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## **ENVIRONMENTAL PROTECTION**

### **WATER RESOURCE MANAGEMENT**

#### **DIVISION OF WATER QUALITY**

##### **Ground Water Quality Standards; Discharges of Petroleum and Other Hazardous Substances Rules**

**Adopted Amendments: N.J.A.C. 7:1E Appendix A and 7:9C-1.7 and 7:9C Appendix;**

Proposed: April 3, 2017 at 49 N.J.R. 596(a).

Adopted:, by Bob Martin, Commissioner, Department of Environmental Protection.

Filed: as R.2017 d. **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 13:1D-1 et seq., 13:1D-125 through 133, 13:1K-1 et seq., 58:10-23.11, 58:10-46 through 50, 58:10A-1 et seq., and 58:11A-1 et seq.

DEP Docket Number: 03-17-03.

Effective Date:

Expiration Date:

The Department is adopting amendments to incorporate interim specific ground water quality criteria, interim practical quantitation levels (PQLs), and interim standards for 23 constituents of ground water as specific ground water quality criteria, PQLs, and standards. The Department is also proposing amendments providing that the Department may, in the appropriate case, use alternative values and/or modified equations in the derivation of interim specific and specific ground water quality criteria in order to ensure the criteria reflect the best available

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science. The Department is also proposing to add one of the constituents (specifically, perfluorononanoic acid or PFNA) to the List of Hazardous Substances at N.J.A.C. 7:1E Appendix A of the Discharges of Petroleum and Other Hazardous Substances rules.

**Summary of Hearing Officer's Recommendation and Agency Response:**

The Department held a public hearing on the notice of proposal on Friday, May 5, 2017, at the Department's Public Hearing Room, 401 East State Street, Trenton, New Jersey. Kimberly Cenno, Chief of the Department's Bureau of Environmental Analysis, Restoration and Standards, was the hearing officer. Two persons commented at the public hearing. After reviewing the comments received, the Hearing Officer recommended that the proposal be adopted. The Department accepts the Hearing Officer's recommendations. 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

Attention: DEP Docket No. 03-17-03

401 East State Street, 7th floor

Mail Code 401-04L

P.O. Box 402

Trenton, NJ 08625-0402

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**Summary of Public Comments and Agency Responses:**

The Department accepted comments on the proposal through June 2, 2017. The following individuals provided written and/or oral comments:

1. Susan Babbitt
2. Janice Banks
3. EA Berg
4. Richard Bizub, Director for Water Programs, Pinelands Preservation Alliance
5. Sara Bluhm, Vice President, Government Affairs, Energy and Environment, New Jersey Business and Industry Association
6. Hon. John J. Burzichelli, Assemblyman, District 3
7. Rebecca Canright
8. Tracy Carluccio, Deputy Director, Delaware Riverkeeper Network
9. Tracy Carluccio and Maya van Rossum, Delaware Riverkeeper Network
10. Gina Carola
11. Anne Dente
12. Ryan Dodson
13. Scott Drew, L.S.R.P., Geosyntec, on behalf of New Jersey Licensed Site Remediation Professionals Association
14. Christopher Dunham
15. Michael Egenton, New Jersey State Chamber of Commerce

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16. Ann Finneran, Sierra Club Atlantic Chapter
17. Robin Freisem
18. Sharon Furlong
19. Joseph Ganci
20. Chuck Graver
21. Mark Harris
22. Dennis Hart, on behalf of the Chemistry Council of New Jersey and the Site Remediation Industry Network
23. Andy Kahan
24. Bill Kellner
25. Debbie King
26. Robert Kingsley
27. Rebecca Koo
28. Thomas Koven
29. Lida Lang
30. David LaVerne
31. Madeleine Lee
32. Gerson Lesser, M.D., New York University School of Medicine
33. Felicia Lewis
34. Richard McNutt, President, Tidewaters Gateway Partnership, Inc.
35. David Miller
36. Anthony Montapert

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37. Dwayne Munar

38. Mary O'Malley

39. Christopher Peditto

40. Elizabeth Peer

41. Vincent Prudente

42. Jean Publieee

43. Joseph Quirk

44. Beverly Railsback

45. Christopher M. Roe, Fox Rothschild LLP, on behalf of Solvay Specialty Polymers USE, LLC,

46. James Rosenthal

47. Kelley Scanlon

48. Dennis Schaef

49. Mary Schmidt

50. Kate Schumacher, Moms Clean Air Force

51. P. Scoville

52. Kim Sellon

53. Meg Sleeper

54. Elizabeth Thompson

55. Olga Vannucci

56. Jeff Tittel, New Jersey Sierra Club

57. Kimi Wei

58. Dr. Susan Yatsky

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59. Donna Yavorsky

60. Faith Zerbe

A summary of the timely submitted comments and the Department's responses follows.

The number(s) in parentheses after each comment identify the respective commenter(s) listed above.

### **Public comment period**

1. COMMENT: The due date for comments should be extended an additional four weeks to June 30, 2017. In light of the importance of this rule proposal to the public and industry, the comment period is not sufficient to appropriately review the proposed amendments and available compound-specific toxicological studies. In addition, a report from Rutgers University regarding the analysis of PFNA (and similar chemicals) in blood serum samples of Paulsboro, New Jersey, residents is expected to be completed in June 2017. An extension of time to submit comments would provide the opportunity to thoroughly review this information and further understanding of the associated health effects; also the Department is obligated to consider the best available science in setting regulatory standards. (15 and 22)

RESPONSE: The Department did not extend the comment period because it was not appropriate to defer or delay the rulemaking based on the anticipated publication of a Rutgers study. When the study is completed and the full scientific report available, the Department will evaluate it. The

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Department provided the full 60-day public comment period required by the Administrative Procedure Act, as well as the opportunity to provide comment at the public hearing on the proposal held on May 5, 2017, in Trenton. The Basis and Background document, which was made available on the Department's website at the time the proposal was published, details the technical and scientific basis for the adopted ground water quality standards. (See Basis and Background for Criteria Derivation and Practical Quantitation Levels, Ground Water Quality Standards Rule Amendments N.J.A.C.7:9C, March 2017, [www.nj.gov/dep/rules](http://www.nj.gov/dep/rules).)

### **Comments in support of the amendments**

2. COMMENT: It is extremely important for the Department to establish groundwater standards to address ongoing water quality contamination. (50 and 55)

3. COMMENT: The proposed amendments are supported, including adding PFNA as a Hazardous Substance under the Spill Compensation and Control Act in order to remove this highly toxic contaminant from the environment to protect our drinking water sources, ecosystems and public health; using the most valid scientific methods available to develop water standards that will best protect the public and most effectively remove contaminants from the environment; and incorporating interim specific groundwater quality standards, interim practical quantification levels (PQL), and interim standards for the listed constituents into the official Standards. (1, 3, 4, 7, 10, 11, 12, 14, 16, 17, 18, 19, 20, 21, 23, 25, 26, 27, 29, 30, 31, 32, 33, 35, 36, 37, 38, 39, 41, 42, 43, 44, 46, 48, 49, 51, 52, 53, 57, 58, 59, and 60)

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4. COMMENT: The incorporation of interim specific groundwater quality standards, interim practical quantification levels and interim standards for the 23 proposed constituents into the official standards is supported. This important step to make these official standards removes any doubt as to the enforceability of specific values regarding these constituents and allows New Jersey to authoritatively move forward with the application of these critical standards to protect and clean up groundwater contamination for the benefit of the state's water, public health and the affected ecological systems and habitats. (8)

5. COMMENT: The proposed amendments are supported, including standards for PFNA, cobalt and the rest of the constituents. These amendments are critical because PFNA is becoming more pervasive when it comes to ground water in New Jersey and affecting drinking water supplies. It is critical to clean up the ground water to an appropriate standard because of direct connection between ground water cleanup standards and drinking water. In southern New Jersey and parts of central and northwestern New Jersey, the drinking water for the residents is from ground water that may contain contamination that is from past manufacturing or use of foam and the water must be cleaned up to a level that is appropriate to protect human health. (56)

6. COMMENT: The update of PFNA from an interim specific criterion to a specific criterion is supported, since there has been a lot of attention recently to perfluorinated compounds detected in ground water around military bases nationwide and, in New Jersey, in and around Joint Base-McGuire-Dix-Lakehurst (JB MDL). (4)



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7. COMMENT: The Department's proposal to add PFNA to the Discharges of Petroleum and Other Hazardous Substances (DPHS) Appendix A, List of Hazardous Substances, found at N.J.A.C. 7:1E is supported. PFNA is highly soluble and mobile in the ground water system and is extremely persistent once it enters the environment. In southern New Jersey, the shallow Kirkwood-Cohansey aquifer provides over 90 percent of water as baseflow to streams, rivers and associated wetlands. Protecting the Kirkwood-Cohansey aquifer system from PFNA, and remediating the aquifer once PFNA has been detected is vital to human health and maintaining the integrity of the environment. Including PFNA on the Hazardous Substance List is supported because it will provide a mechanism through the Spill Compensation and Control Act for comprehensive measures to regulate entities involved in the storage and transfer of this organic compound, will impose strict liability for cleanup and removal costs as a result of any discharge to ground waters of the State, and provide a mechanism for compensating individual property owners whose individual wells have been contaminated with PFNA. (4 and 8)

RESPONSE TO COMMENTS 2 THROUGH 7: The Department acknowledges these comments in support of the amended rules.

### **Compliance with Administrative Procedure Act**

8. COMMENT: The Department's proposal to deviate from required equations at N.J.A.C. 7:9C-1.7(c)4 would undermine the due process protections of the Administrative Procedure Act (APA).

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The proposed rule would permit the Department to deviate from the required equations and, where the Department does so, the Department will “explain the basis for using any alternative value or modified equation in supplemental information accompanying a new or revised interim specific ground water quality criterion made available to the public on the Department’s website or in the Summary statement of the rulemaking for a new or revised specific ground water quality criterion.” This aspect of the proposed rule shows that the “flexibility” the Department seeks to grant itself in imposing groundwater standards directly conflicts with the requirements of the APA mandating notice and comment.

If the proposed amendments were adopted, then the Department could deviate from the required equation, or even an IRIS default value, and post the resulting new or revised interim criterion on its website with “supplemental information” to explain the basis for that deviation. The criterion would become immediately enforceable as law under New Jersey environmental clean-up laws, there being no opportunity for notice and comment on the new criterion and on use of alternative values or modified equations in the derivation of that new or revised criterion until the Department determines to replace the interim specific ground water quality criterion with a final specific ground water quality criterion. Affected parties will not have any pre-adoption opportunity to comment on the propriety or scientific validity of the alternative values or modified equations, or on the Department’s explanation of its purported basis for deviating from the prescribed values and equations. (5, 22, and 45)

RESPONSE: The amendments to N.J.A.C. 7:9C-1.7(c)4iv and v, which are being adopted after public notice and comment in accordance with the APA, establish the limited circumstances in

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which the Department might determine it is necessary to derive a criterion using an alternative value(s) in one of the equations set forth in the rule and/or using a modified equation. Specifically, the Department will determine to use an alternative value or a modified equation based on constituent-specific factors and/or data, as well as applicable USEPA guidance, generally accepted scientific evidence and methodologies, and/or applicable peer reviewed sources of information. Should the Department derive a criterion using an alternative value or a modified equation, it will make its basis for doing so publicly available. In the proposal summary, the Department offered examples of constituent-specific factors and data that support the substitution of an alternative value in the equation, including when the IRIS database does not have a toxicity factor for a particular constituent, or if the risk posed by a particular constituent is greater for children than for adults, such that the default exposure assumption is not appropriate. As to when it might be necessary to use a modified equation, the example offered is if a reference dose for non-carcinogenic effects cannot be derived because there is no threshold for the effects since the effects are manifested at any dose level.

The process by which interim specific ground water quality criteria are established pursuant to existing N.J.A.C. 7:9C-1.7(c)2 and 3 was not proposed to be modified. That process was initially promulgated in 1993 (see 24 N.J.R. 181(a); 25 N.J.R. 464(a)) and was recodified and readopted with amendments in 2005 (see 36 N.J.R. 4374(b); 37 N.J.R. 4226(b)) in accordance with the notice and comment requirements of the APA. The criteria become enforceable for purposes of the remediation of contaminated sites in accordance with the Department's Remediation Standards, N.J.A.C. 7:26D, which were promulgated pursuant to and in compliance with the Brownfield and Contaminated Site Remediation Act, N.J.S.A. 58:10B-1 et seq., as well

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as the Water Pollution Control Act, N.J.S.A. 58:10A-1 et seq., and the Spill Compensation and Control Act, N.J.S.A. 58:10-23.11a et seq. The requirements of the Remediation Standards are not the subject of this rulemaking.

9. COMMENT: The Department did not provide a concise explanation of the purpose and effects of the proposed amendments. The proposal contains very little explanation of the implications and effects of all the proposed rule changes. (45)

RESPONSE: As explained in the summary, the purpose of the proposal was to incorporate interim specific ground water quality criteria, interim practical quantitation levels (PQL), and interim standards for 23 constituents of ground water as specific ground water quality criteria, PQLs, and standards. In addition, the proposal included provisions that enable the Department to, in the appropriate case, use alternative values and/or modified equations to derive specific ground water quality criteria. These amendments are intended to ensure the criteria reflect the best available science so as to be most protective of human health.

The Department amended the List of Hazardous Substances at Appendix A of the DPHS rules to add PFNA because ground water contamination caused by PFNA, which is a developmental toxicant, liver toxicant, and immune system toxicant that bioaccumulates in humans, is anticipated to continue in the foreseeable future due to its persistence as well as formation from precursor compounds in the environment. By adding PFNA to the list, owners and operators of major facilities that handle PFNA will be subject to all the discharge and prevention

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and control requirements of the Spill Act and the DPHS rules, funding of PFNA remediation under the Spill Act and payment of damage claims regarding PFNA discharges pursuant to the Spill Act Damage Claims rules will be enabled, and persons with Spill Act liability will be subject to the requirement to remediate discharges of PFNA.

The Department undertook in each of the required statements and analyses included in the proposal in accordance with the APA to identify the overall impacts expected when the ground water quality standards are implemented in the course of cleanups and as a result of the addition of PFNA to the DPHS Appendix A List of Hazardous Substances.

10. COMMENT: The Department did not provide a meaningful description of the expected social impact of the imposition of the final ground water quality criteria, only that the final criteria “will ensure that current and scientifically based standards to protect, maintain, and restore groundwater quality are in place.” As to the social impact of the proposed amendments that would provide that the Department may use alternative values and modified equations in the derivation of specific and interim specific groundwater quality criteria, the Department states only that these changes “will provide appropriate flexibility for the Department to derive standards that are most protective of human health.”

As to the social impact of adding PFNA to the DPHS List of Hazardous Substances, the Department suggests that it would be positive in that major facilities storing or handling PFNA would be subject to rules related to discharge prevention and control. However, the Department also acknowledges that the use of PFNA has been phased out pursuant to USEPA’s 2010/2015 PFOA Stewardship Program. Therefore, this benefit is illusory. Further, the Department suggests

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that if PFNA is listed as a hazardous substance, persons with Spill Act liability will be required to remediate discharges of PFNA. However, under the Department's Remediation Standards, the mere setting of a ground water quality criterion for PFNA subjects PFNA to cleanup requirements under New Jersey's key environmental statutes, regardless of whether the substances are listed as hazardous substances. See N.J.A.C. 7:26D- 2.2(a). Again, the benefit appears to be illusory. The Department asserts that access to the Spill Fund and damage claims are social benefits, but ignores any social impact and disruption that has arisen and will continue to arise from listing PFNA as a hazardous substance in the first place and of regulating PFNA in the groundwater to a level 100 times lower than the level that is consistently detected in the blood samples from Americans nationwide. (5 and 45)

RESPONSE: With regard to the amendments to the GWQS, the commenter does not indicate why the social impact statement is not meaningful. The overall social impact of incorporating the specific ground water quality standards and establishing provisions allowing the use of an alternative value(s) or modified equation to derive criteria in limited circumstances is expected to be, as explained in the social impact statement, the protection, maintenance, and restoration of the ground water in New Jersey, which is the source of approximately 40 percent of the State's potable water.

The Department did acknowledge that the use of PFNA has been largely phased out pursuant to USEPA's 2010/2015 PFOA Stewardship Program. However, the discharge prevention and control provisions of the DPHS rules as applicable to major facilities will help ensure ongoing protection of the environment from potential PFNA contamination. While the Remediation

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Standards do establish that the ground water quality criteria are the minimum standards for the remediation of contaminated ground water, the addition of PFNA to the List of Hazardous Substances subjects persons with Spill Act liability to the requirements of that statute and the Department's implementing rules with respect to remediating PFNA discharges.

The commenter seems to suggest that there is an adverse social impact, or "disruption," that arises from the listing of PFNA as a hazardous substance, as well as from promulgating the PFNA ground water quality standard at 0.01 micrograms per liter, but does not identify what that disruptive social impact might be; consequently, the Department is not able to further address the commenter's concerns.

11. COMMENT: The Department has not presented an adequate regulatory flexibility analysis, job impacts statement (including an assessment of the number of jobs generated or lost), agriculture impact statement, housing affordability impact statement, or smart growth development statement as required by the APA. As to the proposed final ground water quality criteria, each of the required statements relates to the three of 23 constituents for which final specific criteria and PQLs are proposed and are inadequate. (15 and 45)

RESPONSE: The Department identified the overall impacts expected when the ground water quality standards are implemented in the course of cleanups and as a result of the addition of PFNA to the DPHS Appendix A List of Hazardous Substances. The commenter does not specify how the identified statements and analyses, which all reflect aspects of the economic impact of the amendments, are inadequate. The Department explained that the economic impacts of the specific

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ground water quality standards will be site-specific and will depend on various factors, such as the increase in the portion of the plume that must be remediated, the volume and characteristics of wastewater being discharged, the contaminants in the wastewater or ground water, the number of additional monitoring wells required, and the type of treatment currently being implemented.

Accordingly, any impact on employment will depend on the individual business operation decisions of those conducting the remediation and cannot be predicted by the Department. Any impacts to the agriculture industry will similarly depend on whether a particular constituent is used in agriculture such that agricultural entities would be responsible for remediating ground water contamination caused by that constituent. As noted in the Regulatory Flexibility Analysis, the requirements applicable to small businesses under the Department's rules governing site remediation generally do not vary from those applicable to any other person responsible for conducting remediation because the health risks presented by the contamination that must be addressed are the same no matter what entity is responsible for conducting the remediation.

Finally, as to the Housing Affordability Impact and Smart Growth Development Impact Analyses, the Department made the statutorily required findings, specifically, that ensuring up-to-date and scientifically based ground water quality standards are in place, and adding PFNA to the List of Hazardous Substances, are extremely unlikely to evoke either a 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.

12. COMMENT: The Department did not provide an analysis of why the proposed requirements exceed the standards and requirements imposed by Federal law. The Spill Act requires that the



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Department's list of hazardous substances "shall be consistent to the maximum extent possible" with the USEPA hazardous substance lists (N.J.S.A. 58:10-23.11b). The Department's ground water quality standards define reference dose as the "value from the US EPA IRIS data base," which is incorporated by reference (N.J.A.C. 7:9C-1.7(c)4i and ii). The Brownfield Act requires the Department to consider and utilize "toxicity factors, slope factors for carcinogens and reference doses for non-carcinogens from the United States Environmental Protection Agency's Integrated Risk Information Systems" (N.J.S.A. 58:10B-12(b)(5)). The proposed amendments thus do involve New Jersey statutes and regulations that directly refer to and incorporate Federal law.

However, no Federal list includes PFNA as a hazardous substance. In addition, the Federal government has set no cleanup standard of any kind for PFNA. In fact, the Federal government's Agency for Toxic Substances and Disease Registry (ATSDR) has so far concluded that there is no basis upon which to establish a health based cleanup standard for PFNA. (See, e.g., ATSDR, Draft Toxicological Profile for Perfluoroalkyls (August 2015) at 32 (declining to conclude sufficient data exist for derivation of Minimal Risk Level for PFNA); ATSDR, 2015). Therefore, the APA requires that the rulemaking include a statement that includes a discussion of the policy reasons and a cost-benefit analysis that supports the proposed rulemaking and that the proposed standards are achievable. (5 and 45)

RESPONSE: As explained in the Federal Standards Statement, the enabling authorities for the GWQS are State statutes and the rules have no Federal counterpart. References to the use of IRIS information in the GWQS for purposes of the equations for deriving ground water quality criteria and in the Brownfield Act for purposes of developing remediation standards do not of themselves

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trigger a Federal Standards Analysis under the APA. Likewise, the DPHS rules 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. Consequently, the proposed amendments do not exceed any Federal standards and no further analysis is required. As the commenter indicates, and as explained in the Federal Standards Statement, PFNA is not among the substances to which Federal regulations promulgated pursuant to the Federal Water Pollution Control Act and the Comprehensive Environmental Response, Compensation and Liability Act that govern discharge prevention and reporting apply. However, the Department determined that because PFNA poses an unacceptable risk to public health, its addition to the DPHS Appendix A List of Hazardous Substances is appropriate in order to further protect the environment from potential PFNA discharges at major facilities and to facilitate the remediation of PFNA discharges that have and might occur.

13. COMMENT: The 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 ground water quality criteria will 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. For purposes of adopting remedial standards, the Brownfield Act requires, among

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other things, generally accepted and peer reviewed scientific evidence or methodologies, reasonable assumptions of exposure scenarios, and the avoidance of redundant conservative assumptions. N.J.S.A. 58:10B-12. (22 and 45)

RESPONSE: The proposal caption identified the statutory authority for the rules as 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 GWQS rules are not promulgated under the authority of those acts. However, as explained in responses to comments below regarding the basis for the ground water quality criteria for PFNA and other constituents, the methods for deriving the criteria, which are described in detail in the Basis and Background document for the rulemaking (see [www.nj.gov/dep/rules](http://www.nj.gov/dep/rules)), are consistent with the requirements in the Brownfield Act and related statutes for adopting remedial standards.

14. COMMENT: The Department did not provide a full economic analysis for the interim specific ground water quality criteria being incorporated as specific ground water quality criteria. As to the three substances for which stricter final standards are being set, the Department did provide information on the number of sites it expects will be impacted by the change and pointed out that

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none of these three final criteria will be more than an order of magnitude stricter than the interim standard. The Department needs to provide an economic analysis of the proposed specific ground water quality criteria in comparison to the standard that applied prior to the interim specific criteria. (5, 22, and 45)

RESPONSE: The amendments replace the interim specific ground water quality criteria, interim PQLs, and interim ground water quality standards for 23 constituents found in Class II-A ground water with specific ground water quality criteria, PQLs, and standards incorporated into the rules at Appendix Table 1. The applicable ground water quality standard for a discharge to Class II-A ground water and the minimum remediation standard for the cleanup of contaminated ground water is, for any particular constituent, the higher of the criterion and the PQL.

The establishment of the interim specific ground water quality criteria and standards benefited the citizens of New Jersey by aiding in the restoration and protection of the ground water of the State, and facilitating the prompt remediation of ground water contaminated with these constituents. The benefits accrued to manufacturing businesses, farms, small businesses, and other service providers that rely on clean ground water as part of their operations or process, as well as the approximately 40 percent of New Jersey residents who rely on ground water as their drinking water supply, including many schools and homes served by private wells. The persons responsible for the cleanup and restoration of contaminated ground water were also affected by the establishment of the standards.

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The Department notes that for nine of the 23 constituents, the interim specific ground water quality standards were established at the request of the person responsible for conducting the remediation, as follows:

Site location: North Brunswick, Middlesex County

- Cresols (mixed isomers)
- Freon 113 (1,1,2-trichloro-1,2,2 trifluoroethane)
- Tri-cresyl phosphate (mixed isomers)
- Tri-ortho-cresyl phosphate

Site location: West Deptford, Gloucester County

- 1-chloro-1,1 difluoroethane
- 1,1- dichloro-1-fluoroethane
- 1,1,1 trifluoroethane

Site location: Paulsboro, Gloucester County

- Strontium

Site location: Chester, Morris County

- 1,4-Dioxane

The economic impact statement in the proposal focused on the three constituents (caprolactam, 4,6-dinitro-o-cresol, and 2-hexanone) for which the specific ground water quality standard incorporated into Appendix Table 1 became more stringent relative to the interim specific standard. As noted in the proposal summary, for the other 20 constituents, the specific ground water quality standard did not change relative to the interim specific standard.

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The economic impact analysis in the proposal stated: “As of December 31, 2016, of the 14,357 active site remediation cases, there were no active site remediation cases in which caprolactam was detected at concentrations above either the interim specific ground water quality standard or the proposed specific ground water quality standard.” As of August 31, 2017, there were 14,236 active cases. As of August 31, 2017, there still were no active site remediation cases in which caprolactam was detected at concentrations above either the interim specific ground water quality standard or the proposed and now-adopted specific ground water quality standard. The economic impact also stated: “There were 13 active cases in which 2-hexanone was detected at concentrations between the interim and the proposed standard and the person responsible for conducting the remediation had not obtained an approved or certified RAW.” As of August 31, 2017, the number of active cases in which 2-hexanone was detected at concentrations between the interim and the now-adopted standard and the person responsible for conducting the remediation had not obtained an approved or certified RAW increased to 16. The rule proposal also stated: “There were two cases in which 4,6-dinitro-o-cresol was detected at concentrations between the interim and proposed standard and the person responsible for conducting the remediation had not obtained an approved or certified RAW.” As of August 31, 2017, the number of active cases in which 4,6-dinitro-o-cresol was detected at concentrations between the interim and the now-adopted standard and the person responsible for conducting the remediation had not obtained an approved or certified RAW increased to five.

In 99.5 percent of the 14,236 total number of active cases, the other 20 constituents have not been detected or have been detected at concentrations below the now-adopted specific ground

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water quality standard. The numbers of cases in which these 20 constituents have been found at concentrations above the now-adopted specific ground water quality standard are as follows:

- 1-Chloro-1,1-difluoroethane (1 case)
- Cobalt (84 cases)
- Cresols – mixed isomers (52 cases)
- 1,1-Dichloro-1-fluoroethane (2 cases)
- Dichloromid (0 cases)
- 1,4-Dioxane (257 cases)
- Diphenyl ether (15 cases)
- 2-Ethyl-1-hexanol (14 cases)
- Hexahydro-1,3,5-trinitro-1,3,5-triazine (1 case)
- 2-(2-Methyl-4-chlorophenoxy) propionic acid (23 cases)
- 2-Methylnaphthalene (762 cases)
- Metolachlor (0 cases)
- Perchlorate (0 cases)
- Perfluorononanoic acid (PFNA) (3 cases)
- Strontium (1 case)
- 1,1,2-Trichloro-1,2,2-trifluoroethane (7 cases)
- Tricresyl phosphate – mixed isomers (3 cases)
- 1,1,1-Trifluoroethane (5 cases)
- 2,4,6-Trinitrotoluene (TNT) (0 cases)
- Tri-ortho-cresyl phosphate (0 cases)

To address the commenter's concern, the Department has compared all 23 specific criteria to the interim generic criteria that, pursuant to N.J.A.C. 7:9C-1.7(c)6, applied prior to the establishment of the interim specific criteria for the constituents. The interim generic criteria (found in Appendix Table 2) apply to any synthetic organic chemical (SOC) not listed in Appendix Table 1. The interim generic water quality criteria are five micrograms per liter ( $\mu\text{g/L}$ ) for any

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SOC defined as a carcinogen and 100 µg/L for any SOC defined as a non-carcinogen. The specific ground water quality criterion for 12 (identified below) of the 23 constituents is more stringent than the applicable interim generic ground water quality criterion.

- Cresols – mixed isomers (non-carcinogen)
- 4,6-Dinitro-o-cresol (non-carcinogen)
- 1,4-Dioxane (carcinogen)
- Hexahydro-1,3,5-trinitro-1,3,5-triazine, (carcinogen)
- 2-Hexanone, (non-carcinogen)
- 2-(2-Methyl-4-chlorophenoxy) propionic acid, (non-carcinogen)
- 2-Methylnaphthalene, (non-carcinogen)
- Perchlorate, (non-carcinogen)
- Perfluorononanoic acid (PFNA), (non-carcinogen)
- 2,4,6-Trinitrotoluene (TNT), (carcinogen)
- Tricresyl phosphate – mixed isomers, (non-carcinogen)
- Tri-ortho-cresyl phosphate, (non-carcinogen)

The Department recognizes that there are economic costs associated with the investigation and remediation of ground water constituents at contaminated sites. The implementation of specific ground water quality standards may significantly affect the remediation of contaminated sites to the extent that a person responsible for conducting the remediation may have to modify a remediation plan to address previously unregulated ground water constituents or to remediate to a more stringent standard. When specific ground water quality standards are established, they are applied to new cases and to cases for which the person responsible for conducting the remediation has not submitted a remedial action workplan (RAW) or similar document. Additionally, pursuant to the “order of magnitude” provisions of the Brownfield and Contaminated Site Act, N.J.S.A.



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58:10B-12(j) and -13(e), under certain circumstances, the Department may compel additional remediation when a remediation standard changes. Specifically, even if the Department or a Licensed Site Remediation Professional (LSRP) has approved a RAW or similar plan or has issued a no further action (NFA) letter or an LSRP has issued a Response Action Outcome (RAO) for a site, the Department may compel the use of the changed remedial standard if it differs from the prior-approved standard by an order of magnitude or more. If the Department's review of the specific circumstances of a case where the applicable remediation standard has changed by an order of magnitude or more indicates the selected remedial action does not remain protective of human health, further remediation may be required.

The actual economic impact on persons remediating contaminated sites where the specific ground water quality standard for one or more of the 23 constituents is implemented is site-specific and depends on many factors. It is not possible to determine a specific dollar value for the impact associated with remediating contaminated ground water due to site-specific variability with respect to extent of contamination, geology, ground water transport characteristics, and treatment complexity. The Department believes that, in most cases, best available technology is currently being used to remediate ground water. Best available technology is generally able to achieve a 99 percent reduction of volatile organic and other synthetic organic chemicals and a 90 percent reduction of metals. Because these systems are able to remove contaminants to very low levels, they also are anticipated to effectively treat ground water to the specific ground water quality standards. Where a standard becomes more stringent, the duration of treatment may be longer, but the Department is unable to accurately estimate these impacts as they are highly dependent on site-specific conditions.

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The Department also recognizes that there are economic costs associated with the treatment of discharges to Class II-A ground waters under New Jersey Pollutant Discharge Elimination System (NJPDES) permits. The overall impact on facilities discharging to ground water pursuant to a NJPDES permit depends on many factors such as the size of the plume, the volume and type of wastewater being discharged, the contaminants in the water being discharged, the number of monitoring wells required, and the type of any treatment currently being used.

As noted in the proposal summary, the amendments reflect the best available science concerning the impacts of the regulated constituents on human health. For the same reasons of site-specific variability and complexity relating to contamination and treatment that it is not possible to specifically determine the costs of remediating ground water to the persons conducting the remediation, it is not possible to accurately determine the economic benefits of avoided future negative outcomes attributable to remediating contaminated ground water. However, the reduced risk to New Jersey citizens of implementing the specific ground water quality standards translates to the overall economic benefit of avoided negative health outcomes, including likely fewer mortalities, hospitalizations, and illness, and the corresponding avoided health care expenditures and potential loss of productivity and income.

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

15. 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,

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including the private sector and academia. 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 proposal in a way that imposes the least burden and costs to business, including paperwork and other compliance costs. That the proposed amendments will allow the Department to deviate from the required equations does not promote transparency and predictability regarding regulatory activity. (15, 22, and 45)

RESPONSE: The Department proposed and is adopting the amendments in accordance with the requirements of the APA. Executive Order No. 2 (2010) (see <http://www.state.nj.us/infobank/circular/eocc2.pdf>) sets forth a set of “Common Sense Principles” to inform the executive agencies’ rulemaking process. The Department’s amended rules are promulgated in accordance with the APA and at the same time reflect the principles articulated in Executive Order No. 2 (2010).

The Department initiated a stakeholder process in 2016 to solicit advice and views from various stakeholders. The Department invited stakeholders to attend discussions regarding potential amendments to the GWQS rules, including this rulemaking. The stakeholders included county health departments, Rutgers University, business, industry, and consulting firms, and business associations and environmental groups. The discussions were held at the Department on

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April 11, 2016. Stakeholders were provided by email on March 22, 2017, advance notice of the amendments to the GWQS rules.

The proposed amendments reflect the Department's determination that the costs of implementing the specific ground water quality standards as minimum remediation standards do not outweigh the benefits of protecting, maintaining, and restoring the ground water quality, given that 40 percent of the State's potable drinking water comes from ground water sources. The impacts will be site-specific and will depend on many factors, such as the increase in the portion of the plume that must be remediated, the volume and characteristics of wastewater being discharged, the contaminants in the wastewater or ground water, the number of additional monitoring wells required, and the type of treatment currently being implemented. See also response to Comment 14).

As explained in the Federal Standards Statement, the GWQS rules and DPHS rules 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, an analysis of why the proposed requirements exceed the standards and requirements imposed by Federal law is not necessary.

The Department explained in the summary of the proposal that it had reevaluated the interim specific ground water quality criteria and interim PQLs associated with them to ensure that they reflect the best available science. The Department made available on the Department's website at [www.nj.gov/dep/rules](http://www.nj.gov/dep/rules) a Basis and Background document containing technical detail in support of the amendments.

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As discussed in the Regulatory Flexibility Analysis, the amendments to the GWQS rules and DPHS rules may require small businesses to conduct remediation to comply with the standards or may affect small businesses that meet the threshold hazardous substance storage capacity requirements in the Spill Compensation and Control Act, N.J.S.A. 58:10-23.11 et seq., and DPHS rules, under certain circumstances. However, the risk to public health posed by the contamination is the same whether or not the person responsible for conducting the remediation is a small business. Consequently, the Department's rules governing site remediation do not provide for reduction in clean up requirements based on small business status, except in limited circumstances. Likewise, the DPHS rules that are applicable to any person responsible for a discharge will also apply to small businesses.

The commenter does not indicate in what way the amendments providing that the Department may derive a criterion using an alternative value(s) or a modified equation do not promote transparency and predictability regarding regulatory activity. The amendments establish the limited circumstances in which the Department might determine it is necessary to do so and provide that, if the Department should determine to derive a criterion using an alternative value or a modified equation, it will make its basis for doing so publicly available.

**Use of alternative values and modified equation should be subject to formal peer review**

16. COMMENT: The proposed amendments to allow the use of alternative values and/or modified equations in the derivation of interim specific and specific GWQC is arbitrary, based on the Department's subjective professional judgment, and does not allow for transparency,

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external peer review, and scientific consensus. The selection of alternative values and/or modified equations should undergo a formal peer review process by a qualified and independent third party group. An external peer review process provides more scientific credibility and consensus, as well as a more balanced scientific weight of the evidence approach as compared to mere reliance upon “peer reviewed sources of information” and the subjective professional opinions by the Department’s Office of Science.

Given NJDEP’s deviation from the generally accepted, RfD-based equation and approach required in N.J.A.C 7:9C-1.7(c)4 in its calculation of a ground water quality criterion for PFNA, per U.S. Office of Management and Budget (OMB) (USOMB, 2004) and numerous EPA policies and guidance (USEPA 2003, 2006, 2013a, 2015), the PFNA ground water quality criterion must undergo external peer review by independent experts to ensure the derivation is consistent with standard scientific principles. Both EPA 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 New Jersey Drinking Water Quality Institute’s (DWQI) work on PFNA does not qualify as an independent peer review. The NJDEP’s technical support documents for the PFNA GWQC and DWQI’s health-based support documents for PFNA share the same principal author. Moreover, individuals with public health experience from NJ Department of Health are stakeholders in the results of the PFNA toxicology analysis and are not completely independent from the NJDEP. They are also not “peers” who routinely conduct toxicity assessments for environmental contaminants. Both EPA and OMB are clear that public comment and other stakeholder processes, although important, do not qualify as the intended peer review (USEPA, 2015). (15, 22, and 45)

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RESPONSE: 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. Peer review of the derivation of a ground water quality criterion using an alternative value(s) and/or a modified equation is an option that could be used on a case-specific basis, but the Department does not at this time have a formal peer review process or procedure for developing ground water quality criteria. USEPA has not, to date, conducted peer review in the development of ambient water quality human health criteria. 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 USEPA when they do conduct peer review; the guidance does not require that peer review be conducted.

DWQI is established by the New Jersey Safe Drinking Water Act, at N.J.S.A. 58:12A-20, and has a statutorily specified role as an advisory body to evaluate scientific information and make recommendations to the Commissioner of the Department for the implementation of the Department's drinking water quality program, including maximum contaminant levels (MCLs). DWQI does not function as a peer review group. However, because DWQI develops health-based levels for constituents in drinking water for which MCLs will be recommended to the Department, the Department utilizes its work when developing ground water quality criteria.

The use of alternative values and/or modified equations is not arbitrary. As the rule provides, the use of alternative values and/or modified equations will be based on constituent-specific factors and/or data, as well as applicable USEPA guidance, generally accepted scientific evidence and methodologies, and/or peer-reviewed sources of information. Contaminants vary

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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 in order to adequately protect public health. The default values and the equations in the rules may not be scientifically appropriate and/or protective in every case.

The Department notes that, with respect to the development of the ground water quality criterion for PFNA, the Department twice sought public comment on the draft interim specific ground water quality criterion. The Department took into consideration in establishing the criterion the comments and information developed by scientists and experts that were submitted by commenters. See <http://www.state.nj.us/dep/dsr/supportdocs/>.

## **Ground Water Quality Criterion for PFNA**

### Uncertainty Factors

17. COMMENT: In its draft interim PFNA groundwater criterion for PFNA (NJDEP, 2014), NJDEP proposed a cumulative or composite uncertainty factor (CUF) of 300, now revised to a CUF of 1000 (NJDEP, 2015a). The revised CUF of 1000 is based on a UF of 10 for intraspecies differences (human variation), a UF of 10 for extrapolation from nonchronic to chronic, a UF of 3 for incomplete database (notably for the lack of carcinogenic studies), and a UF of 3 (3.16) for extrapolation from animal to human (interspecies) for toxicodynamic differences. We concur that toxicokinetic differences between species (human and test animals) is accommodated since the target tissue in both species is blood serum level. Therefore, no UF is needed for toxicokinetic



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interspecies extrapolation and the total UF for interspecies is 3, based on the  $\frac{1}{2}$  log unit of 10 (square root of 10) for each of toxicokinetic and toxicodynamic interspecies differences, or 3 rounded from 3.16 for toxicodynamic differences alone. This is consistent with EPA's position: "interspecies differences in TK are defined as differences in the external dose producing the same level of the dose metric in the target tissue of interest in test animals" (USEPA, 2014a). We concur with use of a UF of 10 for intraspecies variation in humans and a UF of 10 for extrapolation from non-chronic to chronic, as these UFs are consistent with EPA guidance. NJDEP uses a UF of 3 for incomplete database although important toxicological endpoint data are missing for PFNA, notably cancer testing in animals. A UF of 10 could also be reasonably applied as the default for incomplete database. If we use a UF of 10 for lack of data then a CUF would be 3000. However, uncertainty values chosen are inherently subject to bias, and therefore a resultant calculation can be manipulated – either towards a conservative or a less conservative result. We have no scientific basis to assign a more conservative UF value for incomplete database, underscoring the use of professional judgment where a UF of 3 and 10 are often equivalently applied in risk assessments for lack of data, as an expression of the range of missing data. We concur with a CUF of 1000, which is consistent with CUF's commonly applied in other health risk assessments for non-carcinogenic endpoints. We note that although a CUF of 3000 could also be reasonably applied, it generally represents the highest CUF level used in risk assessments. (9)

18. COMMENT: The uncertainty factors (UFs) used in the GWQC calculation are misapplied and overly conservative, thereby rendering the final PFNA GWQS overly stringent and technically unsupportable. NJDEP characterized the total uncertainty factor (UF) as 1,000 in its calculation of

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the PFNA GWQC, which included a factor of 10 to account for variation in human susceptibility, a factor of 3 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 3 to account for an incomplete PFNA database. This characterization ignores the uncertainty inherent in the unproven equation NJDEP used based on internal dose and liver enlargement in mice, which, when compared to the traditional and standard approach based on administered dose, makes NJDEP'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 GWQC that is overly stringent. (45)

19. COMMENT: NJDEP (2016, page 48) shows that its choices of uncertainty factors are applied to internal concentration. However, there is no generally accepted scientific evidence or established guidance that supports applying these uncertainty factors to internal dose, in contrast to numerous publications that support the application of such factors to external dose. To apply such factors to internal concentrations assumes linearity between internal and administered doses. This would need to be demonstrated before applying these factors to internal dose. The serum level of PFOA versus external exposure is slightly better modeled with a nonlinear curve (the r-squared values are slightly higher for the nonlinear curves) indicating that the traditional approach of applying uncertainty factors to the external dose is most appropriate. NJDEP's use of a default uncertainty factor for within-human variability of 10 is correct. Specific data do not exist to change this default value.

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Using specific data rather than a default 3-fold uncertainty factor for the kinetic portion of the experimental animals to humans is now the standard approach (IPCS, 2005; USEPA, 2014), but it requires the choice of a dose metric, either area-under-the-curve (AUC) maximum concentration (Cmax), or clearance. NJDEP chose an AUC dose metric, which is related to the ratio of serum to water concentration of 200:1. However, data exist to question this choice of dose metric. For example, Das et al. (2015, page 22) state “As in the case of PFOA, the mechanism(s) responsible for the PFNA-induced early pregnancy loss is unknown, but the perturbations apparently took place at the early stage of organogenesis.” This statement suggests that Cmax rather than AUC could be the most appropriate dose metric. Thus, to be consistent with generally accepted scientific principles, NJDEP needs to explore use of the Cmax or otherwise provide a strong rationale for its choice of AUC dose metric. If NJDEP chooses to maintain the latter, then it needs to explore other sources of PFNA exposure that contribute to a higher AUC than would be observed from drinking water alone. Based on the data of Emmett et al. (2006), such sources are occurring. We strongly encourage NJDEP to follow the guidance of either IPCS (2005) or USEPA (2014) for this exploration. A kinetic extrapolation would also be useful for extrapolating between rats and humans, especially since the critical effect, liver histopathology, appears to be found in rats. If the extrapolation between experimental animals and humans cannot be quantified, but is still considered to be different, for example, because of the uncertainty associated with a potentially longer half-life in humans, then some additional factor might be appropriate. In fact, the Committee of Toxicology of the United Kingdom has taken this approach, using an additional 2-fold factor for this specific uncertainty.

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Using specific data rather than a default 3-fold uncertainty factor for the dynamic portion of the experimental animals to humans is now the standard approach for this subfactor as well (IPCS, 2005; USEPA, 2014). NJDEP (2016) uses the default value of 3-fold for this uncertainty factor on page 43. However, rather than just using the default, a dynamic extrapolation from either or both rats and mice and humans should also be explored. For example, in NJDEP's December 8, 2015 (NJDEP, 2015a), response to public comments on the draft interim specific ground water criterion for PFNA (page 14 response top of page), NJDEP stated that the effects and underlying mode of chemical action in mice and rats is relevant to humans, but then did not follow up with a more important question, whether a quantitative difference between these species can be determined. This same question should be pursued between rats and humans. In vitro data in mice, rats and humans appears to exist to pursue this investigation (NJDEP, 2016, pages 42 and 43). If NJDEP is to use specific data to step away from the default uncertainty factor for experimental animals to humans, a very appropriate endeavor, then it needs to consider all of the available data. Again, an independent external peer review would have suggested this. In fact, in vitro PFAS or related chemical data may support a chemical-specific dynamic uncertainty factor that is less than 1-fold. NJDEP shows a response to public comments (NJDEP, 2015a, page 14 bottom of page and page 15 top) on their use of this factor that is appropriate in general, but several of the PFNA studies are longer than subchronic. For example, Stump et al. (2008) exposed 18 male F1 rats for up to 28 weeks (see Figure 2 of Stump et al., 2008, post weaning dosing time for F1 males was 22 weeks, plus in utero of 21 days, and 21 days weaning or 28 weeks overall). Thus, some consideration of a reduced uncertainty factor for subchronic to chronic exposure is appropriate here, since the study is more than double the usual subchronic study. A 3-fold factor might be

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reasonable. It is worth noting that the USEPA PFOA assessment used a factor of 1 for this extrapolation based on the observation that steady state serum levels were reached in the range of subchronic study duration and the chronic studies did not identify a lower point of departure (POD). (45)

RESPONSE TO COMMENTS 17 THROUGH 19: It is generally agreed upon that interspecies comparisons for perfluorinated compounds such as PFNA should be based on serum levels (a measure of internal dose) rather than administered dose (e.g., 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. The commenter (Comment 19) suggests that internal dose versus external dose of PFOA is slightly better modeled with a nonlinear curve for data from a study of a community exposed to PFOA via contaminated drinking water (Emmett et al., 2006). These data are not relevant to the use of a benchmark dose limit (BMDL) based on animal serum data instead of the standard uncertainty factor for interspecies kinetic extrapolation for several reasons. The relevant data for use of serum data for dose response are the administered dose versus serum data from the animal study, not human data such as those mentioned by the commenter. Additionally, the data based on “tap water” consumption do not accurately reflect external exposures to PFOA from drinking

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water in this community, because, as explained in the response to Comments 37 and 38, these data from Emmett et al. (2006) represent only consumption of plain tap water and do not include consumption of cold or hot drinks or food made with tap water, and represent tap water consumption only at the time of the survey when participants were aware that their drinking water was contaminated, not potentially higher tap water consumption during earlier time periods. The dose-response data used in the risk assessment are based on internal dose (serum levels), rather than administered dose; therefore, the default uncertainty factor of 3 for the kinetic portion of the animal-to-human extrapolation is irrelevant. The animal serum data used are the Cmax rather than the AUC, since the serum data are from the end of the dosing period and represent the maximum serum levels experienced by the animals during the study.

The Department reviewed the Committee on Toxicity of the United Kingdom PFOA risk assessment (COT, 2009), including the use of the additional 2-fold toxicokinetic uncertainty factor. COT's use of this factor is based on the derivation of the European Food Safety Authority (EFSA, 2008) Tolerable Daily Intake (TDI) of 1.5 µg/kg/day for PFOA. The Department previously evaluated the basis for the EFSA (2008) TDI and concluded that it is not scientifically supportable or adequately protective of human health. As discussed in detail in the Technical Support Document Technical Support Document: Interim Specific Ground Water Criterion for Perfluorononanoic Acid (PFNA, C9) (CAS #: 375-95-1; Chemical Structure: CF3(CF2)7COOH) (NJDEP, 2016) , as well as DWQI (2015) and DWQI (2017), it is generally accepted that the comparison between animals and humans should quantitatively consider the much higher internal dose that will result from the same administered dose in humans and animal, either by use of serum PFOA levels or the ratio of half-lives in the two species. EFSA's TDI is based on administered

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dose, and it includes only an additional uncertainty factor of 2 that does not sufficiently account for the much larger toxicokinetic differences for PFOA between humans and rodents. In recognition that the current TDI is not up to date, EFSA is currently reviewing and updating its

TDI for PFOA as shown at

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFS>

[A-Q-2015-00526](#). Similarly, the 2-fold factor used by the COT is many fold too low to account for the much longer human than animal half-life of PFNA.

An uncertainty factor of 3 to account for toxicodynamic differences between animals and humans is standard risk assessment practice. The default uncertainty factor of 3 for toxicodynamic differences between humans and animals is used because there are no data to support a chemical-specific value for PFNA. The *in vitro* data mentioned in Comment 19 are not sufficient to support a chemical-specific value. The default value for this uncertainty factor is used in almost all risk assessments based on animal toxicology data, including risk assessments for perfluorinated chemicals.

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 NJDEP (2016), “No 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.” Mertens et al. (2010) and Stump et al. (2008) cannot be used as the basis for quantitative risk assessment because the serum PFNA data needed for dose-response modeling were not published nor submitted to the Department, as was requested; however, these studies do

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support the need for the uncertainty factor of 10 for duration of exposure. The part of the comment about the duration exposure uncertainty factor in the USEPA PFOA risk assessment is not factually correct. USEPA (2016a) evaluated several studies in its PFOA risk assessment and applied uncertainty factors to each study as judged appropriate. An uncertainty factor of 10 for duration of exposure was applied to the point of departure in one of the studies (DeWitt et al., 2008) evaluated by USEPA. The commenter (Comment 19) notes that USEPA used a duration of exposure factor of 1 in its PFOA risk assessment. As the Department explained in its comments on the draft USEPA Office of Water PFOA risk assessment (USEPA, 2014b), the Department disagrees with not including an uncertainty factor for duration of exposure based on the rationale that steady state serum levels have been reached. As stated in the Department's comments to USEPA:

This uncertainty factor is intended to protect for additional or more severe effects than can occur from exposures of longer duration, not because steady state serum values have not been reached during the dosing period. This uncertainty factor is routinely applied in Reference Dose development without consideration of the time needed for the chemical to reach steady state, including for RfDs for chemicals with very short half-lives for which steady state is reached quickly, long before dosing ends.

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.



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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.

20. COMMENT: NJDEP uses a factor of 3-fold as the database uncertainty factor; however, one could easily argue for a 1-fold factor. This is because two species bioassays are available and rats appear to be more sensitive, a 2-generation reproductive study is available, and little in the database suggests that neurological effects are critical. NJDEP notes that the absence of chronic studies is also a basis for this factor. This is not correct as per USEPA (2002). (45)

21. 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 their revised Reference Dose (RfD) derivation for PFNA, DWQI applies a database uncertainty factor of 3 (DWQI, 2015). The DWQI’s nearly 200-page 2015 Support Document for their recommended PFNA Maximum Contaminant Level (MCL) illustrates that the toxicology database for PFNA is robust, especially for the endpoint that DWQI 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.

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Aside from the lack of a chronic study in animals, the rationale provided in the 2015 DWQI PFNA MCL Support Document for a database uncertainty factor of 3 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 NJDEP 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 DWQI 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 (Fang et al., 2012, Mertens et al., 2010, and Stump et al., 2008 as summarized in the 2015 DWQI Support PFNA MCL Document); 2) the kinetics of PFNA in mice and rats are different, so much so that DWQI 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, DWQI did not consider the database uncertainty factor to be of consequence, only adding it later in a subsequent iteration of their PFNA

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risk assessment. Given the database summarized by DWQI in the PFNA health assessment and the other uncertainty factors, the application of a UF greater than 1 is unjustified. Furthermore, the record shows that the incorporation of this UF into the derivation of the DWQI RfD for PFNA was an afterthought, and gives the appearance of an arbitrary process as opposed to one based on best science. (22).

RESPONSE TO COMMENTS 20 AND 21: USEPA (2012a) 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 DWQI (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 low dose developmental effects 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 or other persistent PFCs (that is, PFOS, PFHxS) exhibited permanent neurobehavioral effects accompanied by changes in critical brain proteins. Lack of data on the potential for PFNA to cause these effects raises concerns 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 doses much lower than the doses in the study used for dose-response modeling.

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

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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 much 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 nor submitted to the Department, as was requested. 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. DWQI conducted only one risk assessment of PFNA and it included a database uncertainty factor of 3. The inclusion of this uncertainty factor in the DWQI risk assessment was not arbitrary or an afterthought. The DWQI Health Effects Subcommittee conducted an in-depth review of the application of the database uncertainty factor in previous USEPA, NJDEP, and DWQI risk assessments. The Subcommittee concluded that an additional uncertainty factor of 3 is appropriate, is consistent with USEPA guidance, and is consistent with its use in previous USEPA, DWQI, and NJDEP risk assessments. The Department reviewed the Subcommittee’s evaluation of the choice of uncertainty factors for development of a health-based

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value for chronic exposure to PFNA in drinking water and concurs with the Subcommittee's conclusions on this issue.

#### Benchmark Dose Modeling and Reference Dose (RfD)

22. COMMENT: Based on the final technical support document (NJDEP, 2016), it is still apparent that NJDEP did not conduct the dose-response modeling in a manner that is consistent with EPA guidance (USEPA, 2012b). EPA's benchmark dose software (BMDS) is traditionally used to assess the dose-response relationships within empirical data from a toxicity study, and as such, EPA provides the standard of practice and guidance for using BMDS (USEPA, 2012b). However, as described in significantly more detail in Integral comments submitted in May 2015 (See Appendix Exhibit C; Integral, 2015a), the benchmark dose modeling used to derive the PFNA toxicity value used as the basis for the GWQC is not supported by the evidence presented in the technical support document. DWQI and NJDEP either ignored or misunderstood EPA's guidance on model selection. No model adequately fits the internal serum dose-response data from Das et al. (2015). Furthermore, inconsistent statements in the technical support document further confuse and create a nontransparent and technically flawed dose-response modeling for the PFNA GWQC. Given the same data and a clear description of the software and methods applied, benchmark dose analysis should be completely reproducible in a manner that is compliant with EPA guidance. The dose-response modeling conducted by NJDEP is not reproducible, and therefore is inconsistent with EPA guidance (USEPA, 2012b) and generally accepted scientific methodology. (45)

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RESPONSE: This comment was previously addressed by the Department (NJDEP, 2015a), as follows:

The Hill model and the Exponential model 5 gave almost identical AIC statistics, and these were the lowest AIC values of the models run. Both of these models had small scaled residual values for the dose closest to the BMD and also show an excellent visual fit to the data. For these reasons, the average of the BMDLs from these two models are used as the Point of Departure. The BMDLs for the Exponential model 5 and the Hill model are 4.43  $\mu\text{g/ml}$  and 5.43  $\mu\text{g/ml}$ , respectively. The average of these values is 4.93  $\mu\text{g/ml}$ , which rounds to 4.9  $\mu\text{g/ml}$ .

Regarding the use of models for which a p value cannot be calculated, the BMDS software provides two model-based measures of the fit of a given model to the observed data, the chi-squared goodness-of-fit test (the “p” value referred to in the comment) and the AIC statistic. As the commenter states, the chi-squared p statistic is a global measure of fit. The AIC statistic, on the other hand, reflects both goodness of fit and parsimony of fit. The inability of the BMDS software to calculate the p-value for the Hill model, and (in our revised benchmark dose calculation), the exponential model 5 model merely means that the degrees of freedom for the fitted model (for example, the Hill model) and the “full” model that are compared in test 4 of the BMDS output are identical. This does not reflect one way or the other on the suitability of the fit of the given model. In this case, one can

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still make a good determination of the model fit from the AIC statistic, the scaled residual (particularly for the dose closest to the BMD), and from a visual assessment of the graphical fit of the model. In the case of both the Hill and Exponential-5 models, the AIC statistic (essentially identical for both models) is quite small, as are the scaled residuals. Visual examination of the graphical fit shows that both models fit the data nearly perfectly. We are, therefore, confident that both of these models provide a more than adequate fit of the data and that the resulting BMDs and BMDLs are appropriate.

Additional information that addresses this concern was included in NJDEP (2016), as explained in the Department's previous response to comments:

Regarding completeness of presentation of information related to BMD modeling, outputs of all BMD models that were run are included in an Appendix in the final document. Additionally, a complete table that includes the results of all of the models run, including the parameters in the tables presented by the commenters (above) are included. It will certainly be possible to easily replicate the BMD modeling presented in the final document.

The USEPA guidance (USEPA, 2012b) cited by the commenter was, in fact, followed with regard to model selection (and all other aspects of the benchmark dose modeling). As explained in this response here and in response to the earlier Integral comments, the issue raised by the

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commenter regarding the inability of the software to generate p-values for the chi-square goodness-of-fit test says nothing about the suitability of the model, as confirmed by the Department in discussions with USEPA benchmark dose modeling experts in 2014. The models selected were the most appropriate models with respect to all applicable criteria as per the USEPA guidance on model selection. As above, all input and output information for the models – as generated by the USEPA modeling software – are presented in the Appendix of NJDEP (2016).

23. COMMENT: NJDEP's RfD derivation for PFNA is convoluted and does not adhere to acceptable USEPA standards or regulatory guidance. In addition to the concerns outlined above regarding the transparency of dose metric selection and the application of inappropriate uncertainty factors, the RfD for PFNA presented in Appendix T in the Basis and Background document for NJDEP's proposed amendments is not clear, and does not reflect the rationale presented in the DWQI Technical Document. In fact, the DWQI Technical Document does not derive an RfD, but instead proposed a PFNA serum target concentration for humans. As such, the RfD presented by NJDEP in Appendix T (0.74 ng/kg/d) is not derived from the Das et al. (2015) BMD Level (BMDL) selected by DWQI as the critical POD, but rather looks to be back calculated, lacking substantial justification for what is clearly a deviation from standard USEPA procedures. For these reasons, the RfD presented by NJDEP should be removed from Appendix T. (22)

24. COMMENT: NJDEP's use of internal dose, rather than administered (external) dose required as the reference dose (RfD) in the equation at N.J.A.C 7:9C-1.7(c)4ii, is an unproven approach for PFNA that lacks transparency and introduces significant uncertainty that is neither fully



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acknowledged, disclosed, nor justified. To our knowledge, no other GWQC or ISGWQC for a chemical with a non-cancer endpoint has been developed or proposed by NJDEP without first calculating an RfD based on an estimate of a human equivalent administered dose. According to NJDEP documents describing the technical basis for the GWQC, the use of internal dose was necessary to account for differences in the kinetics of PFNA in the body of humans 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 NJDEP. With very few exceptions (for example, lead – for which extensive animal toxicology and epidemiology study data exist), use of an internal dose metric to represent dose-response is not a standard risk assessment approach, even for chemicals with a relatively long half-life in the body. NJDEP 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. In the case of NJDEP's GWQC for PFNA, it is instead based on multiple unsubstantiated assumptions with significant associated uncertainty. This uncertainty is not acknowledged, clearly explained or well represented by NJDEP in the technical support documents. NJDEP'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 RfD in mg/kg-day, as specified by N.J.A.C 7:9C-1.7(c)(4) and consistent with standard risk assessment practice. (45)

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25. COMMENT: NJDEP 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 a GWQC/MCL for PFNA, NJDEP, and DWQI 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 NJDEP back-calculated from DWQI'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). Note: RfD calculation based on the BMD analysis presented by Das et al. (2015): Applying mouse-to-human allometric scaling (approximately 7) to BMDL5% of 0.19 mg/kg/d (increased pup liver weight) results in a Human Equivalent Dose (HED)5% = 0.027 mg/kg/day. Applying uncertainties [3 for interspecies difference; 10 for intraspecies differences; 1 for exposure duration (per USEPA since exposure throughout gestation is considered chronic duration for fetus); 1 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, NJDEP did not consider the liver PFNA data in its dose-response assessment. This is a significant technical oversight

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given that the argument for using serum levels is based on using a dose metric relevant to the target tissue. However, NJDEP 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 NJDEP 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 NJDEP must evaluate and include in a comparative analysis to ensure transparency and scientific defensibility of its risk assessment. It is imperative, therefore, that DWQI and NJDEP 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 DWQI and NJDEP dose-response assessment for PFNA is deficient and inadequate for serving as the basis of GWQC/MCL for PFNA. (22)

RESPONSE TO COMMENTS 23 THROUGH 25: The derivation of the RfD for PFNA is presented in detail in the technical support documents cited in Appendix T of the Basis and Background Document for this rule proposal (<http://www.nj.gov/dep/rules/notices/bbdoc-20170403b.pdf>)

As explained in the summary of the proposal, the equations, data sources, and conventions for deriving interim specific and specific ground water quality criteria are set forth at N.J.A.C. 7:9C-1.7(c)4. The rule sets default values for the variables in the equations. If a default value is not appropriate for the constituent for which a criterion is being derived, as is the case for PFNA, the criterion is derived using alternative values. USEPA guidance recommends the use of values specific to the constituent being evaluated, when available, because doing so strengthens the scientific basis for the derived criterion. See, for example, Methodology for Deriving Ambient

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Water Quality Criteria for the Protection of Human Health (USEPA, 2000)

<https://nepis.epa.gov/Exe/ZyPDF.cgi/200003D2R.PDF?Dockey=20003D2R.PDF>.

It is well accepted that Reference Doses (RfDs) for biologically persistent perfluorinated chemicals such as PFNA must take into account the much longer (estimated to be about 50- to more than 100-fold for PFNA) half-life in humans than experimental animals. The allometric scaling factor of 7 used in the RfD suggested by the commenter (Comment 25) does not take this much larger difference into account. Additionally, the comparison of the RfD suggested by the commenter to the RfD used as the basis for the ground water criterion is not valid because several uncertainty factors used for the criterion were omitted. The commenter's suggested RfD is based on a developmental endpoint and therefore does not include a duration of exposure uncertainty factor, while the Department's criterion is based on a systemic endpoint from short term exposure and therefore includes a duration of exposure uncertainty factor. Additionally, the commenter's suggested RfD does not include a database duration uncertainty factor that is needed for reasons explained in the responses regarding uncertainty factors (see Response to Comments 17 – 19). As is the case for almost all other contaminants, including those which cause hepatic toxicity, data are not available to derive a criterion for PFNA based on PFNA concentrations in liver. Use of serum levels from animal studies for dose-response modeling is the accepted approach for risk assessment of persistent perfluorinated chemicals such as PFNA.

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

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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. The Department's approach for risk assessment of PFNA was explained in NJDEP (2016) and the same approach was used for development of risk assessment of PFOA in drinking water that was published in a peer-reviewed paper (Post et al., 2009). 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.

#### Critical Effect

26. COMMENT: NJDEP should consider the current state-of-the-science with regard to the correct evaluation of adverse versus adaptive effects in the liver. NJDEP's choice of adaptive effect in liver from the Das et al. (2015) 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 (Hall et al., 2012) 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

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concomitant evidence of PPAR $\alpha$  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 USEPA's current assessment of perfluorooctanoic acid (PFOA), summarized in the final Office of Water 2016 Health Effects Support Document for PFOA released in May 2016 (USEPA, 2016a), NJDEP/NJ Drinking Water Quality Institute (DWQI) should re-evaluate 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 standards for PFNA. (22)

RESPONSE: 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. Such 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 ground water quality criterion 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 perfluorooctanoic acid (PFOA), a perfluorinated chemical

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closely related to PFNA (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 tumour 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 Lowest Observed Adverse Effect

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Levels (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 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.

27. COMMENT: The critical effect of increased maternal liver weight from Das et al. (2015), in the absence of histopathological changes, is not based on generally accepted and peer-reviewed evidence and methodologies and is not appropriate as an adverse effect endpoint. Adverse effect is defined by EPA as “A biochemical change, functional impairment, or pathologic lesion that affects the performance of the whole organism, or reduces an organism’s ability to respond to an additional environmental challenge.” U.S.EPA Integrated Risk Information System Glossary, 2011 (USEPA, 2011a) Das et al. (2015) did not include a histopathological examination of the liver, which is critical to determining the relevance of liver weight as an adverse effect in humans (Hall et al., 2012). Liver enlargement was an observation of the Das et al. (2015) study; the study was not designed to study liver effects. NJDEP continues to take the position that there are data



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from other studies that provide supporting evidence of histopathological changes in the liver, such that changes in liver weight in any study that lacks concurrent histopathology can nevertheless be considered a critical effect. A critical effect is defined by EPA as “The first adverse effect, or its known precursor, that occurs to the most sensitive species as the dose rate of an agent increases.” (USEPA, 2011a). However, no studies support the liver weight changes from Das et al. in mice at this dose level. The two rodent toxicity studies with PFNA (Stump et al., 2008; Mertens et al., 2010) were conducted in rats (not mice) at different doses, and it is well documented that the kinetics of PFNA distribution and elimination are not the same between these species (See Integral, 2015b; Tatum-Gibbs, et al., 2011; and Ohmori, 2003). These two studies used administered dose ranges that are different than Das et al. (2015), and there are no kinetic models for PFNA that would support extrapolations of relationships between dose and response among different species. Kinetic models are mathematical models using chemical specific information and species-specific physiological parameters that allow one to estimate and compare the rate and volume of chemical absorption, distribution, and excretion that occurs for rats, mice and/or humans. In relying on liver enlargement from the Das et al. study, NJDEP did not base the PFNA criteria on generally accepted and peer reviewed evidence and methodologies and did not select an appropriate adverse effect endpoint for derivation of the PFNA GWQC. (45)

28. COMMENT: Perhaps the most significant issue associated with the development of any RfD is the determination of the critical effect. The NJDEP (2016, page 46) judgment is that the critical effect for PFNA is increased liver weight based on a mouse LOAEL of 1 mg/kg-day. However, liver histopathology in male rats is found at a dose that is 50 times lower than the NJDEP choice,

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specifically a LOAEL of 0.019 mg/kg-day. More specifically, page 36 states that "The incidence of necrosis in the control, low, mid, and high dose groups was 0/30, 2/30, 5/30, and 5/30 in the F0 males and 0/30, 3/30, 4/29, and 8/30 in the F1 males." This is the lowest dose with adverse effect. Thus, liver necrosis in male rats appears to be the critical effect. F1 is more severely affected and also exposed to longer time. See page 34 for serum levels or better, Figure 3B of Mertens et al. (2010) 90-day subchronic study. Moreover, the chosen study by NJDEP did not monitor for this critical effect, as NJDEP acknowledged. Page 36 of the NJDEP report states "It is notable that histopathological changes in the liver, including necrosis, occurred at 0.025 mg/kg/day Surflon S-111 (0.019 mg/kg/day PFNA) in males, a dose at which liver weight was not increased. This suggests that histopathological changes in the liver are more sensitive endpoint for PFNA than increased liver weight." NJDEP's comment strongly argues against using Das et al. as the appropriate choice of study, since it did not monitor liver histopathology. NJDEP needs to rethink its judgment of the critical effect as per definition of USEPA (2011a), perhaps by choosing a different effect in mice, or refocusing on male rats, especially since the kinetics of elimination in male rats is not dissimilar to the elimination found in both sexes of mice (NJDEP, 2016, Table 1, page 11). (45)

RESPONSE TO COMMENTS 27 AND 28: The Department agrees that liver necrosis occurred in the two-generation rat study (Stump et al., 2008) at a PFNA dose 50-fold lower than the LOAEL for increased liver weight in Das et al. (2015). In Stump et al. (2008), histopathological changes including hepatic necrosis occurred at doses below those that caused increased liver weight in the same study, indicating that hepatic necrosis is a more sensitive endpoint for PFNA than increased

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liver weight. As discussed in NJDEP (2016), analysis of the graphical information from Stump et al. (2008) and Mertens et al. (2010) suggests that the serum PFNA level at the lowest dose that caused hepatic necrosis in male rats (0.019 mg/kg/day) is well below the serum PFNA level at the lowest dose (1 mg/kg/day), which was the LOAEL in the Das et al. (2015) study used as the basis for quantitative risk assessment. Quantitative risk assessment based on liver histopathology from Stump et al. (2008) and/or Mertens et al. (2010) could, therefore, result in a substantially lower BMDL than the one based on Das et al. (2015); however, Das et al. (2015) was selected as the study appropriate for use as the basis for quantitative risk assessment because it provides the numerical serum PFNA data, including statistical parameters, needed for dose-response analysis.

It is generally accepted that interspecies comparison for persistent PFCs such as PFNA must be made on the basis of internal dose (serum level) or another approach that accounts for the large differences in half-lives between humans and experimental animals (Butenhoff et al., 2004; Post et al., 2009; Tardiff et al., 2009; USEPA, 2009; MDH, 2017; NCDENR, 2012; USEPA, 2016a). It is not appropriate to base the interspecies comparison on administered dose because a given administered dose results in very different internal doses in humans and experimental animals. Of the numerous effects observed in Das et al. (2015), increased maternal liver weight was selected as the basis for quantitative risk assessment because serum levels and liver weights were both measured at the same time point (gestation day 17), one day after the last dose.

Although Stump et al. (2008) found more severe hepatic toxicity at a much lower dose than the lowest dose used in Das et al. (2015), Stump et al. (2008) was not used for dose-modeling because the serum PFNA data needed for dose-response analysis were not provided. Stump et al. (2008) provide only area under the curve graphs for serum levels of the Surflon S-111 mixture,

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but not graphical or numerical data for PFNA or other individual perfluorinated chemicals. It should be noted that the serum PFNA data mentioned by the commenter (Comment 27) (p. 34 of NJDEP, 2016 and Figure 3B of Mertens et al., 2010) as being useful for dose-response modeling of the 2-generation study (Stump et al., 2008) do not come from Stump et al. (2008) but rather from a different study (90-day mouse study; Mertens et al., 2010). Therefore, even if they were available in numerical form, these data are not appropriate for dose-response modeling of liver necrosis from Stump et al. (2008). Furthermore, Mertens et al. (2010) present serum PFNA levels in graphical form but do not provide the numerical data that are needed for dose-response modeling; the serum levels for the lower dose levels cannot be accurately estimated due to the scale of the graphs. The Department requested the numerical serum PFNA data from both of these studies so they could be evaluated for use in dose-response modeling but the data were not provided.

#### Relative Source Contribution (RSC)

29. COMMENT: NJDEP did not follow EPA guidance, nor use correct and transparent chemical-specific data, for the calculation of the relative source contribution (RSC) term and therefore this calculation is not based on generally accepted and peer reviewed scientific evidence and methodologies. The RSC term is routinely applied to a drinking water threshold calculation when the dose metric is based on the administered dose. The RSC is intended to represent the average, rather than the lower or upper bound, contribution of drinking water to total dose (USEPA, 2000). In deriving the GWQC for PFNA, NJDEP calculated the RSC based on the 95th percentile baseline

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serum PFNA from outdated National Health and Nutrition Examination Survey (NHANES) data (2011-2012) (CDC, 2017). NJDEP's choice to use the 95th percentile instead of the median results in a lower RSC, which in turn yields a lower GWQC number. NJDEP did not justify its selection of a 50 percent RSC, and did not demonstrate the uncertainty and sensitivity of their RSC assumptions. We believe that data support an RSC of 80 percent (rather than the current 50 percent). In calculating the RSC, NJDEP did not follow EPA guidance (USEPA, 2000), which requires use of the median rather than the upper bound (95th percentile); did not justify its assumptions and associated uncertainty in selecting a 50 percent RSC; and did not use the most recent data (for example, NHANES PFAS data from 2013-2014, published in July of 2016 (CDC, 2017)), which further support a much higher RSC. NJDEP's unsupported and unscientific choices resulted in an understated RSC, which in turn resulted in a lower GWQC for PFNA. (22 and 45)

RESPONSE: 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 such ambient water quality criteria, a mean value for RSC is used 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

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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 another biologically persistent perfluorinated compound, 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 ground water quality criterion for PFNA. Use of the 95th percentile serum PFNA in NHANES data from 2013-14, which became available after the criterion was developed, instead of the data from 2011-12, would result in only a small change in the RSC and would not affect the value of the ground water quality standard.

30. COMMENT: NJDEP provides an inadequate discussion of RSC uncertainty. The selection of chemical-specific RSC is an important component to the GWQC calculation, and as such it is critical that NJDEP provides a substantial discussion of the derivation and uncertainty associated with this value. In its critique of the USEPA's Exposure and Relative Source Contribution Analysis for Fluoride, the peer review group recognized the importance of the RSC determination and provided several recommendations for improving the scientific rigor of the USEPA's value (USEPA, 2010a). The RSC analysis describes sources of uncertainty, but does not attempt to show how the RSC would be affected if different assumptions were made. A sensitivity analysis would help show how different assumptions would affect the RSC. In its fluoride assessment, USEPA

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recognized this as a deficiency in the RSC analysis and included such an analysis in its final assessment (USEPA, 2010a). NJDEP should provide a clear rationale why it believes these are reasonable estimates to justify this RSC with New Jersey data. Including a sensitivity analysis for the NJDEP RSC selection will add scientific rigor to a section that – like USEPA’s fluoride assessment – is deficient in this area. The RSC does not adequately consider sources of uncertainty (for example, “technological limitations”), and should be more explicit in discussing the uncertainties associated with PFNA analysis in serum from the NHANES as well as any other available PFNA studies. There is evidence (for example, 2011 U.S. Government Accountability Office report on the Safe Water Drinking Act (USGAO, 2011)) that the methodology has a strong influence on results. NJDEP should provide a clear explanation that its methodology does have direct influence on the ground water standard. (22)

RESPONSE: The rationale for the RSC used in deriving the PFNA criterion is described in detail in NJDEP (2016). Because of considerations unique to fluoride in drinking water, the level of detail in the USEPA evaluation of the RSC for fluoride is not relevant to PFNA and other contaminants. A more extensive analysis is needed for determination of the RSC for fluoride in drinking water than for PFNA and other contaminants. Fluoride is intentionally added to drinking water for a beneficial purpose (prevention of dental caries) or may be naturally present in drinking water at beneficial concentrations, while higher levels cause adverse effects (severe dental fluorosis and bone toxicity). There is a very small window between the doses of fluoride that causes beneficial versus adverse effects, since the Adequate Intake (recommended dose) is 0.05 mg/kg/day and the Reference Dose (should not be exceeded to protect from adverse effects) is

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0.07 mg/kg/day (USEPA, 2010b). Therefore, an extensive analysis of exposure to fluoride from non-drinking water sources (that is, RSC determination) is necessary to ensure that the Adequate Intake is received but the Reference Dose is not exceeded. These considerations do not apply to PFNA since it does not have beneficial effects or a dose at which there is an “Adequate Intake.” Data from NHANES, and not other studies of serum PFNA, were used to develop the RSC. The uncertainties in the NHANES analysis of PFNA in serum have been documented, and they do not impact the basis of the RSC. Specifically, the coefficient of variation for the serum PFOA analytical results from NHANES is reported to be low (15.4 percent or lower; Calafat et al., 2007). This small variation in serum PFNA measurements would lead to non-differential variability which would not tend to bias the results in one direction or the other.

31. COMMENT: If NJDEP states that the RSC should be 50 percent, then how can it, at the same time, maintain a ratio of 200:1, or did NJDEP assume that this ratio excluded other sources? If such an assumption were made, then NJDEP needs to revisit the underlying support for this assumption. If NJDEP did not make this assumption, then an RSC is not needed in this determination of a water criterion. (45)

RESPONSE: As explained in NJDEP (2016), the RSC was applied to the target human serum level (analogous to a Reference Dose, but in terms of serum level) used in the development of the ground water quality criterion for PFNA. Using the subtraction method, the contribution to human serum from non-drinking water exposures was subtracted from the target human serum level to determine the contribution to the target human serum level that may come from drinking water. The 200:1



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ratio between serum and drinking water is based on exposure to drinking water only and is not relevant to the choice of RSC. Also, the RSC is not relevant to the range of serum levels resulting from exposure to drinking water with other levels of contamination.

32. COMMENT: We urge a stricter ground water quality standard for PFNA of 5 ng/L based on expert technical analysis submitted to NJDEP in 2015 and resubmitted with this comment. PFNA is one of the most highly toxic perfluorinated compounds known. It is toxic to humans, potentially affecting the liver and immune system, and may have negative developmental effects on babies and children – hitting them when they are most vulnerable with effects that can be indelible for a person’s entire life. PFNA does not break down in the environment and builds up in the human body. As before, we advocate that revisions be made to uncertainty factors and relative source contribution factors used in the development of the specific ground water quality criterion (ISGWQC) for PFNA and request that the Ground Water Quality Standard be adopted at 5 ng/L rather than the proposed 10 ng/L. The stricter value recommended is based on two things. One is the use of the reference dose for children ages 1 to 6 years to provide protection to this vulnerable group. The second is the consideration of a greater contribution factor from sources other than drinking water containing PFNA such as vegetables grown in contaminated areas, fish consumption, indoor air, and local soils. (9)

RESPONSE: As explained in NJDEP (2016), USEPA recommends using chemical specific factors rather than default factors when sufficient data are available; therefore, the Department used the higher chemical specific RSC of 0.5, rather than the default RSC of 0.2, for PFNA. Since ground

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water quality criteria for Class II ground waters are derived based on lifetime exposure it is not appropriate to use the short term higher drinking water exposure rates for children to derive these criteria. The uncertainty factor of 10 for intra-individual human variation is intended to protect sensitive human subpopulations including children, and the criterion was based on the average daily water consumption value recommended by USEPA (2011b) of 0.016 L/kg/day. The PFNA risk assessment utilizes an estimated 200:1 serum to drinking water ratio, and the approach proposed by the commenter would entail additional manipulations of this ratio, introducing additional uncertainty into the exposure evaluation.

Additionally, USEPA generally recommends that a mean value be used for the RSC. It should be noted that the 95th percentile for serum PFNA from NHANES (2011-12)(CDC, 2017) is about 3-fold higher than the mean value. Elevated levels of PFNA were found in two species of fish (white perch and channel catfish) in the Delaware River near the presumed source of PFNA contamination in 2004-2007, suggesting that local residents could be exposed to PFNA through consumption of recreationally caught fish. However, PFNA was not detected in more recent monitoring of the same two species of fish in 2010-2012, a time period during which discharge of PFNA from the presumed source had ceased. PFNA levels in these two fish species may not necessarily be indicative of all recreationally consumed fish species, and the lack of data on other fish species is an uncertainty in the exposure assessment. However, the Department is not aware of any data suggesting that elevated exposure from fish consumption is currently occurring in this region. The Department also is not aware of any data on PFNA in crops or PFNA in indoor air in areas of New Jersey where drinking water is contaminated with PFNA. In regard to uptake into locally grown crops, it should be noted that several publications on experimental studies of uptake

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of perfluorinated compounds (PFCs) into plants have shown that uptake decreases logarithmically as chain length increases, and that uptake of PFNA into plants is less than for PFOA and much less than for the shorter chain PFCs (Blaine et al., 2013; Yoo et al., 2011).

#### Blood Serum Data

33. COMMENT: NJDEP chose to ignore the serum:water data from Paulsboro, New Jersey (Integral, 2015c), which were admittedly not collected in a scientifically rigorous way. However, these data can be used to ground truth the NJDEP serum to water ratio of 200:1. When such ground truthing is attempted, the NJDEP ratio is not supported (Integral, 2015b, page 12). (45)

RESPONSE: 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; the full history of the PFNA concentration in individual wells is

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not known; the time at which different individuals began to receive PFNA-contaminated water is not known; once contamination was known to the public, individuals may have switched partly or entirely to bottled sources of drinking water; and 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.

34. COMMENT: Additional research is needed to better understand the possible human health effects from exposure to PFNA in water. In January 2014, a public health advisory was issued to the residents of Paulsboro regarding the detection of PFNA in one of the borough's drinking water supply wells. Thereafter, through an agreement with a local company, a treatment system was installed that removes PFNA from that well. In addition, the residents of Paulsboro were provided the opportunity to have their blood sampled and tested for the presence of PFNA and similar chemicals. More than 1,300 Paulsboro residents participated. The data collected from Paulsboro residents should provide valuable information that is directly relevant to the relationship between PFNA in water and PFNA in human blood. In response to the unique blood sampling effort in Paulsboro, Rutgers University initiated a publicly funded study to learn what it could about the occurrence of PFC substances, including PFNA, in the blood of users of the Paulsboro water supply through direct outreach to Paulsboro residents. Rutgers gathered the PFNA blood serum results and other relevant information from 181 Paulsboro residents who agreed to share their results. This information is currently being evaluated by a Rutgers team led by Dr. Judith Graber. The Department is issuing a ground water standard for PFNA without considering potentially

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relevant information from the Rutgers study. It is NJDEP's obligation to consider the best available science in setting any regulatory standard. (6)

RESPONSE: The Rutgers study consists of a statistical analysis of serum concentration of several per- and polyfluoroalkyl substances (PFAS), including PFNA, from the 181 people in Paulsboro who voluntarily agreed to share their serum PFNA results with Rutgers. It is the Department's understanding that participants will be asked about their health history, residential history, drinking water consumption, and potential occupational exposure to PFNA. The statistical analysis will include summarizing the concentrations of the PFAS in this group and comparing the resulting statistical moments (for example, mean, standard deviation) to national data from NHANES data from 2013 and 2014 (CDC, 2017). These data are a non-random sample from the Paulsboro population. Even if these data were a statistically valid sample of the Paulsboro population exposed to PFAS, they would only provide information on the serum concentration of the PFAS at the time of sampling. 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 criterion development. Additionally, as discussed with respect to the Paulsboro serum data in response to Comment 33, the Rutgers study will not provide useful quantitative information on the relationship between drinking water exposure and PFNA serum levels because the participants' historical exposure to PFNA in drinking water will remain undetermined.

35. COMMENT: To the extent that the Department continues to be unwilling to rely on the blood serum data from Paulsboro, the New Jersey Department of Health has already announced that it will be conducting a program this year to gather blood serum data from communities affected by

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PFNA in drinking water to, among other things, "[e]stimate serum: drinking water ratios for PFNA, and assess how they may inform the risk assessment of PFNA in drinking water." New Jersey Department of Health, New Jersey Biomonitoring Grant Program Overview and Update, dated Nov. 18, 2015, available at <https://biomonitoring.ca.gov/sites/default/files/downloads/NewJerseyHighlights111815.pdf>. The Department should not move forward to finalize the ground water standard for PFNA while ignoring information that has been collected, and is being currently supplemented by further studies, in favor of overly conservative assumptions that assume that data is unavailable. (45)

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 New Jersey Department of Health (DOH) study will collect serial samples of serum that will be analyzed for 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 DOH 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

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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 DOH study will not provide data on the quantitative relationship between PFNA in drinking water and the resulting PFNA in serum.

The Department notes that the DOH initiated sampling in 2017, the first year of a multi-year sampling design. Deferring this rulemaking based on the anticipated completion of a study that has only just begun and that may not provide a benefit in refining the scientific basis of the criterion is not appropriate.

36. COMMENT: The literature search described in the Technical Support Document is incomplete, omitting numerous relevant epidemiologic studies of PFNA. Prior to conducting a systematic literature review, the methods used to locate, select, and appraise individual studies on a well-defined topic and to evaluate the overall body of evidence should be formulated and documented (Institute of Medicine, 2011). A priori development of these methods is important to reduce bias in the selection and assessment of the available literature. However, such methods are not specified in the Technical Support Document, thereby raising concerns about the completeness and objectivity of the literature identification and review process. A more recent evaluation of the

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existing epidemiologic literature on PFNA yields the same overall conclusion as that expressed in the Technical Support Document, namely, that the extent of epidemiologic data available for evaluating potential associations between PFNA and specific health outcomes is limited. However, the total number of epidemiologic studies of PFNA is rapidly increasing. Based on the currently available weight of scientific evidence, no public health or regulatory agency has reached the conclusion that PFNA is causally associated with any adverse human health outcome. (45)

RESPONSE: The Department's literature search was comprehensive. Additional epidemiology studies identified in comments submitted in 2014 on the draft interim specific ground water quality criterion for PFNA were added to NJDEP (2016). The Department did not conduct a formal systematic review and NJDEP (2016) does not state that such a systematic review was conducted.

The Department acknowledges the current limitations of the epidemiologic evidence for PFNA and that the Department did not use human epidemiology as the basis for the risk assessment (see NJDEP, 2016). This is also the case for most human health risk assessment of environmental contaminants developed by USEPA, the Department, and the Drinking Water Quality Institute. Most human health risk assessments developed by these agencies are based on toxicological data from animal studies based on the default assumption that toxicological effects observed in animals are relevant to humans. As discussed in NJDEP (2016), some studies identified associations of PFNA with health effects at exposures found in the general population. However, the extent of the available epidemiologic data for PFNA is limited and. Therefore, causality cannot be proven for the reported associations since they primarily come from cross-sectional studies. The inability to establish causality does not preclude the conclusion that there is compelling evidence of



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associations of PFNA with some human health effects. Furthermore, a demonstration of causality for human health effects is not a requirement for development of a ground water criterion.

#### Serum:Drinking Water Ratio

37. COMMENT: PFNA internal and external exposure assumptions are incorrect and are not based on reasonable, validated assumptions of exposure, and data-driven factual information. NJDEP'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, NJDEP 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 of these 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 NJDEP. NJDEP 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

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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 8 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, NJDEP 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). (45)

38. COMMENT: No kinetic models for PFNA exist to support the difference in clearance that NJDEP estimated for PFOA and PFNA; there is no generally accepted or peer-reviewed scientific evidence supporting the factor-of-two multiplier on which NJDEP relies. To support its assumptions about relative kinetics of PFNA and PFOA, NJDEP 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

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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 NJDEP 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. (45)

RESPONSE TO COMMENTS 37 AND 38: 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

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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 in 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 DWQI (2015) and DWQI (2017). As discussed in NJDEP (2016) and DWQI (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 2 to 30-fold longer than for PFOA. Data presented by Zhang et al. (2013) indicate the median and geometric mean

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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 DWQI (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 3 µg/L) levels of PFOA in their drinking water but also considered data from communities with a range of drinking water concentrations (60 – 4,300 ng/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

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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 NJDEP (2016), 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 DWQI (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 USEPA researchers 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

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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 ground water quality criterion for PFNA.

**Ground Water Quality Criteria for Other Constituents (1,4-dioxane; 2,4,6-trinitrotoluene; hexahydro-1,3,5-trinitro-1,3,5-triazine; and perchlorate)**

1,4-Dioxane Ground Water Quality Criterion

39. COMMENT: NJDEP should use a threshold-based mode of action to assess 1,4-dioxane toxicity, based on recent re-analyses of rodent liver tumor data (Dourson et al., 2014, 2017). The NJDEP's draft interim specific ground water quality criterion (GWQC) for 1,4-dioxane is based on the 2013 USEPA Integrated Risk Information System (IRIS) oral cancer slope factor (USEPA, 2013b), derived using linear, low dose extrapolation from a mouse liver tumor study (Kano et al., 2009). As such, the toxicity value assumes that 1,4-dioxane induces liver carcinogenesis through an assumed linear, non-threshold mode of action (MOA). While the weight of the evidence presented in the literature do not support a genotoxic/mutagenic (and thus linear) MOA (USEPA, 2005a, 2013b), the USEPA (and NJDEP) assume a linear MOA because it remains the default approach recommended for quantifying chemical carcinogenicity in the absence of evidence to the contrary, per USEPA cancer risk assessment guidelines (USEPA, 2005a, b). Since the 1,4-dioxane

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toxicology literature does not lend strong support for a linear, non-threshold MOA, scientists have been exploring the best approach to illustrate that the weight of the evidence supports a non-linear threshold-based MOA. It was noted that in cancer bioassays conducted in past decades, it was common for pathologists to only record primary lesions associated with chemical exposures. As a result, in cases where tumors were present as the primary lesion, less substantial histopathology findings that can be indicative of a non-genotoxic cancer MOA (cell hyperplasia) often went unrecorded.

There have been two recent efforts published in the peer-reviewed literature that reconsider the pathology findings from two of the three liver cancer bioassays. Dourson et al. (2014) re-read the rodent liver slides that formed the basis of the liver tumor incidence, as reported in the 1978 National Cancer Institute (NCI) bioassay in which male and female mice were exposed to varying dose levels of 1,4-dioxane in drinking water. Dourson et al. (2014) reported “dose-related non-neoplastic changes in the liver; specifically, a dose-related increase in the hypertrophic response of hepatocytes, followed by necrosis, inflammation and hyperplastic hepatocellular foci.” According to Dourson et al. (2014), the weight of the evidence suggested that 1,4-dioxane causes liver tumors in rodents via cytotoxicity followed by regenerative hyperplasia. NJDEP was made aware of this study in comments to the 2014 draft interim specific GWQC for 1,4-dioxane. In its response, NJDEP discounted the findings of Dourson et al. (2014), pointing to some inconsistencies in the inflammation/ hyperplasia findings in the female mice, and noting that the USEPA IRIS cancer slope factor was based on a later study (Kano et al., 2009) which reported no such threshold based observations. In its response, NJDEP concluded that “[i]n summary, the data



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and explanation provided by Dourson et al. (2014) do not indicate that the non-threshold approach used by USEPA (2013b) is inappropriate or that a threshold approach should be used instead.”

However, recently Dourson et al. (2017) published an update to their 2014 analysis, in which they revisited the results of the Kano et al. (2008, 2009) rodent subchronic and chronic drinking water studies. Since the chronic study (Kano et al., 2009) forms the basis of the USEPA (and NJDEP) oral cancer slope factor, this re-analysis is critical to elucidating the 1,4-dioxane MOA. It turns out that Kano et al. (2008, 2009) are based on assays conducted in Japan in the late 1980s, whose reports were issued in 1990 (JBRC, 1990a,b). Dourson et al. (2017) requested and received the laboratory reports for these studies (JBRC, 1990a,b), and conducted their evaluation based on translations of the reports. In the rat studies, Dourson et al. (2017) found that the pooled incidence of centrilobular swelling and single cell liver necrosis from the 13-week studies preceded the development of development of liver adenomas and carcinomas in the chronic studies in both dose and time. Specifically, they report: “...liver cell swelling, hypertrophy and liver weight increase occur at doses of 42-55 mg/kg-day; this precedes necrosis at doses of 94-219 mg/kg-day; which has a lower overlapping range of hyperplasia and foci development found at 55-389 mg/kg day; which precedes in dose the development of adenomas and carcinomas at doses of 274-1015 mg/kg-day.”

Dourson et al. (2017) note that the mouse data are less clear on the sequence of histological events, as tumors appear at lower doses in the chronic studies than the liver swelling and necrosis do in the subchronic studies. The authors note that the lack of noncancer histopathology in the chronic mouse study is inconsistent with reported changes in liver enzymes in the same study, inconsistent with the precursor liver injury histopathology findings in the subchronic study mouse

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study, and inconsistent with their prior, re-read observations in the 1978 NCI study. The authors consulted several pathologists about the contrasting findings of the chronic mouse bioassays, reporting that the collective pathology opinion supported the hypothesized MOA considered by USEPA (2013b) and supported by Dourson et al. (2014), namely that “the liver tumors from oral exposure to 1,4-dioxane occur after metabolic saturation, accumulation of the parent 1,4-dioxane molecule, liver toxicity and a regenerative hyperplasia.” Based on this evidence, Dourson et al. (2017) concluded:

In the current work, a reanalysis of data from two chronic mouse cancer bioassays on 1,4-dioxane, one 13-week mouse study, seven rat cancer bioassays, coupled with other data such as 1,4-dioxane’s negative mutagenicity, its lack of up-regulated DNA repair, and the appearance of liver tumors with a high background incidence, support the conclusion that rodent liver tumors, including those in mice, are evoked by a regenerative hyperplasia MOA. The initiating event for this MOA is metabolic saturation of 1,4-dioxane.

These recent findings further strengthen the weight of evidence that liver tumors resulting in rodents orally exposed to 1,4-dioxane over a chronic time-period are the result of a threshold-based MOA. In accordance with the 2005 USEPA Cancer Guidelines (USEPA, 2005b), these findings should compel USEPA and NJDEP to revisit their assumptions on 1,4-dioxane MOA and derive a threshold-based cancer value. The use of Dourson et al. (2014, 2017) is in keeping with the “best available science” and, therefore, consistent with NJDEP’s requirements. Finally, it should be

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noted that this approach would be in keeping with prior risk assessments by others (Health Canada, 2005; Neumann et al., 1997; NICNAS, 1998; Netherlands, 1999; and Stickney et al., 2003). (22)

RESPONSE: The commenter asserts, based on the recent paper by Dourson et al. (2017), that 1,4-dioxane is carcinogenic through a threshold mode-of-action (MOA) involving cytotoxicity, necrosis, and regenerative hyperplasia, and that the default linear extrapolation from the point-of-departure (POD) is, therefore, not appropriate. The Department has reviewed Dourson et al. (2017) and has re-reviewed the other papers cited by the commenter that were reviewed previously, including Dourson et al. (2014) and the Kano et al. (2009) study that is the basis of the USEPA's cancer slope factor for 1,4-dioxane. Based on these publications, the Department concluded that Dourson et al. (2014; 2017) have proposed a possible mode of action for the carcinogenicity of 1,4-dioxane, but it has not been demonstrated that this mode of action is likely or that other modes of action are not equally likely for purposes of explaining 1,4-dioxane carcinogenicity. Furthermore, there are some problems with the conclusions of Dourson et al. (2017), both with respect to the overall evidence on the proposed carcinogenic mode of action of 1,4-dioxane and with respect to the evaluation of the data from Kano et al. (2009).

With respect to the overall dataset for the carcinogenicity of 1,4-dioxane, Dourson et al. (2017) adjusted doses from 13-week studies, dividing them by a factor of 3, to compare them with results from a two-year study. This adjustment is predicated on the risk assessment practice of adjusting subchronic points of departure (PODs; that is, NOAELs, LOAELs, BMDLs) for chronic exposure by dividing them by a factor of 3 or 10. While this approach is appropriate for risk assessment where the goal is to not underestimate the risk of adverse effects, it is not intended to be a

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quantitatively precise approach. It is not appropriate to compare data from different studies for the purpose of attempting to define a quantitative relationship across studies by adjusting doses for effects in sub-chronic studies, as was done by Dourson et al. (2017).

In Figs. 2, 3 and 4, and elsewhere in their paper, Dourson et al. (2017) make assertions regarding the chronology of the appearance of various endpoints that they claim proceed in a chain of causation for liver tumors. However, those claims largely rest on the appearance of various types of liver pathology at increasing doses, rather than with respect to the passage of time. One cannot infer chronology from dose-response data only. The inferred chronology is, in fact, back-projected onto the dose-response data from the mode of action hypothesized by Dourson et al. (2017). Alternatively, these data can be interpreted as showing independent effects for which the respective causes are unrelated and whose occurrence is simply a function of dose.

Dourson et al. (2017) argue that the toxicity pathway for 1,4-dioxane is dependent on saturation kinetics, with decreased metabolism of the parent compound leading to increased toxicity. However, none of the two-year exposure data presented by Dourson et al. (2017) for the various liver effects appear to show dose-response relationships that indicate a dependence on saturation kinetics. Rather, the incidence of these effects increases linearly or positively exponentially over the whole range of doses used in the studies. A clear indication of saturation kinetics would be an essentially flat dose-response until a saturation dose is reached, at which point the dose-response would proceed linearly or exponentially. Furthermore, Dourson et al. (2017) note that tumors found in mice in the low dose group (Kano et al. (2009)) are an exception to this postulated mode of action. If, as argued by Dourson et al. (2017), saturation kinetics are key to the chain of toxic steps leading to tumors, and the tumors observed in the mice in the low dose group in Kano et al.

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(2009) do not occur under conditions of saturation kinetics, this would imply that tumor formation and non-tumor toxicity are decoupled.

The Department's previous response to public input on the Dourson et al. (2014) re-analysis of the NCI (1978) study is also relevant to these issues (see <http://www.state.nj.us/dep/dsr/supportdocs/11-chemicals-response.pdf>). It was noted that in NCI (1978), the incidence of hypertrophy, necrosis, inflammation, and Kupfer cell hyperplasia occurred in the controls in the absence of tumors. Specifically, hyperplasia occurred in controls at an incidence of about 15 percent and 25 percent in males and females, respectively, with adenoma incidence at approximately 5 percent in both sexes. At the next dose (350 mg/kg/d, based on USEPA (2013b)) hyperplasia incidence dropped to about 10 percent but adenoma incidence increased to 30 percent. These data strongly suggest no significant linkage between hyperplasia and adenomas.

Dourson et al. (2017) present a schema of dose and time correlations for the various liver endpoints in rats compiled across multiple studies (with time points corresponding to the duration of individual studies). However, in order to use these data to make the case for a sequential mode of action leading to tumors, it is logical and necessary that the studies utilized should be those studies that demonstrated tumors. Otherwise, there is no basis for asserting that the sequence of toxicity ends in tumors. Of the seven studies included in Table 1 of Dourson et al. (2017), only three provide tumor data. In the two-year Kano et al. (2009) inhalation study, hypertrophy and hyperplasia/foci occurred at 1,000 parts per million (ppm) but, importantly, the intermediate step in this schema, necrosis/inflammation, was not seen at this dose. Necrosis/inflammation is critical to the pathway hypothesized by Dourson et al. (2017), since hyperplasia in the absence of necrosis

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can be attributed to induction of growth factors. All of the steps in the Dourson et al. (2017) schema, including tumors, occurred at 5,000 ppm in the Kano et al. (2009) study. In the Kociba (1971, 1974) two-year drinking water study, hypertrophy and necrosis occurred at the 1 per cent concentration, as did tumors. Notably, however, hyperplasia/abnormal liver foci were not observed at this dose. In the Kasai et al. (2009) inhalation study, all of the steps in this schema, including tumors, were observed at 1,250 ppm. These comparisons of the results of these studies raise two problems for the Dourson et al. (2017) schema. The first is that critical intermediate steps (effects) in this causal chain are missing even when subsequent steps are observed, including at doses identified by Dourson et al. (2017) as resulting in saturation kinetics. The second is that, in this schema, tumors are a late occurring and ultimate step. If the steps included in this schema were necessary for the production of tumors, it would be expected to see at least some studies where all the steps except the late-occurring tumors were observed (either sequentially, with increasing dose, or possibly concurrently except for the late-occurring tumors), with tumors occurring only at the highest dose. The occurrence of all the steps, including the tumors at the same dose as in the high dose groups in Kano et al. (2009) and Kasai et al. (2009), provides no evidence for a mode of action that involves a stepwise schema.

Relevant to the issue of the mode of action of carcinogenicity for 1,4-dioxane, the only carcinogen for which the USEPA has, to date, accepted a threshold approach (based on a cytotoxicity mode of action) is chloroform (USEPA, 2001). For chloroform, actual temporal data from multiple studies show the chronology of the various effects in the pathway resulting in tumor formation. Also, there is close consistency between doses causing cytotoxicity and tumors. In contrast, as noted above, this is not the case for 1,4-dioxane, for which the data supporting such a

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mode of action do not rise to the level of those supporting the mode of action for chloroform. Furthermore, as described above, there are some important inconsistencies between the proposed schema and the available data.

Finally, there are alternative non-threshold modes of action for the carcinogenicity of 1,4-dioxane that appear equally likely and equally consistent with the data. For example, as the USEPA (2001) stated with respect to chloroform:

It may also be that continuous stimulus of proliferation by growth factors involved in inflammatory responses increases the probability that damaged cells may slip through cell cycle checkpoints carrying DNA alterations that would otherwise be repaired. Current views of cancer processes support both possibilities. There are no data on chloroform that allow the events that occur during cell proliferation to be directly observed. A high proliferation rate alone is not assumed to cause cancer; tissues with naturally high rates of turnover do not necessarily have high rates of cancer, and tissue toxicity in animal studies does not invariably lead to cancer.

Regarding the prior risk assessments cited by the commenter (Health Canada, 2005; Neumann et al., 1997; NICNAS, 1998; Netherlands, 1999; and Stickney et al., 2003), all of these documents precede the USEPA (2013b) IRIS assessment, and USEPA considered the studies from these evaluations.

In conclusion, the mode of action for 1,4-dioxane carcinogenicity remains unknown. The data and explanations provided by Dourson et al. (2017) do not establish a firm or unique link to the

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proposed mode of action, and they do not indicate that a threshold approach is appropriate for risk assessment for this compound. As such, the information provided by Dourson et al. (2017) does not invalidate the conclusion made by USEPA(2013b) that the available information does not establish a plausible mode of action for 1,4-dioxane, and that the available data are not sufficient to establish significant biological support for a non-linear (threshold) mode of action. For these reasons, the Department continues to believe that the risk assessment approach used by USEPA (2013b) which develops an oral cancer slope factor for 1,4-dioxane based on the USEPA default approach, linear low dose extrapolation, is appropriate.

#### 2,4,6-Trinitrotoluene (TNT) Ground Water Quality Criterion

40. COMMENT: NJDEP's additional uncertainty factor (UF) of 3 for lowest observed effect level (LOAEL) to no observed adverse effects level (NOAEL) extrapolation is not warranted. The IRIS assessment for TNT (USEPA, 2017a) does not provide a detailed discussion of the derivation of its UF, other than stating that the UF accounts for inter-individual sensitivity, interspecies extrapolation, subchronic to chronic extrapolation, and LOAEL to NOAEL extrapolation. USEPA states a confidence level of "medium" in the reference dose (RfD). The NJDEP states that these same four categories are accounted for in the NJDEP UF, but uses an uncertainty factor of 3 for the LOAEL to NOAEL extrapolation, without providing a basis or rationale for use of a more conservative UF than that used by USEPA. However, this change does not significantly impact the outcome of the GWQS derivation process; use of the USEPA RfD without modification would result in a noncancer GWQC of 3.5 µg/L, which is greater than the cancer-based GWQC of 1 µg/L.



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Therefore, the GWQS would remain at 1 µg/L. NJDEP should provide a clear rationale for why a different UF from that in IRIS is used for the RfD for TNT. (22)

RESPONSE: As explained in the Basis and Background document for the proposal, the Department “applied a total uncertainty factor of 3,000 to account for interindividual sensitivity, interspecies variability, subchronic-to-chronic extrapolation, and for extrapolation from a LOAEL to a NOAEL...” The uncertainty factors applied to derive the RfD are shown as 10 for interindividual sensitivity, 10 for intraspecies variability, 10 for subchronic-to-chronic extrapolation, and 3 for LOAEL-to-NOAEL extrapolation, for a total uncertainty factor of 3,000. (See <http://www.state.nj.us/dep/rules/notices/bbdoc-20170403b.pdf>, Appendix G). As noted by the commenter, use of the USEPA uncertainty factor would not result in a different outcome since the USEPA UF to derive an RfD would result in a less protective criterion than the cancer slope factor, which is not disputed by the commenter.

#### Hexahydro-1,3,5-Trinitro-1,3,5-Triazine (RDX) Ground Water Quality Criterion

41. COMMENT: NJDEP should use a more recent oral cancer slope factor (CSFo) of 0.04 mg/kg/d in the draft IRIS Toxicological Summary (USEPA 2016b). The ground water quality criterion for both cancer and non-cancer effects are based on the current USEPA IRIS toxicity values (that is, RfD and CSFo), with no modifications to either the toxicity values or to the default exposure assumptions. Note that the IRIS assessment for RDX is currently undergoing reassessment, and a draft IRIS toxicological summary was issued by USEPA in September 2016

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(USEPA 2016b). This draft report specifies an oral RfD of 0.003 mg/kg/day, which is the same value as the current IRIS RfD (USEPA, 2017b), so its use would not have an impact on the noncancer-based ground water quality criterion. However, the draft report also specifies an oral cancer slope factor of 0.04 mg/kg/day, which is almost three times lower (less conservative) than the current IRIS CSF of 0.11 per mg/kg/day. Use of this draft CSF would result in a cancer-based ground water quality criterion of 0.9 µg/L (rounded to one significant figure), which is higher than both the Department's cancer-based ground water quality criterion of 0.3 µg/L and PQL of 0.5 µg/L. USEPA IRIS states that the toxicological review for RDX has undergone both public comment and peer review, but does not state when the final assessment for RDX is expected. (22)

RESPONSE: The Department acknowledges that the ground water quality criterion for RDX was derived based on the current IRIS cancer slope factor, but, as stated by the commenter, USEPA has not indicated the timeframe for a revised IRIS assessment for RDX. The appropriate time to consider modifying the RDX ground water quality criterion is when USEPA has finalized the IRIS assessment.

#### Perchlorate Ground Water Quality Criterion

42. COMMENT: NJDEP's use of body weight of 67 kg to account for pregnant adult exposure is not warranted. With respect to exposure parameters, NJDEP used an alternative body weight in the calculation of ground water quality criterion, substituting the body weight (67 kg) for a pregnant adult for the default body weight of 70 kg. Presumably, NJDEP used this body weight because the development of the reference dose (RfD) (based on the inhibition of iodide uptake by

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the thyroid) includes a 10-fold uncertainty factor to account for the fetuses of pregnant women who might have hypothyroidism or iodide deficiency. However, NJDEP does not provide specific justification for altering the default body weight and using this more conservative value. The RfD already incorporates an uncertainty factor to account for this sensitive subpopulation. Moreover, it is based on a no observed effects level, and therefore represents a conservative level. Based on this, no further adjustment of body weight is warranted.

Furthermore, more recent data are available to characterize body weight, and suggest that the default 70 kg typically used for ground water quality criteria is adequately protective of sensitive subpopulations. The NJDEP references USEPA (2004) as the source of the 67-kg value used in derivation of GWQC; this document presents body weight information obtained from a United States Department of Agriculture study conducted in the 1990s. Average body weights for the U.S. population have increased over the past several decades, however. The 2011 USEPA Exposure Factors Handbook (USEPA, 2011b) recommends an overall increased mean body weight of 80 kg for the general population, and provides body weight data specific to pregnant females. Two studies summarized in this document reference mean body weights of approximately 73 kg and 75 kg. This information suggests that the NJDEP body weight of 67 kg is overly conservative for the general population, and we would therefore recommend that the default body weight of 70 kg be retained for perchlorate. However, we note that use of the default body weight of 70 kg does not change the calculated GWQC (4.9  $\mu\text{g/L}$  versus 4.7  $\mu\text{g/L}$ ), and still results in a ground water quality criterion of 5  $\mu\text{g/L}$  when rounded to one significant figure. (22)

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RESPONSE: The commenter is correct that the Department derived the specific ground water quality criterion for perchlorate using 67 kg as the assumed body weight of a pregnant woman, rather than the 70- kg default, to be protective of the sensitive population and that this was based on USEPA (2004). However, as acknowledged by the commenter, changing the assumed body weight based on the 2011 USEPA Exposure Factors Handbook (USEPA, 2011b) would not change the value of ground water quality criterion for perchlorate.

43. COMMENT: NJDEP should acknowledge the role of natural atmospheric and anthropogenic background contributions of perchlorate to groundwater supplies. Note that with the development of more sensitive analytical methods for perchlorate, various studies have found low level concentrations (less than 4 µg/L; ATSDR, 2008) of perchlorate in the environment that do not appear to be related to a distinct release at a disposal site. In addition to various anthropogenic sources (for example, blasting, fireworks displays, fertilizer use), perchlorate may be generated from natural atmospheric sources, and may be deposited in the ground through rain and snow events (however, this appears to be more significant in the western, more arid portion of the United States; USEPA, 2014c). While background concentrations in groundwater are expected to be lower than the proposed ground water quality criterion of 5 µg/L, it is important to acknowledge in the GWQS document that there may be a background contribution of perchlorate to groundwater supplies. (22)

RESPONSE: There is no need to acknowledge the role of natural atmospheric and anthropogenic background contributions of perchlorate to ground water in the Basis and Background document

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with respect to the derivation of the ground water quality standard for perchlorate because the human health-based criterion for perchlorate is derived based on the health effects of exposure to the constituent, not the level of perchlorate in the ground water.

### **Laboratory Capacity for Analysis of Certain Constituents to Meet Ground Water Quality Standards**

44. COMMENT: Upon review of the Department's Office of Quality Assurance information, we believe that laboratory certification for the analysis of several of the compounds in the proposal is not currently available. In particular, dichlormid, MCP, 2-ethyl-1-hexanol, and perhaps other compounds do not appear on the Part III Analytical Testing Parameter list. While provisions of the Department's Technical Requirements for Site Remediation, at N.J.A.C. 7:26E-2.1 do cover general requirements for the analysis of parameters for which certification is not available, it is anticipated that there will be limited availability of qualified laboratories to perform the analysis of the compounds listed above as well as other parameters with new standards. The Department should consider a phase-in period that will allow analytical laboratories to develop procedures for analysis. (13)

RESPONSE: The Department acknowledges that certification under the Department's Regulations Governing the Certification of Laboratories and Environmental Measurements, N.J.A.C. 7:18, is not currently available for the analysis of two of the three constituents identified by the commenter, dichlormid and 2-ethyl-1-hexanol. The Department's Office of Quality Assurance (OQA) is in

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the process of updating the Department Sanctioned Analytical Methods (DSAMs) contained in the Part III of the laboratory certification application package and anticipates including dichlormid and 2-ethyl-1-hexanol as part of this update, at which time certification will be available for these constituents. OQA currently offers certification for 2-(2-methyl-4-chlorophenoxy) propionic acid (MCP). Three laboratories in New Jersey are certified by OQA, as well as 22 laboratories located out of State. The laboratories are certified for the following methods: SW846 Methods 8151A, 8321A/B and/or USEPA method 615.

In the case of constituents for which certification is not available, compliance with the ground water quality standards as remediation standards is governed by the provision in the Technical Requirements for Site Remediation (Technical Requirements) at N.J.A.C. 7:26E-2.1(a)2, which specifies that the person responsible for conducting the remediation must ensure that the laboratory selected to analyze samples is capable of performing the analysis and meeting the data quality objectives specified in the site-specific quality assurance project plan that must be prepared in accordance with the Technical Requirements at N.J.A.C. 7:26E-2.2. It should be noted that dichlormid, MCP, and 2-ethyl-1-hexanol are not common constituents and are used at a very small number of sites in New Jersey, limiting the number of samples required to be analyzed. Consequently, the analysis of samples for these compounds should not burden laboratory capacity.

### **Practical Quantitation Levels (PQLs)**

#### PQL for PFNA

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45. COMMENT: NJDEP did not derive the PFNA PQL based on scientifically acceptable methodology. NJDEP used the “Bootstrap Estimate of a confidence interval of the mean” to determine the concentration level that would encompass the certified laboratory quantification capability, using the upper 95 percent confidence interval. However, NJDEP did not demonstrate that this method of deriving the PQL is more appropriate or more accurate for PFNA compared to the methods described in N.J.A.C. 7:9C-1.9(c)3. When a sample size is small (for example,  $n < 10$  to 15 based on USEPA guidance), standard bootstrap methods (that is, random resampling with replacement) do not yield a sufficient number of unique estimates of the arithmetic mean to provide a statistically valid 95 percent upper confidence limit for the arithmetic mean. A larger sample size is needed, or a more statistically valid approach should be applied, such as applying a Chebyshev multiplier to the mean MDL. (See, for example, ITRC 2012. Incremental Sampling Methodology, available at [http://www.itrcweb.org/ism-1/pdfs/ISM-1\\_021512\\_Final.pdf](http://www.itrcweb.org/ism-1/pdfs/ISM-1_021512_Final.pdf).) (45)

RESPONSE: The PQL for PFNA incorporated into Appendix Table 1 in the proposal did not reflect the work of the Drinking Water Quality Institute (DWQI, 2015), which, on July 1, 2015, recommended an MCL of 13 nanograms per liter (equivalent to 0.013  $\mu\text{g/L}$ ) for PFNA to the Commissioner of the Department, and a PQL of 5 nanograms per liter (equivalent to 0.005  $\mu\text{g/L}$ ), based on a larger interlaboratory performance dataset than was used to develop the PQL for the interim specific ground water quality standard for PFNA. The Commissioner accepted DWQI’s recommendation and the Department published a proposal to establish the MCL, and PQL, for PFNA on August 7, 2017 (see 49 N.J.R. 2361(a), including reference to the DWQI

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recommendation and subcommittee report available at [http://www.nj.gov/dep/watersupply/g\\_boards\\_dwqi.html](http://www.nj.gov/dep/watersupply/g_boards_dwqi.html)). Therefore, on adoption, the Department is incorporating into Appendix Table 1 the PQL of 0.005 µg/L for PFNA recommended by DWQI and accepted by the Department. The applicable ground water quality standard will continue to be 0.01 µg/L, the higher of the specific criterion of 0.01 µg/L and the PQL, as revised on adoption, of 0.005 µg/L. The Basis and Background document for this rulemaking has been revised to reflect the revised PQL and its derivation based on the DWQI subcommittee report.

#### PQL for 1,4-Dioxane

46. COMMENT: NJDEP should reference standard USEPA methods 522, 8260, or 8270 in selected ion mode (SIM) for deriving a Practical Quantitation Limit for 1,4-dioxane. NJDEP sets a PQL of 0.1 µg/L based on Method 522 listing in the National Environmental Methods Index (NEMI). However, the NJDEP had received extensive public comment and input that indicates New Jersey laboratories are often required to analyze by USEPA Method 8270C, 8270D, or 8260B SIM because Method 522 (designed and intended for fairly “clean” samples of drinking water) will often not achieve the advertised NEMI detection limits in the presence of other chemicals. If NJDEP intends to compel only Method 522 for 1,4-dioxane, NJDEP must acknowledge that this method is not widely available, requires a stand-alone method for 1,4-dioxane, comes at a higher cost, and does not allow for isotope dilution/recovery correction if matrix impacts become evident in the laboratory (which explains why Method 522 is not routinely applied to industrial samples).



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We recommend that NJDEP reference standard USEPA methods (that is, 8260 SIM and 8270 SIM) as acceptable alternatives to achieve the desired PQL for 1,4-dioxane. (22)

RESPONSE: As explained in the Basis and Background for the rule proposal, 1,4-dioxane appears as a listed parameter in the National Environmental Methods Index (NEMI) for published USEPA Method 522 entitled Determination of 1,4-Dioxane in Drinking Water by Solid Phase Extraction (SPE) and Gas Chromatography/Mass Spectrometry (GC/MS) with Selected Ion Monitoring (SIM). The Department believes Method 522 is widely available as it was used on a nationwide basis for purposes of the monitoring that public community water systems serving more than 10,000 people conducted for the contaminants USEPA included on the list issued in 2012 pursuant to the Federal Unregulated Contaminant Monitoring Rule (which list is referred to as UCMR3) (see 77 FR 26072). The published method detection limit (MDL) for water ranges from 0.020 parts per billion (ppb) to 0.026 ppb depending on the absorbent cartridge used to isolate this compound. The Department selected the higher end of this range as the MDL for 1,4-dioxane. Pursuant to N.J.A.C. 7:9C-1.9(c)3, the PQL for 1,4-dioxane was derived by multiplying the method detection limit (MDL) by five, rounded to one significant figure, and expressed in  $\mu\text{g/L}$  resulted in a PQL of 0.1  $\mu\text{g/L}$ .

The PQL of 0.1  $\mu\text{g/L}$  was previously established as an interim PQL on November 25, 2015 as a revision to the previous interim PQL of 10  $\mu\text{g/L}$  established in 2004. The 10  $\mu\text{g/L}$  interim PQL was derived based on a published analytical method, "USEPA 1624, Volatile Organic Compounds by GC/MS," for which a limit of detection in the method was not specified and the Minimum Reporting Level or ML, which is a quantitation level, was 10 ppb ( $\mu\text{g/L}$ ). Comments received

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regarding the revised interim PQL of 0.1 µg/L included submission of USEPA Method 522 performance information from the National Environmental Laboratory Accreditation Program (NELAP) certified laboratories showing that two of the four laboratories could achieve the reporting limit (0.07 µg/L and 0.04 µg/L), at or below the recommended PQL value of 0.1 µg/L. Another commenter provided a reporting limit for 1,4-dioxane of 0.1 µg/L by Method 8270 selective ion monitoring from their laboratory. The Department pooled the provided data to evaluate this information. The MDL information was combined with the values used to determine the PQL by multiplying the interlaboratory MDL by five. The Department also used a “bootstrap” estimate of the mean and upper confidence level determination for comparison to the USEPA methodology. The results of this statistical approach yielded an interlaboratory MDL upper confidence limit (UCL) of 0.06 µg/L. The two laboratories that could not achieve the reporting limit exceeded the UCL of 0.06 µg/L for the MDL and the Department determined to exclude these values from consideration. Therefore, the Department established an interim PQL of 0.1 µg/L. The Department re-evaluated this PQL for purposes of this rulemaking and found it remained valid. It should be noted that the applicable constituent standard for 1,4-dioxane is the ground water quality criterion of 0.4 µg/L, which is the higher of the ground water quality criterion and the PQL.

#### PQL for 2,4,6-Trinitrotoluene (TNT)

47. COMMENT: NJDEP should reference standard USEPA methods 529 or 8330B for deriving a PQL for TNT. NJDEP indicates that no published method is available for TNT in the National Environmental Methods Index (NEMI), and sets a PQL of 0.3 µg/L based on a literature study.

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However, NEMI indicates that USEPA standard methods 529 and 8330B are available to analyze this compound. Method 529, a GC/MS method, has detection limits for TNT ranging from 0.046 µg/L to 0.084 µg/L (Munch, 2005). Method 8330 with modifications/updates (for example, 8330B) is the most widely used analytical method and provides sensitive detection limits in the low parts-per-billion range (USEPA, 2014c). Use of the upper end of the detection limit range (0.084 µg/L) for USEPA Method 529, multiplied by five, results in a PQL of 0.4 µg/L. Use of the detection limit for USEPA Method 8330B would result in a PQL of 0.5 µg/L. Both PQLs are higher than the proposed PQL of 0.3 µg/L. While these higher PQLs are both lower than the ground water quality criterion of 1 µg/L, and thus would not alter the proposed GWQS of 1 µg/L, we recommend NJDEP reference standard USEPA methods 529 or 8330B for deriving a PQL for TNT. (22)

RESPONSE: As explained in the Basis and Background document for this rule proposal, no published method was listed for 2,4,6-trinitrotoluene in the National Environmental Methods Index (NEMI); however, there are many analytical method references for the determination of a method detection limit (MDL). The detection level that most closely meets the criterion of 1 µg/L, as reported in the published literature, is 0.06 µg/L (Walsh, M.E. and T. Ranney, 1998). Pursuant to N.J.A.C. 7:9C-1.9(c)3, the PQL for trinitrotoluene was derived by multiplying the MDL by five to yield a PQL of 0.3 µg/L. The Department acknowledges that three separate analytical methods for TNT have been identified in the National Environmental Method Index database (NEMI) as of March 21, 2017, which postdates the submittal of the proposal for publication in the New Jersey Register. The Department will consider the updated information and determine if the PQL should be modified through future rulemaking.

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PQL for Hexahydro-1,3,5-Trinitro-1,3,5-Triazine (RDX)

48. COMMENT: NJDEP should reference standard USEPA methods 529 or 8330B for deriving a PQL for RDX. NJDEP indicates that no published method is available for RDX in the NEMI, and sets a PQL of 0.5 µg/L based on a literature study. However, NEMI indicates that RDX may be analyzed by USEPA Method 8330B or Method 529. Method 529 reports detection limits for RDX ranging from 0.006 µg/L to 0.12 µg/L, and Method 8330 provides comparable detection limits. The upper end of the range for Method 529, multiplied by five, results in a PQL of 0.6 µg/L. Because this higher PQL exceeds the ground water quality criterion of 0.3 µg/L, the ground water quality standard would increase slightly to 0.6 µg/L. We recommend that NJDEP reference standard USEPA methods (that is, 8330B or 529) to derive a PQL for RDX, and update the standard accordingly. (22)

RESPONSE: As explained in the Basis and Background document for the rule proposal, no published method was listed for RDX in the National Environmental Methods Index (NEMI). The PQL of 0.5 µg/L generated for this parameter was based on a journal article by TM Chow, (J Chromatogr. Sci. 2004 Oct;42(9):470-3.) in which the author describes a trace level analysis of hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX) and its biodegradation intermediates in liquid media by solid-phase extraction (SPE) and high pressure liquid chromatography analysis. The method detection limit (MDL) using this method is 0.1 ppb (µg/L). Pursuant to N.J.A.C. 7:9C-1.9(c)3, the PQL was derived by multiplying the MDL by five to yield a PQL of 0.5 µg/L. The Department

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acknowledges that three separate analytical methods for RDX have been identified in the National Environmental Method Index database (NEMI) as of March 21, 2017, which postdates the submittal of the proposal for publication in the New Jersey Register. The Department will consider the updated information and determine if the PQL should be modified through future rulemaking.

### **Relationship Between Ground Water Quality Standards and Safe Drinking Water Maximum Contaminant Levels (MCLs)**

49. COMMENT: According to the proposal summary, the Department establishes interim specific and specific ground water quality criteria for ground water constituents in two ways: (1) where a maximum contaminant level (MCL) for a constituent is promulgated in the Department's Safe Drinking Water Act rules (N.J.A.C. 7:10), the health-based level used to establish the MCL is the specific ground water criterion for that constituent; and (2) for all other constituents, the Department develops criteria based on the weight of evidence available regarding the particular constituent's carcinogenicity, toxicity, public welfare, or organoleptic effects, as appropriate for the protection of potable water. The equations, data sources, and conventions for deriving interim specific and specific ground water quality criteria are set forth in the rule at N.J.A.C. 7:9C-1.7(c)4).

The specific groundwater quality criteria, and ultimately the ground water quality standards, should be consistent with, and no lower than, MCLs established pursuant to the Safe Drinking Water Act. The final numeric value established as the GWQS, when based on an MCL, should be consistent (to the same level of precision) with the final numeric value of the MCL as established by the work of the three Drinking Water Quality Institute subcommittees (the Health

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Effects Subcommittee, the Testing Subcommittee, and the Treatment Subcommittee). The Department should use a consistent approach to rounding and significant figures so that the health-based MCL and ground water quality standard are identical for any given constituent. Treatment limitations that are considered in establishing the MCL should also be incorporated into the ground water quality standard, again to ensure consistency.

When ground water is required to be remediated to ground water quality standards that are lower than the drinking water MCLs, this inconsistency causes confusion among regulators, water suppliers, responsible parties, licensed site remediation professionals (LSRPs), and regulated community. For example, the Department's Immediate Environmental Concern (IEC) Guidance Document (NJDEP, 2015b) indicates "a Potable Well IEC exists when discharges of hazardous substance(s) have resulted in the presence of contaminants above the Class II Ground Water Remediation Standards (GWRS), per N.J.A.C. 7:26C. This applies to water from a domestic well used for potable purposes or when contamination above federal and state drinking water standards (Maximum Contaminant Levels) is found in public supply wells or raw surface waters used for public water supplies." The definition of the potable well IEC indicates that the GWRS only apply to domestic wells, whereas state and federal MCLs apply to public supply wells. This inconsistency can be interpreted that there are more standards for remediating ground water and individual domestic wells than for drinking water from public supplies. (13)

RESPONSE: The Department acknowledges that there can be a difference between the ground water quality criterion and the MCL for a particular constituent. This can be due to the requirement in the GWQS, at N.J.A.C. 7:9C-1.7(c)4iii, that the derived ground water quality criterion be

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rounded to one significant figure, which is a convention not consistently utilized in the development of MCLs by the Drinking Water Quality Institute (DWQI). The Department is evaluating the issue of rounding and use of significant figures in establishing water quality standards and MCLs; if the outcome of that evaluation indicates a change to the rounding provision in the GWQS might be appropriate, the Department will undertake rulemaking as necessary. The difference between the ground water quality criterion and the MCL for a particular constituent can also be due to the fact that GWQS provisions governing the derivation of a ground water quality criterion for constituents in Class II ground water at N.J.A.C. 7:9C-1.7 consider only the risk to human health from exposure through the ingestion pathway, whereas, in accordance with the Safe Drinking Water Act, the process for deriving an MCL includes consideration of not only “any adverse effect [of a contaminant] on the health of persons,” N.J.S.A. 58:12A-3k(2), but also whether “it is economically and technologically feasible to ascertain the level of such contaminant in water in public water systems,” N.J.S.A. 58:12A-3k(3).

The Department acknowledges the commenter’s concern with respect to the Department’s IEC Guidance Document and is reviewing the IEC Guidance Document to determine if clarification is necessary.

### **Addition of PFNA to DPHS Appendix A List of Hazardous Substances**

50. COMMENT: NJDEP has not provided clear or compelling scientific evidence that PFNA in the environment is hazardous to human health, particularly when present in ground water at the part-per-trillion (ppt) levels indicated by the proposed ground water quality criterion. PFNA does

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not appear on any Federal list of hazardous substances, no PFNA-specific health-based values have been developed by other government agencies in the United States or elsewhere. A few risk-based cleanup standards or drinking water advisories for PFNA do exist, yet are based on extrapolations from perfluorooctanoic acid (PFOA) and are not based on PFNA-specific toxicity information. For example, Texas issued a cleanup standard for PFNA in groundwater that is 29 times higher than NJDEP's proposed ground water quality criterion and that is based on their analysis of PFOA.

Following a comprehensive evaluation of the available literature, the Federal Agency for Toxic Substances and Disease Registry (ATSDR) recently concluded that it is premature to establish a health based exposure level for PFNA due to insufficient scientific evidence (ATSDR, 2015). ATSDR specifically noted that the toxicology and epidemiology data on PFNA are insufficient to identify any hazard of relevance to human health at environmentally relevant concentrations, and that rodent studies are not appropriate to determine human health effects of exposure to poly- and perfluoroalkyl substances (PFASs), including PFNA. 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. No Federal list identifies PFNA as a hazardous substance. NJDEP itself has also acknowledged that no information is available to suggest that PFNA is a carcinogen (Post and Gleason, 2015). NJDEP's January 2014 "Health Advisory" to Paulsboro stated that "the DEP is not aware of any studies that have directly linked consumption of water with PFNA with human health effects." Furthermore, as acknowledged in the materials that were issued to support the ISGWQC for PFNA, PFNA is ubiquitous in human blood in the



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majority of the U.S. population at levels in the ppt to part per billion range. Therefore, it is premature to list PFNA as a hazardous substance. (45)

RESPONSE: As explained in the proposal summary, PFNA is a developmental toxicant, liver toxicant, and immune system toxicant that bioaccumulates in humans. PFNA is also extremely persistent in the environment and highly soluble and highly mobile in water. In the pending proposal of an MCL for PFNA (see 49 N.J.R. 2361(a)), in the discussion of the findings of the DWQI Health Effects Subcommittee, the Department explained that PFNA accumulates in the human body and exposure to low drinking water concentrations of PFNA (for example, 0.010  $\mu\text{g}/\text{l}$ ) increases concentrations in human blood serum that persist for many years after exposure ends. The toxicological effects of PFNA in mice include weight loss, toxicity to the liver, immune system, kidney, and testes; and effects on the developing fetus or offspring including early death, persistent decreased body weight, and delays in reaching developmental milestones. 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. PFNA is transferred to breast milk and infants drink more fluid (for example, breast milk or formula prepared with drinking water) on a body weight basis than older children and adults consuming the same contaminated drinking water source. These higher exposures are of concern because developmental effects from early life exposures to PFNA occur at lower exposures than other toxic effects of PFNA. 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

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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."

The ATSDR (2015) Draft Toxicological Profile for Perfluoroalkyl Substances was published as a draft document for public review and comment and is subject to revision. The Department and the New Jersey Department of Health jointly submitted extensive comments (NJDEP/NJDOH, 2015) pointing out deficiencies and omissions in the information presented. Specifically, the Department and NJDOH commented that ATSDR cited only five of the 16 available toxicological studies of PFNA, and none of the four toxicology studies most relevant to the derivation of the PFNA ground water criterion were cited; therefore, in the Department's view, the ATSDR's conclusion that the scientific information is insufficient to characterize PFNA toxicity was itself based on an incomplete review of the available literature.

The Department notes that the January 2014 "health advisory" cited by the commenter was a letter from DEP to the Paulsboro Water Department regarding the detection of PFNA in one of its wells including a fact sheet for the Department to use in its communications with the public. The letter and fact sheet acknowledge that the science concerning the health effects was, at that time, emerging but that studies were under way. Since that time, as explained above, the Department has determined that the science does support the designation of PFNA as a hazardous substance.

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51. COMMENT: DEP has failed to explain why it is singling out PFNA to add to the hazardous substance list, as compared to the other compounds it is proposing to convert from interim to permanent groundwater quality standards. Of the 23 compounds that the DEP is proposing to take from interim to permanent standards, 14 – including PFNA – are not currently on the hazardous substance list. Yet PFNA is the only one of the 14 that the DEP proposes to add to the list. The DEP has not explained why it is treating PFNA differently from the other compounds for which it seeks to convert interim standards to final. (45)

RESPONSE: Nine of the constituents for which specific ground water quality criteria and PQLs are incorporated into Appendix Table 1 in the Ground Water Quality Standards are already identified as hazardous substances pursuant to the Discharge of Petroleum and Other Hazardous Substances (DPHS) rules, N.J.A.C. 7:1E-1.7 (that is, petroleum and petroleum products as well as the substances listed in Appendix A, with certain exclusions): Freon 113 (1,1,2-trichloro-1,2,2-trifluoroethane); 1,1-dichloro-1-fluoroethane; 1,4-dioxane; 1-chloro-1,1-difluoroethane; mecoprop (2-(2-methyl-4-chlorophenoxy) propionic acid (MCP)); 4,6-dinitro-o-cresol; cobalt; cresol (mixed isomers); and perchlorate. The Department added PFNA to the list of hazardous substances in Appendix A at this time because of its documented toxicity and persistence in the environment (see Response to Comments 20 and 21) and to help address the extensive area of PFNA contamination affecting at least three southwestern New Jersey counties for which no party has acknowledged or assumed responsibility to remediate. PFNA has been detected in exceedance of the 0.01 µg/L ground water quality standard in, as of this writing, 20 public supply wells and 91 private potable wells, and the Department's investigation of potential additional receptors is

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ongoing. To date, the Department has borne the entire burden and cost of investigating the contamination, as well as providing potable water to affected residents and businesses by either installing point of entry treatment or extending potable water lines. Adding PFNA to the list of hazardous substances enables funding of PFNA remediation under the Spill Compensation and Control Act (Spill Act), N.J.S.A. 58:10-23.11 et seq., enables payment of damage claims regarding PFNA discharges pursuant to the Processing of Damage Claims Pursuant to the Spill Compensation and Control Act rules (Spill Act Damage Claims rules) at N.J.A.C. 7:1J, and subjects persons with Spill Act liability to the requirement to remediate discharges of PFNA.

The Department has determined that adding to the List of Hazardous Substances the other 13 constituents for which specific ground water quality criteria and PQLs are incorporated into Appendix Table 1 in the Ground Water Quality Standards (caprolactam; dichlorimid; diphenyl ether; 2-ethyl-1-hexanol; hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX); 2-hexanone; 2-methylnaphthalene; metolachlor; strontium; tricresyl phosphate (mixed isomers); 1,1,1-trifluoroethane; 2,4,6-trinitrotoluene (TNT); and tri-ortho-cresyl phosphate) is not warranted at this time because parties have assumed responsibility for remediating the contamination at the sites where the constituents have been detected.

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### **Federal Standards Statement**

Executive Order 27 (1994) and N.J.S.A. 52:14B-1 et seq. (P.L. 1995, c. 65), require that State agencies that adopt, readopt, or amend State rules that exceed any Federal standards or requirements include in the rulemaking document a Federal standards analysis.

The adopted amendments to the GWQS that incorporate interim specific ground water quality criteria for 23 constituents of ground water as specific ground water quality criteria, and that provide that the Department may use alternative values and modified equations in the derivation of specific and interim specific ground water quality criteria, do not exceed any Federal

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standards or requirements. The authority for the GWQS comes solely from New Jersey law and has no Federal counterpart. The GWQS 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, standards, or requirements.

The DPHS rules 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. While there are Federal regulations promulgated pursuant to the Federal Water Pollution Control Act and the Comprehensive Environmental Response, Compensation and Liability Act that govern discharge prevention and reporting that are generally analogous to the DPHS rules, PFNA is not among the substances to which those Federal programs apply. The Department has determined that, because PFNA in the environment poses an unacceptable risk to public health, it is appropriate to include PFNA on the DPHS Appendix A List of Hazardous Substances. Doing so will enable the Department to, in accordance with the Spill Act, direct persons with Spill Act liability to remediate discharges of PFNA, use Spill Fund monies as necessary to conduct remediation, and undertake cost recovery actions against the party responsible for the discharge.

**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]\*):

## CHAPTER 9C

### GROUND WATER QUALITY STANDARDS

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APPENDIX

Table 1

Specific Ground Water Quality Criteria—Class II-A and Practical Quantitation Levels

Constituent	CASRN	Ground Water Quality Criterion*	Practical Quantitation Level (PQL)*	Higher of PQL and Ground Water Quality Criterion*
...	...	...	...	...
Perfluorononanoic acid (PFNA)	375-95-1	0.01	*[0.003]* <b>*0.005*</b>	0.01
...	...	...	...	...

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Based on consultation with staff, I hereby certify that the above statements, including the Federal Standards Statement addressing the requirements of Executive Order 27 (1994), permit the public to understand accurately and plainly the purposes and consequences of this adoption. I hereby authorize this adoption.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Bob Martin, Commissioner  
Department of Environmental Protection