach the detection limit required. EPA Method 524.2 cannot detect 1,2,3-TCP at levels as low as the MCL.

65. COMMENT: There is an issue using the 40 CFR Part 136 MDL procedure as the basis for proposing an MCL for 1,2,3-TCP. In summary, multiplying a theoretically calculated MDL value by five is incorrectly referenced by the Institute as a PQL and should not be proposed as an MCL. (28)

RESPONSE: The Institute's Testing Subcommittee presented several different calculations of the PQL in its recommendation, including the median MDL multiplied by a factor, and instead chose to recommend a PQL based on the bootstrap analysis of the reporting limits from laboratories performing EPA 504.1 and EPA 524.3. In 1994, the median MDL was used during the development of MCL for 1,2,3-TCP based on research that determined that a multiplier between four and six could be used to yield a supportable PQL value (Eaton, 1993). At that time, the Testing Subcommittee utilized five as a multiplier for the PQL for 1,2,3-TCP. In 2009, the Institute noted that due to the ongoing work of the USEPA in addressing the issues surrounding the MDL process, the Institute would monitor developments in this area and might incorporate new approaches to the development of PQLs.

Since EPA Method 504.1 is an older method, it includes the requirement for obtaining MDLs for each analyte but does not mention MRLs as do the more recently developed USEPA analytical methods, such as EPA Method 524.3. In order to obtain reporting limit information

for EPA 504.1, the Department contacted New Jersey laboratories certified for EPA Method 504.1 on behalf of the Institute. Subsequently, the Institute was able to calculate PQLs using several methods: the interlaboratory median MDL multiplied by five, the mean and median of the reporting limits used by laboratories, and the bootstrap analysis of the upper confidence limits of the MDL and the reporting limits; and recommended the bootstrap analysis of the reporting limits from laboratories performing EPA Method 504.1 and EPA Method 524.3.

Treatment for PFNA and 1,2,3-TCP

66. COMMENT: The Institute Treatment Subcommittee's finding that granular activated carbon is used to remove PFCs and that effective treatment is not a limiting factor in implementing the MCL is supported. The best available technology to remove PFOS, PFOA, and PFNA from dilute aqueous streams, economically achievable for large scale municipal drinking water systems, is concluded to be activated carbon. (15)

RESPONSE: The Department agrees that granular activated carbon (GAC) is commonly used for removal of PFCs from drinking water and is both effective and feasible for this purpose. Furthermore, the Department agrees that a GAC treatment system must be designed in careful consideration of the background water quality, including the natural organic matter. The commenter's support is acknowledged.

67. COMMENT: The Institute's Treatment Report itself provides inadequate review of generally insufficient information concerning the availability of treatment technologies (Activated Carbon, Membrane Filtration, Anion Exchange, and Advanced Oxidation) that could achieve the proposed MCL under the current circumstances. In addition, the Treatment Report does not provide sufficient analysis of whether it would be reasonable to expect New Jersey water suppliers to locate, design, install, operate, and maintain any such technology to meet the MCL; effectively integrate such technology with existing water supply treatment systems; or whether such technology would be feasible (technically effective and technically and administratively implementable) or practicable (cost effective). The Treatment Report fails to analyze whether water suppliers across the State could feasibly and practically install, implement, and maintain one or more additional treatment technologies to their water supply systems to consistently achieve 0.013 µg/L. (52)

68. COMMENT: The Institute's Treatment Report fails to note that while GAC treatment is proven for PFOA and PFOS, little data are available with regard to the treatment of PFNA to the levels of the health-based MCL recommendation of 0.013 µg/L provided in the Health Effects Subcommittee report. Of the three case studies provided in the Treatment Report, none specifically evaluate PFNA removal, although it is assumed that PFNA will be removed similar to PFOA. Further, the Little Hocking, Ohio study did not provide a treatment goal, only stated that the plant maintained "no detectable level" of PFOA and related compounds without providing the relevant detection limits. Also, the target treatment concentration for PFOA for the

Oakdale, Minnesota study was an order of magnitude higher than the Health Effects Subcommittee's proposed health-based MCL (0.3 µg/L vs. 0.013 µg /L). Finally, the New Jersey American Water – Penns Grove case study does not appear to have been implemented full scale, as it states "the new treatment plant combined designed capacity is 3 MGD to achieve removal PFC removal [sic] below the Department guidance level of 0.04 µg/L..." Given the weak relationship of the selected PFOA case studies to PFNA scenarios under the Institute's proposed regulatory standard, the Treatment Report's discussion of these GAC case studies is inadequate to evaluate the practicability and feasibility of GAC for full-scale PFNA removal. (52)

RESPONSE TO COMMENTS 67 AND 68: As stated in the notice of proposal Summary, the role of the Institute's Treatment Subcommittee is to evaluate the best available and feasible treatment technologies for attaining removal of the contaminants from drinking water to achieve the health-based level, while considering the limits of available testing methodologies. The Subcommittee reviewed both relevant literature, as well as data from drinking water treatment plants, including facilities in New Jersey, with full scale treatment for long-chain PFCs, such as PFNA, PFOA, and PFOS, and concluded that the ability to remove these contaminants is not a limiting factor in setting an MCL. The Subcommittee's review did not identify any drinking water facilities treating for PFCs using treatment technologies other than GAC; thus, limited information was available for these technologies. Given the data available, the Institute recommended the use of "granular activated carbon or an equally efficient technology" but

also noted that GAC is the most commonly used treatment for PFC contamination (see http://www.nj.gov/dep/watersupply/pdf/pfna-pfc-treatment.pdf).

The Department reviewed the Subcommittee report and agrees with its conclusion. As stated in the notice of proposal Summary, treatment options for long-chain perfluorinated compounds do not differ due to the similar properties of those compounds, such as water solubility, similar chemical structure, strong carbon-fluorine bonds, and high polarity. There are multiple full-scale facilities with varying influent and effluent concentrations referenced in the Subcommittee report that establish that it is both practical and feasible to treat for long-chain PFCs below the MCL of 0.013 µg/L that is being adopted for PFNA. This includes the New Jersey American Water Penns Grove water system that, in contrast to what the commenter states, has maintained a full-scale GAC treatment system that has been operational since May 2012. Treated water quality data from this system shows that concentrations of PFNA in the raw water between 0.018 and 0.072 µg/L are being removed below the PQL of 0.005 µg/L.

Since publication of the notice of proposal, the Department has become aware of more data that support the use of granular activated carbon to treat PFCs (McNamara et al., 2018). McNamara et al. summarizes third-party test work and field installations in support of their finding that GAC is commonly used in treatment of municipal drinking water. This further supports the Institute's conclusions and demonstrates that granular activated carbon can be feasibly used to treat PFCs.

69. COMMENT: The Department does not evaluate the regulatory compliance challenges of increasing PFC treatment requirements for existing water supply systems. The regulatory implications of the potential need to increase flow from existing supply wells to assure performance of PFC treatment systems is an example of such a challenge. In addition, added treatment processes may require increased pressures from supply wells. Either eventuality would trigger repermitting and potentially significant upgrades of these systems' infrastructure. Also, the Institute Treatment Subcommittee Report does not consider that water supply stakeholders are all subject to permits that may have to be altered, with associated costs, to maintain regulatory compliance, and, it should be noted, that that may not even possible in some cases. (52)

RESPONSE: It is unclear whether the commenter is referring to GAC treatment, the most common treatment for PFCs. With respect to GAC, the Department does not agree that the installation of GAC treatment for PFCs would trigger a potential need to increase flow, which would lead to repermitting. GAC is a pressurized treatment system that results in a pressure drop throughout the system. The commenter incorrectly implies that the water system may need to increase flow from the supply wells in order to account for this pressure loss. However, this pressure loss occurs when water is pumped through the GAC filters used to remove the PFCs. If the GAC material in the filters is too deep then the pump may struggle to push the water through the treatment system. This is addressed in the design phase of the treatment system by ensuring that the GAC is not too deep, so that there is not a significant loss in

pressure. Additionally, the public water system can add another GAC filter so that the pressure is split between more than one treatment unit. If the treatment system is designed properly and accounts for these potential issues during the design phase, then no re-permitting would be anticipated.

70. COMMENT: The Department suggests that an effective advanced oxidation process (AOP) exists for the subject compounds, yet the information presented in the Proposed Rule and the Institute Treatment Report does not support a positive effectiveness determination. Contrary to the Treatment Report's suggestions, reliable AOP options do not exist to date, although bench-scale studies indicate PFOA and PFNA may be amenable to advanced oxidation. Research is underway to develop an effective AOP approach for PFOA and PFNA. (52)

71. COMMENT: Advanced oxidative processes, such as chlorination, ozonation, and UV peroxide have been found very effective in breakdown of organic compounds, including complex organics, but are not expected to provide significant removal of PFCs due to the strength of the C-F bond. In a study by Arvaniti et al. no significant removal of PFCs was observed using ultraviolet (UV) and UV peroxide. As noted in the Institute Treatment Subcommittee Report, one study showed relatively modest PFOS removals between 10 and 50 percent, dependent on the oxidative process used. (15)

72. COMMENT: The information presented in the Institute Treatment Subcommittee Report for powdered activated carbon is not definitive with regard to effectiveness or

implementability as a stand-alone technology. In addition, even if this method is assumed to be effective, treatment and residuals management costs are not evaluated. Of the reports cited, no data were provided on the influent PFC concentrations or the target treatment concentrations. The Water Research Foundation's Project #4344 cited did find that ">90% removal of PFNA and PFOS was possible but only with unreasonably high adsorbent dosages unless contact times could be extended..." The more challenging treatment requirements resulting from the 0.013 µg/L MCL will likely require even higher carbon dosages and/or extended contact times, as this technology requires physical contact between the powdered activated carbon and the PFNA molecule. Such extended contact times become increasingly difficult at lower target treatment concentrations. (52)

73. COMMENT: Reverse osmosis and nanofiltration and broad spectrum membrane filtration have been evaluated at bench scale, only. However, vendor information should have been used in the Institute's Treatment Report to evaluate their effectiveness at field scale. While the Report discusses the implementation of reverse osmosis in general, it does not meaningfully address the field scale implementation of reverse osmosis specifically for PFC removal, or implementation costs. A single report (Tang et al. 2007) is cited to support a 90 percent removal of PFOS using nanofiltration without any consideration to influent or target PFC concentrations. Accordingly, the Report's technical analysis of reverse osmosis as a membrane filtration treatment method for PFC removal is incomplete. (52)

74. COMMENT: While it is true that ion exchange resins designed for perchlorate removal have been patented for PFC removal, the Institute Report does not analyze vendor information to evaluate the effectiveness of such methods for PFAS removal at field scale, particularly to the MCL in the Proposed Rule. Specialty anion exchange resins have been developed by vendors to specifically treat PFOA and PFOS and are assumed applicable to other ionic PFC species, such as PFNA. We are not aware of disposable exchange resins for the subject compounds. There are also synthetic ion exchange resins now being applied at field scale that are not addressed in the Treatment Report but should be evaluated. (52)

RESPONSE TO COMMENTS 70, 71, 72, 73, AND 74: As stated in the notice of proposal Summary, the role of the Institute's Treatment Subcommittee is to evaluate best available treatment technologies for attaining removal of the contaminants from drinking water to achieve the MCL while considering the limits of available testing methodologies. Given the data available, the Institute recommended the use of "granular activated carbon or an equally efficient technology" but also noted that GAC is the most commonly used treatment for PFC contamination. No full-scale drinking water facilities were identified that treated PFCs using alternate treatment technologies, such as reverse osmosis or anion exchange. The Institute noted that based on site-specific factors an "equally efficient technology" may be used for a particular water system. Pursuant to N.J.A.C. 7:10-5.7(a), a water system is required to take any action necessary to remove a contaminant when the MCL is exceeded, such as the use of an alternative water supply or the installation of treatment. The Department does not specify a

particular treatment process for the removal of PFNA below the MCL.

75. COMMENT: The Institute Treatment Subcommittee Report does not adequately address the implementability of waste disposal for ion exchange resin generation or membrane filtration (reverse osmosis) rejectate. As mentioned in the Institute Report, membrane filtration produces a high strength brine, which, in the case of an application designed for PFC removal, would also contain a concentrated PFC component, further complicating disposal. Implementability considerations include the increasing administrative challenges to conventional disposal of brines to sanitary sewer systems, surface waters, land, and deep injection wells. These brine disposal options do not necessarily guarantee that PFCs, as well as other contaminants (for example, radionuclides), present in the residuals will not be re-released into the environment. This is a potential liability issue for waste generators, with associated costs. The Institute Treatment Subcommittee Report fails to consider either these implementability considerations or their added costs. (52)

RESPONSE: As stated in the Institute's Treatment Subcommittee report, water systems are advised to consider costs and methods for disposal of brine, reject water, resins, or spent media waste products when selecting a treatment technology. Systems should ensure that contaminants are not simply released back into the environment.

76. COMMENT: The Treatment Report's analyses are very general (15 different organic constituents are discussed, not specifically 1,2,3-TCP) and provide insufficient analysis of whether implementable and cost-effective treatment technologies can be installed, operated, and maintained by New Jersey water suppliers to meet the MCL for 1,2,3-TCP of 0.030 µg/L and implementation for private well owners remain unevaluated. In addition, several treatment options are discussed that are ineffective or have not yet been proven effective for removal of 1,2,3-TCP to the proposed MCL (for example, air stripping, biological degradation, and membrane filtration). For instance, the Treatment Report suggests an effective advanced oxidation process (AOP) exists for 1,2,3-TCP, yet the information presented in the Treatment Report cites only a single application of AOP for treatment of 1,2,3-TCP. Many AOP technologies exist, yet our research and vendor communications indicate that proven AOP options for 1,2,3-TCP are likely limited to the combined ozone and hydrogen peroxide AOP; however, these data are limited and dated. AOP processes are heavily influenced by overall water quality, including pH, total dissolved solids, metals, and organics, so the technology may perform with one water source, but not another, and/or require significant pretreatment. Finally, no field-scale tests appear to have been performed, which are required to fully evaluate the technology's effectiveness and implementability. On the other hand, other technologies are not fully evaluated. For instance, reverse osmosis is briefly discussed in the Treatment Report as potentially applicable for the removal of 1,2,3-TCP (up to 85 percent removal); however, additional information is required to evaluate its effectiveness, at field scale. (28)

RESPONSE: The 2009 Treatment Subcommittee report indicated that while GAC was the best available treatment, AOP was the second best available treatment. However, when the Institute re-evaluated their 2009 recommendation, they also reviewed more recent technical information, including information from GAC facilities treating for 1,2,3-TCP. No full-scale drinking water treatment facilities were identified that used AOP to treat for 1,2,3-TCP. Based on their review, the Institute, therefore, determined that GAC is still the best available treatment for the removal of 1,2,3-TCP from drinking water.

Treatment Costs

77. COMMENT: PFNA is likely to be present throughout the State, with numerous potential sources throughout New Jersey and within the Delaware River Watershed in Pennsylvania. Neither the Institute Treatment Subcommittee nor the Department have incorporated complete information on how many water systems in New Jersey may be required to implement treatment on their drinking water supplies in response to the proposed MCL, or evaluated the direct and indirect cost implications, such as operation, maintenance, or administrative costs, for these parties. (28 and 52) Separate economic analyses should be considered for large and small systems, as the costs of compliance can vary widely for systems of different sizes. (30) Pre-treatment is commonly required to make the water suitable for GAC treatment (for example, particulate filtration, soluble iron removal, pH adjustment) and should be evaluated to provide a range of potential unit costs. (28)

RESPONSE: As stated in the Response to Comments 21 and 22 above, the Department has investigated PFNA use in New Jersey and believes it has identified the sources associated with detections at public water systems. These detections were found through Statewide sampling conducted pursuant to UCMR3 and Department-initiated sampling. Therefore, PFNA is unlikely to be present throughout the State. As stated in the Economic Impact statement, the Department is aware of 11 public water systems with detections above the MCL. The Department recognizes that there are economic costs associated with treatment of PFNA. These costs, including for construction, operation, and maintenance, vary based on the type of treatment selected, site condition, initial concentration of the contaminant, the presence of other contaminants and organic materials in the raw water, the need for pre-treatment, and the size of the water system.

78. COMMENT: Spent GAC residuals management and disposal costs are not thoroughly evaluated in the Treatment Report and can be very significant. Not all GAC vendors have the ability to regenerate spent GAC, which reduces competitiveness in the GAC regeneration marketplace (kiln temperatures need to be in excess of 1800°F for PFCs). Additionally, to regenerate at all is dependent on the influent concentration: if the mass loading onto the GAC is too high, then a vendor may not be able to regenerate without violating their permits. In these cases, spent GAC must be sent to a landfill, which significantly increases costs. Additionally, the removal of naturally occurring radioactive materials in source water can

complicate and increase costs for disposal. Again, this issue remains unaddressed in the evaluation of the practicability, feasibility, and costs of the proposed MCL and PQL. (52)

RESPONSE: The Institute's Treatment Subcommittee noted in its report that residual management and waste disposal costs are considered when it selects an appropriate treatment method. The Department acknowledges that in some cases an equally efficient technology may be considered in lieu of GAC depending on site specific factors. However, GAC is recognized as a cost-effective technology for treating PFCs due to the ability of most major manufacturers to regenerate the carbon and reduce disposal costs. Spent carbon is transported to a regeneration facility by the manufacturer and the temperature of the regeneration process fully breaks down the PFCs, so that there is no waste or additional disposal cost. The cost of the regeneration process is assessed by the manufacturer as part of the cost associated with supply of carbon. As stated in the notice of proposal, costs associated with the operation and maintenance of a GAC system, including periodic regeneration or replacement of the carbon, vary depending on site specific factors, such as the background quality of the source water, the size of the installation, and the concentration of the target contaminant in the source water. When selecting an appropriate treatment, the cost considerations for each treatment method requires a case-by-case evaluation which includes residual and disposal costs.

79. COMMENT: The Department misrepresents the findings of the Institute's Treatment Subcommittee in the Rule Proposal. The Department makes the following statements as to the

costs of treatment to the proposed MCLs: "[GAC] was identified by the [Institute] in its 2015 report as the best available technology for the removal of PFNA and 1,2,3-TCP. According to the Institute's report, the estimated cost of installing a GAC ranged between $500,000 and $1 million for large systems that process one million gallons per day." The primary problem with the statement about the Institute's report on the costs of GAC is that it is patently false. The only costs related to GAC treatment mentioned by the Treatment Subcommittee of the Institute in Appendix C, Recommendation on Perfluorinated Compound Treatment Options for Drinking Water, to the July 1, 2015 Institute Basis and Background document as to GAC are as follows: Oakdale, MN -- $3 million cost to construct; $25,000 annual operational costs; plus $250,000 of carbon every year and a half and Penns Grove, NJ -- $12.2 million cost to construct; annual operating costs of $80,000. Nowhere in the Institute's report does it say that GAC treatment could be installed for a $1 million or less. The range of costs to construct GAC treatment for PFNA, according to the only examples with costs in the Institute's report, is $3 million to $12.2 million. The O&M costs identified in the Institute's report examples ranged from approximately $80,000 to $191,000 per year (when the carbon costs for Oakdale are annualized). Though these numbers in the Institute report would obviously be significant for a water purveyor, a range of annual operation costs are not even provided in the Proposed Rule. (28 and 52)

RESPONSE: The Department erroneously attributed its estimated cost range ($500,000 to $1 million per one million gallons of water treated) to the Institute's Treatment Subcommittee

report. The estimated cost range was not presented in the Institute report but was derived from Department data. New Jersey public water systems submit estimated project costs and plant capacity as part of an application for a permit to install granular activated carbon for the treatment of PFCs or 1,2,3-TCP. For example, in June 2011, a New Jersey American Water system was issued a permit to install GAC treatment for PFOA at a 1.008 MGD capacity treatment plant at an estimated cost of $610,000. In January 2018, Brick Township Municipal Utilities Authority was issued a permit to treat 16 MGD for PFCs at an estimated cost of $16,067,300. Greenwich Township Water Department was issued a permit for GAC treatment of PFCs at its 1.008 MGD capacity treatment plant in January 2017 at an estimated cost of $614,257. Finally, Maple Shade Water Department was issued a permit to treat 1,2,3-TCP at their 3.60 MGD treatment plant at an estimated cost of $2.34 million. The examples provided above are within the Department's estimated cost range.

Monitoring schedule for PFNA and 1,2,3-TCP

80. COMMENT: Monitoring for PFNA should not be phased in slowly in 2019-2020, as proposed by the Department. Monitoring should begin rapidly in order to locate all water systems that are contaminated with this toxic compound, so that PFNA can be quickly removed from our water. (14, 15, 58, and 59)

RESPONSE: As stated in the notice of proposal Summary, the phase-in of monitoring will allow laboratories time to purchase equipment, train staff, and obtain certification in New Jersey, as

necessary. The Department must also prepare training materials, guidance documents, forms, standard operating procedures, and data systems.

With the adoption of these rules, all public community water systems using a groundwater source(s) serving a population of 10,000 or less and public noncommunity water systems will begin monitoring within the first quarter of 2019. The Department is proposing monitoring starting in 2020 for public community water systems using a surface water source(s) and all public community water systems serving a population greater than 10,000. However, the Department has recent 1,2,3-TCP and PFNA testing information for these systems conducted pursuant to UCMR3, and most of the systems have already acted to provide treatment. Therefore, by 2019, the Department anticipates that it will be aware of the locations of all public water systems that are contaminated with PFNA and 1,2,3-TCP. Further, under N.J.A.C. 7:10-5.7(a), if a water sample demonstrates an exceedance of an MCL that constitutes a violation, the supplier of water must take any action necessary to bring the water into compliance with the applicable MCL.

Amendments to the Private Well Testing Act Rules

Private Well Testing

81. COMMENT: The mandatory PWTA testing requirements that will make real estate transactions more expensive are unsupportable. Buyers should have the option to request any private well tests that can be negotiated as part of a real estate transaction. The Department

can assist in this effort by increasing awareness of contaminants that can occur in private wells, so buyers and sellers can make the decision as to which tests they would like to have on a home with a private well. (54)

RESPONSE: The testing of private wells in New Jersey is required pursuant to N.J.S.A. 58:12A-26 et seq., and the PWTA rules at N.J.A.C 7:9E. In the Department's experience, outreach efforts alone are not enough to adequately inform residents of the condition of their drinking water and are, therefore, not sufficiently protective of public health. Some parameters, like arsenic, are not uniformly distributed in the groundwater in any given area. It is possible that high concentrations can be extremely localized making a regional analysis only suggestive of the possible threat from such parameters. Site-specific testing is the only way to know exactly what risks a homeowner or resident and their family will be exposed to from their well water.

The Department increases awareness via education and outreach efforts, but these programs only result in testing for a portion of the targeted private well owners. In a recent Department-funded effort in an area known to have high arsenic levels in groundwater, only 47 percent of households that were offered a free private well test participated (see Flanagan et al. 2016. Arsenic in private well water part 2 of 3: Who benefits the most from traditional testing promotion? Science of the Total Environment 562:1010–1018).

82. COMMENT: The Department should ensure that under the Spill Compensation Fund, the contaminants being added for testing under the PWTA are eligible for funding. (54)

RESPONSE: The Department is adopting amendments to the PWTA rules to require Statewide testing for 1,2,3-TCP, EDB, and DBCP. All three contaminants are on the Discharges of Petroleum and Other Hazardous Substances rules list at N.J.A.C. 7:1E Appendix A that, in addition to petroleum and petroleum products, are considered hazardous substances under the Spill Act. The Spill Act establishes a comprehensive scheme to control the transfer and storage of hazardous substances and provides strict liability for cleanup and removal costs as a result of any discharge of a hazardous substance on this list. The Spill Act also provides a fund for compensating businesses and other persons damaged by a discharge of any substance on the list. Thus, any business or person damaged by the discharge of 1,2,3-TCP, EDB, and DBCP would be eligible for compensation under the Spill Act.

The Department is also adopting requirements to extend the required testing for gross alpha particle activity and arsenic Statewide, and to establish a requirement to test for uranium in the northern counties of New Jersey. Naturally occurring radionuclides, such as gross alpha and uranium, do not appear on the list of hazardous substances at N.J.A.C. 7:1E Appendix A. A person affected by the discharge of these substances is not eligible for compensation under the Spill Act. Arsenic is naturally occurring; however, some discharges are traced to contaminated sites. Thus, a person affected by the discharge of arsenic must demonstrate that the source of the discharge is man-made to be compensated under the Spill Act.

83. COMMENT: In addition to concerns over the proposed items being added for testing under the PWTA, there are concerns that these items will have to be tested for every five years where the private well is located at a property being rented in addition to if it is sold. For example, with uranium and arsenic being added as items for testing under the PWTA, the U.S. Cooperative Extension Service (USCES) only requires testing for these items once in the life of a well (and only annually if arsenic is detected). Subsequently, the sale or rental of a property should not cause a trigger for testing of items such as these. In addition, the USCES advocates for the testing of items being included in this rule (TCP, EDB, and DBCP) once every five years. The Department should follow these guidelines if adding these items for testing under the PWTA. (54)

RESPONSE: The Private Well Testing Act requires testing at the time of a real estate transaction or every five years for rental properties. Testing is intended to provide buyers and tenants with information regarding their drinking water quality. Testing every five years ensures renters have current test results. Department studies show that many homeowners and landlords do not recall if they ever tested their well or do not correctly recall the test results (Flanagan et al. 2016. Arsenic in private well water part 1 of 3: Impact of the New Jersey Private Well Testing Act on household testing and mitigation behavior. Science of the Total Environment 562:999–1009). The Private Well Testing Act only requires testing of a non-rental property at the time of sale.

84. COMMENT: It may not be possible to find companies capable of testing for certain items being added under the PWTA. For example, we are unaware of any facilities capable of testing for EDB. If a homeowner cannot find a company capable of testing for certain contaminants, it could make it impossible for a home with a private well to be sold in New Jersey. (54)

RESPONSE: Currently, there 37 laboratories certified in New Jersey to test for EDB. Eight of these are also certified for Private Well Testing Act analyses. It is expected that other laboratories will obtain certification prior to adoption of these requirements. In 2017, the Department conducted a survey of New Jersey-certified laboratories and determined that seven additional laboratories are seeking certification from the Department's Office of Quality Assurance to test for EDB.

Private Well Treatment

85. COMMENT: Treatment with carbon filtration will remove many dangerous pollutants from drinking water, in addition to PFNA. Treatment should be required to be installed immediately. (58 and 59)

RESPONSE: The PWTA requires testing and notification to potential buyers and tenants. While treatment of private wells is not required under the PWTA, the PWTA allows for a potential home buyer or tenant to consider treatment or alternate sources of water.

86. COMMENT: The finding that point-of-use (POU) devices can be effectively used to remove PFCs at residences that depend on individual water wells employing granular activated carbon in combination with reverse osmosis to achieve complete removal of PFCs is also supported. Point-of-use devices can effectively remove PFCs at individual residences using well water; POU devices using GAC combined with reverse osmosis demonstrate complete removal of PFCs. GAC filter devices without reverse osmosis work very well to remove PFCs, but have a finite life. The addition of a reverse osmosis component considerably extends GAC useful life in POU applications and increases treatment redundancy. In under-sink POU devices, there are relatively minor differences in cost between GAC and combined GAC/reverse osmosis systems, with added benefit that GAC/reverse osmosis systems provide redundancy in PFC removal. (15)

87. COMMENT: The Institute's Treatment Subcommittee Report contains no analysis of direct and indirect costs and implementation challenges for point of entry treatment (POET) nor POU treatment systems. (52)

RESPONSE TO COMMENTS 86 AND 87: While the water delivered to the public by public water systems must meet all applicable State and Federal drinking water standards, point-of-entry treatment (POET) or POU systems are installed inside individual homes or businesses. Installation of these systems is at the discretion of the home or business owner.

<u>Cost of Additional Testing Requirements</u>

88. COMMENT: The new PWTA requirements are going to essentially double the cost of the testing for the homeowners. In addition, the cost to a laboratory for necessary analytical equipment may cost in excess of $60,000. (35)

RESPONSE: The Department expects the cost of the analysis for 1,2,3-TCP, EDB, and DBCP to decrease following the promulgation of the MCL for 1,2,3-TCP as more laboratories become certified to perform analysis of the contaminants. The costs to private well owners are increasing by approximately $240.00 in the northern areas of the State and up to $140.00 in the southern portions of the State. These costs are minimal compared to the value of the water quality information provided.

Private Well Testing for PFNA

89. COMMENT: PFNA does not bio-degrade, persists in the environment, concentrates in human blood, and can have serious negative health effects. PFNA should be added to the contaminants that must be tested for and removed under the Private Well Testing Act. There could be private water users whose wells have not been sampled yet in various parts of New Jersey who are drinking water contaminated with PFNA, but they do not know it and, unless it is required, their wells will never be sampled. While sampling at the point of sale or lease does not, by itself, provide the level of protection needed, it is the level of protection available under the PWTA and should be made available. All New Jerseyans need protection, whether they are private well users or are on public water systems. (14, 15, 58, and 59)

RESPONSE: The occurrence of PFNA in New Jersey is infrequent and localized near known dischargers. In New Jersey, the two areas of contamination are being actively investigated by the Department and private well owners with contaminated supplies are being identified. Given this information and the relatively high cost of analysis to individual homeowners at the time of proposal (that is, $400.00 per sample), the Department did not propose to include PFNA as a parameter to test for pursuant to the PWTA. As the Department considers the regulation of more ubiquitous perfluorinated compounds, such as PFOA, which are analyzed using the same method, the Department may consider requiring broader testing.

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Federal Standards Statement

Executive Order No. 27 (1994) and N.J.S.A. 52:14B-1 et seq. (P.L. 1995, c. 65), require State agencies that adopt, readopt, or amend State rules that exceed any Federal standards or requirements to include in the rulemaking document a Federal Standards Statement.

The Department's Safe Drinking Water Act (SDWA) rules at N.J.A.C. 7:10 incorporate by reference the National Regulations 40 CFR 141, as amended and supplemented, promulgated by the U.S. Environmental Protection Agency (USEPA) pursuant to the Federal Safe Drinking Water Act (Federal Act), 42 U.S.C. §§ 300f et seq., including all siting requirements, filtration and disinfection requirements, maximum contaminant levels, monitoring and analytical requirements, reporting requirements, public notification requirements, and recordkeeping

requirements as the New Jersey primary drinking water rules, applicable to all public water systems. The Department's safe drinking water rules are, therefore, the Federal standards, except with respect to those areas for which the Department has determined, as authorized by the SDWA and allowed by the National Regulations, to establish New Jersey-specific requirements.

The Drinking Water Quality Institute (Institute) has recommended maximum contaminant level (MCLs) for PFNA and 1,2,3-TCP of 0.013 µg/L and 0.03 µg/L, respectively. Pursuant to the SDWA, N.J.S.A. 58:12A-13, the Department is authorized to promulgate MCLs based on those recommendations. Under the existing rules, the Department has MCLs for 14 contaminants that are more stringent than the Federal standards and for five contaminants for which no Federal standard has been established. With the addition of PFNA and 1,2,3-TCP New Jersey will have seven State-established MCL where no Federal standard exists.

The Institute's process for recommending MCLs is similar to the Federal process, with the differences noted below. The Institute considers three factors when recommending MCLs: health effects, technological ability to measure the contaminant level, and ability of existing treatment technologies to meet the MCL. For chemicals causing effects other than cancer (noncarcinogens), such as PFNA, New Jersey's goal is the elimination of all adverse health effects resulting from ingestion, within the limits of practicability and feasibility. With respect to carcinogens, such as 1,2,3-TCP, the goal of the recommended MCL is to permit cancer in no more than one in one million persons ingesting that chemical for a lifetime. The New Jersey

SDWA does not permit economic factors to be used in development of MCLs for carcinogens. In contrast, the health-based goal (that is, Maximum Contaminant Level Goal) for Federal MCLs for carcinogens is zero, and cost-benefit may be considered. The Institute evaluated the most current information available regarding PFNA and 1,2,3-TCP in drinking water before recommending MCLs to the Department.

The adoption of New Jersey-specific MCLs for PFNA and 1,2,3-TCP is necessary to protect public health. As established in the Institute's Health Effects Subcommittee reports both contaminants are associated with serious health effects. According to the Health Effects Subcommittee, PFNA is persistent in humans with a half-life for elimination of several years, exposure to relatively low drinking water concentrations is expected to substantially increase human body burden and the toxicological effects are relevant to humans. With respect to 1,2,3-TCP, the Health Effects Subcommittee indicated this contaminant is a potent carcinogen and that the non-carcinogenic effects include toxicity to liver, kidney, heart, nasal tissue, lung, and other organs.

Both contaminants were detected in public water systems in New Jersey as part of the third round of sampling pursuant to the Federal Unregulated Contaminant Monitoring Rule (UCMR3). While the Department has encouraged systems with elevated levels to continue to monitor and where necessary, install treatment to remove these contaminants, systems were under no obligation to comply with this request because MCLs had not yet been established. Therefore, with the adoption of State-MCLs the Department can mandate steps to reduce

exposure and protect public health. Through the Department's stakeholder process some water systems expressed support for the adoption of MCLs for unregulated contaminants because adopted regulations provide predictability. Design of treatment systems in the absence of a removal target can be both challenging and risky as the target is susceptible to change. Thus, systems are hesitant to invest in treatment without an MCL.

The Federal standards do not require public nontransient noncommunity water systems to monitor for radionuclides. However, the Department is adopting rules to require these water systems to monitor for radionuclides because these water systems, which include schools and office parks, serve populations that could be potentially exposed to radionuclides on a long-term basis. The negative health effects resulting from exposure to these carcinogens are well established.

The Private Well Testing Act (PWTA) rules, N.J.A.C. 7:9E, are not promulgated under the authority of, or in order to implement, comply with, or participate in any program established under Federal law or under a State statute that incorporates or refers to Federal law, Federal standards, or Federal requirements. Therefore, the Department has determined that a Federal standards analysis is not required.

The Regulations Governing the Certification of Laboratories and Environmental Measurements, N.J.A.C. 7:18, establish a certification program for laboratories seeking to become certified environmental laboratories. These rules also establish administrative procedures to be followed by certified environmental laboratories when performing

environmental analyses conducted in conformance with the SDWA and the PWTA. The Federal government does not administer a corresponding laboratory certification program and has no law that corresponds to this aspect of either the current rules or the proposed amendments. Therefore, no Federal standards analysis is required.

Full text of the adoption follows (additions to the proposal indicated in boldface with asterisks ***thus***; deletions from the proposal indicated in brackets with asterisks *[thus]*):

7:9E-2.1 Parameters for which testing is required

(a) Each water sample shall be analyzed for the following parameters:

1.-10. ((No change from proposal.))

11. As of *[(180 days after the effective date of these amendments)]* ***March 3, 2019***, the synthetic organic compounds 1,2,3-trichloropropane, ethylene dibromide, and 1,2-dibromo-3-chloropropane.

(b)-(c) (No change from proposal.)

7:10-12.30 Water quality analysis and treatment

(a)-(b) (No change from proposal.)

(c) Upon completion of construction of a water system, the owner of a nonpublic water system shall sample and analyze the raw water from the system for the parameters listed at (c)1 through 11 below. The administrative authority may require sampling and analysis for inorganic

chemicals, volatile organic compounds and/or radionuclides as appropriate based on the region and the aquifer in which the water source is located.

1.-8. (No change from proposal.)

9. As of *[(180 days after the effective date of these amendments)]* ***March 3, 2019***, the synthetic organic compounds 1,2,3-trichloropropane, ethylene dibromide, and 1,2-dibromo-3-chloropropane;

10.-11. (No change from proposal.)

(d)-(i) (No change.)