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EPA Response to External Peer Review Comments on the Draft Sewage Sludge Risk Assessment for Perfluorooctanoic Acid (PFOA) CASRN 335-67-1 and Perfluorooctane Sulfonic Acid (PFOS) CASRN 1763-23-1

January 2025

U.S. Environmental Protection Agency
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division 1200 Pennsylvania Avenue, NW Washington, DC 20460

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I. INTRODUCTION

Versar Global Solutions, an independent contractor for the United States Environmental Protection Agency (EPA), coordinated an external letter peer review of the *Draft Sewage Sludge Risk Assessment for Perfluorooctanoic Acid (PFOA) CASRN 335-67-1 AND Perfluorooctane Sulfonic Acid (PFOS) CASRN 1763-23-1* report. The peer review was conducted for the EPA's Office of Water, Office of Science and Technology, Health and Ecological Criteria Division in August of 2024.

Assessing the potential risk of pollutants found in biosolids is a priority of the EPA's Biosolids Program. The EPA identifies pollutants found in sewage sludge through open literature reviews and sewage sludge surveys to assess their potential risk to public health and the environment. Sewage sludge that has been treated in accordance with 40 CFR part 503 for land application is often called biosolids by the EPA (although others treat the terms sewage sludge and biosolids as synonyms).

The EPA's PFAS Strategic Roadmap includes conducting a biosolids risk assessment for two PFAS compounds, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS). The current version of this assessment is a draft. After the risk assessment process is complete, the EPA will consider risk management options for PFOA and PFOS in biosolids, if appropriate.

External peer review process

Versar conducted an independent search for scientific experts with one or more expertise in evaluating: fate, transport, exposure and risk from PFOA/PFOS in terrestrial environments (e.g., agricultural sites or superfund sites); modeling groundwater transport and aquifer contamination resulting from soil contamination; uptake of chemicals from soil into plants; uptake of chemicals by livestock.

As a result of this search, Versar identified and contacted 39 experts. Of these experts, Versar received seven positive responses expressing interest and availability to participate. The remaining 32 experts either had a conflict of interest, were not available during the peer review timeframe, or did not respond to the invitation. For each interested and available peer reviewer, Versar evaluated their qualifications and conducted conflict of interest (COI) screening to ensure that the experts had no COI. Versar selected the following five scientific experts to serve as peer reviewers:

Xindi Hu, ScD
Mathematica Policy Research

Ramon Lavado, PhD
Baylor University

Charles Newell, PhD, PE, BCEE
GSI Environmental

P. Barry Ryan, PhD
Emory University

Marc-Andre Verner, PhD
Montreal University

Charge to peer reviewers

The peer reviewers were asked to evaluate the scientific and technical merit of the draft document and provide their responses to the following charge questions:

1. *Programmatic, statutory, and regulatory context*. The Clean Water Act[1] and its implementing regulations[2] directs EPA to assess and manage risks associated with the disposal or use of sewage sludge to protect public health and the environment. Please comment on the extent to which the description of EPA's Biosolids Program, including its statutory and regulatory authorities, provides the context and basis for the risk assessment (see Section 1).
2. *Problem formulation*. Please comment on the characterizations of the environmental fate, exposure, and toxicity of PFOA/PFOS in the problem formulation section of the risk assessment (see Section 2, Appendix A).
3. *Ecological risk assessment*. As described in Section 2.6.3, available data indicate that risk to aquatic and terrestrial life from land application of biosolids contaminated with PFOA and/or PFOS is expected to be lower than the potential risk to human health from same/similar biosolids applications. As a result, the quantitative risk assessment (risk estimates, risk characterization) is scoped to focus solely on human health. Please comment on the conceptual and technical basis for limiting the assessment of ecological risk and focusing on human health for PFOA/PFOS.
4. *Pathway evaluation, model selection, model parameterization, risk estimation and risk discussion*. The draft risk assessment shows that human health risks associated with drinking water and diet are expected to be the greatest among modeled scenarios and pathways. Please comment on the technical basis and clarity of the following elements in supporting this interpretation. Be as detailed as possible about deficiencies and suggested improvements:
    a. Models and parameters selected for these scenarios and pathways, including comment on the inclusion of relevant scenarios (e.g., pasture farm) and pathways (e.g., groundwater, fish consumption) – see Sections 2.9.2, 2.9.3, Appendix B and Appendix C.
    b. Modeling of groundwater behavior for PFOA and PFOS. (see Section 2.9.2 and Appendix C focused on groundwater modeling).
    c. Risk estimation and discussion, including clarity of results (see Sections 3 and 4) and description of variability, uncertainty, and sensitivity (see Section 5, Appendix D).

[1] 33 U.S. Code § 1345 – Disposal or use of sewage sludge
[2] 40 CFR Part 503 – Standards for the use or disposal of sewage sludge

d. Comparison of modeled results to biosolids investigations conducted in Michigan and Alabama (see Section 5.3).

II. EPA RESPONSE TO GENERAL IMPRESSIONS

Reviewer 1

COMMENT: This document describes the risk assessment for PFOA and PFOS in sewage sludge. Overall, the document is clearly written, and the assumptions and methodological choices are reasonable. The rationale for selecting humans as the most sensitive receptor is spelled out, and the four use and disposal scenarios for biosolids cover a wide range of exposure pathways. Central tendency models used a 1 ppb concentration in biosolids, a concentration that is much lower than those reported in the literature, to estimate risks in a "low-dose" setting. At this concentration, EPA found that risk estimates exceeded both cancer and non-cancer acceptable risk levels. I believe the conclusions of this report are sound, but some moderate revisions could potentially make the document clearer. One thing that stood out is the language used to characterize the human health risks. Exceedances of acceptable/tolerable exposure levels were described as "significant human risks". I believe they should be described as levels exceeding what is considered as acceptable/tolerable, or risk levels that can't be considered as negligible.

RESPONSE: Thank you for the comment that, overall, the document is clearly written with sound methodological choices. The EPA agrees that "significant human health risks" is not well-defined and has revised this text to "exceeds the acceptable risk level." The EPA also included text to define the "acceptable risk level" in this context.

COMMENT: Also, it may be difficult for readers to interpret the results in the context of widespread PFAS contamination. For example, consuming drinking water at the maximum contaminant level (MCL) of 4 ppt for PFOA alone would lead to an excess cancer risk in the order of 2 E-03, which is similar to the highest risk estimates for sewer sludge disposal. It would be valuable to describe whether we expect risk in farm families to exceed risk in the general population, and by approximately how much (an example using some of the reported biosolids concentrations would be useful). A recent paper (https://pubmed.ncbi.nlm.nih.gov/38941944/) could be used to illustrate how much higher exposures can be in farm families compared to the general population.

RESPONSE: The EPA's goal is to use this draft risk assessment, once finalized, to determine if the concentrations of PFOA and PFOS present in sewage sludge may adversely affect public health and the environment when the sewage sludge is disposed of or reused. Future risk mitigation actions (regulatory or otherwise) would consider the scale of risk reduction that is possible through various risk reduction activities. The commentor's suggestion to contextualize risks sourced from biosolids by comparing them to other sources of exposure to the general population is currently outside the scope of this draft risk assessment. Additionally, though the EPA is planning a National Sewage Sludge Survey[3] that would include PFAS analysis of sewage sludge across the U.S., these national-scale data are currently not available.

COMMENT: Another issue is that while modeled PFOA/PFOS concentrations in media and risk estimates are presented, the calculated ADDs and LADDs that are used for risk calculations are not in the report. I suggest including tables presenting the dose estimates.

[3] https://www.federalregister.gov/documents/2024/10/10/2024-23474/agency-information-collection-activities-submission-to-the-office-of-management-and-budget-for

RESPONSE: The EPA agrees that ADDs and LADDs are useful to many readers and has added tables with these values to Section 3.

COMMENT: In terms of format, there are some issues with figures and tables. All figures and tables should be checked for numbering (most tables do not have a number), and abbreviations should be spelled out under tables/figures.

RESPONSE: Thank you for pointing out this error. The EPA has made these corrections.

Reviewer 2

COMMENT: I found the document to be very well written. While not an easy read as it is a technical document, it was organized in a logical manner with sufficient information presented in each section such that the selection could be read alone by a reader interested in that specific subject matter. At times, this resulted in redundancy, but such redundancy was more than offset by the utility of the approach and clear organizational structure. The Table of Contents gives a clear understanding of the structure of the document affording the reader the opportunity to peruse different sections as desired or warranted by the need to understand different aspects of the risk assessment.

The document was very well-referenced with the primary focus on previous EPA review documents, where available, and primary literature when EPA reviews were not available. I noted a few locations where references were not yet available. As this is still a Draft document, these were noted in the text by highlighting with an indication that such would be filled in at an appropriate time, e.g., when a publication had been accepted in the literature. However, it is not clear how this would affect the final version if publication of the specific reference was delayed or the submitted manuscript withdrawn.

Considering the science behind the written document, I found the approach to determining risk associated with sewer sludge to be presented as a well-though out design in general and specifically for the PFOA/PFOS pair of PFAS. The Executive Summary, with one or two exceptions, puts forward the process used to perform the risk assessment, the results, and their meaning in an abbreviated form. The body of the document is dense, comprehensive, and thorough. It is a difficult read, but the complex nature of the problem at hand merits a complex analysis that, in turn, requires a detailed presentation.

RESPONSE: Thank you for your comment. With regard to references to EPA documents pending publication, these documents have since been published and the public comment draft risk assessment includes the citations to the public versions.

COMMENT: The choice of scenarios deserves discussion here. I believe the scenarios tested are appropriate for assessing risk from general deployment of sewer sludge containing PFOA and PFOS. Further, as noted in the text, these scenarios serve to model similar scenarios with the same level of contamination for PFAS in general and, perhaps, even other classes of

environmental contaminants. The roadmap set forth here could be used in other types of risk assessments that are of interest to EPA, of course, with data appropriate for the contaminants of interest and processes that affect their movement through the environment.

Of particular interest is the data gaps noted in the text of this document. Data are lacking for many of the parameters needed to understand risk more fully. These data gaps lead to uncertainties in the results or, in some sense equivalently, broad spread in the risk assessment results. The selected scenarios were chosen to span a wide range of potential risks as well as a substantial range of likely values affecting the outcome. However, real-world data for some (many?) parameters are sparse or even non-existent, tempering the utility of such an analysis. The treatment of such uncertainties is, perhaps, the weakest component of the report. In my specific comments below, I have made some suggestions on how this might be improved and concerns about biased results for exposure and concomitant risk addressed. It is my sense that there is more to be included in the discussion of these uncertainties and I urge the EPA authors to consider this in their final Report.

RESPONSE: Thank you for your comments on the discussion of uncertainties in the draft risk assessment. To clarify, empirical data are available for nearly all the parameters used for modeling in this risk assessment, with the exception of specific uptake factors for each fruit or vegetable that may be grown on a farm. These comments are discussed alongside the more detailed comments from this reviewer in Question 4.

COMMENT: In their final assessment of their analysis, the authors state that the deterministic approach that they have taken coupled with a small number of scenarios chosen for evaluation is sufficient for their purposes. Indeed, their deterministic approaches indicate that there is significant risk in the vast majority of deterministic analyses they made and for all scenarios. A Monte Carlo approach, which would have been my initial thought for this analysis, would have required substantially more work, might have afforded assessment of a probability distribution for risk, and been, possibly, more defensible. However, their argument regarding the utility of the information obtained from the deterministic analysis precludes the need for a more sophisticated approach. When a simple approach using the best quality data available and appropriate models of the fate and transport of contaminants through the environment tells you that essentially any scenario results in significant risk, even one with low level of contaminants in the environment, the more sophisticated approach is not going to tell regulators anything more than the simpler approach. It will just take more time and cost more.

The authors are to be commended. This Report is a Tour de Force- comprehensive, well-developed, properly analyzed, and well-done overall.

RESPONSE: Thank you for your comment. The EPA agrees that in this case the deterministic approach is sufficient to potentially inform risk managment actions. The EPA appreciates that the reviewer found the written rational for that decision (that additional probabalistic modeling will only result in higher risk findings because it aims to protect at the 95th percentile rather than the median percentile) clear and convincing.

Reviewer 3

COMMENT: The risk assessment presented in this document is very well done, providing a clear and easy-to-follow evaluation of the potential human health risks associated with the land application and disposal of sewage sludge containing PFOA and PFOS. The assessment effectively highlights the widespread presence of these chemicals in sewage sludge, their persistence in the environment, and their significant toxicity to humans, including their potential to cause cancer and other serious health effects. By employing a conservative screening approach using the BioSolids Tool and central tendency deterministic modeling, the assessment identifies substantial risks even at low concentrations of PFOA and PFOS, underscoring the need for careful consideration of sludge management practices.

One notable strength of the assessment is its comprehensive analysis of various exposure pathways across different scenarios, including agricultural and non-agricultural settings. However, the primary focus of the risk assessment is on human health, with less emphasis on ecological impacts. This human-centric approach, while critical, represents a limitation in that it does not fully address the broader environmental implications of PFOA and PFOS contamination. Despite this, the assessment provides a robust foundation for understanding the risks posed to humans and offers valuable insights for mitigating these risks through informed decision-making.

RESPONSE: Thank you for this comment. The EPA will respond to the specific items on this topic discussed in Question 3.

Reviewer 4

COMMENT: This document is well-written, technically thorough, and establishes a solid foundation for achieving the objectives of the Sewage Risk Assessment for PFOS and PFOA. I commend the development team for their hard work on this complex draft assessment and have tried to provide constructive, useful input for their consideration. I have summarized my main comments below:

As I understand it, the overall goal of this risk assessment is to estimate the magnitude of risks under different biosolids use and disposal scenarios on a *central tendency (median) risk basis*. However in several parts of the calculation a "conservative" approach (which is designed to overestimate risk) are used. I recommend removing all "conservative" calculation steps, input data, and risk thresholds to and replace them with ones based on median / central tendencies.

The current groundwater exposure model has one unrealistic calculation step, the assumption that the exposure concentration is equal to the highest concentration found in the top 2 meters of the aquifer. This assumption runs counter the hydraulics and behavior of any drilled domestic water well anywhere in the country. A more accurate approach should be evaluated:

- Use average concentrations over a realistic well screen length;
- Recognize that most or almost all domestic wells are either: a) screened at the bottom of the shallowest unconfined aquifer unit, or b) screened in deeper aquifer units.

RESPONSE: Thank you for this comment; the EPA will respond to the commentor's specific

concerns on this topic under question 4.

COMMENT: A key issue in the groundwater modeling work is if a PFAS-specific model that accounts for unusual properties of PFOA/PFOS should be applied, or to use EPACMPT model which has been used before by USEPA for risk assessments. While the situation is complex and somewhat unsatisfying, in the end I agree with the current approach to use EPACMPT is sufficient as a compromise method. I agree that the USEPA should continue evaluating the availability of groundwater and vadose zone models as this assessment is finalized. If there are significant improvements to these PFAS-specific screening models, then a switch to these more PFAS-centric models may be merited.

RESPONSE: Thank you for your comment of support that the use of EPACMTP is the best available option. The EPA will continue to monitor the developments of PFOA and PFOS-specific modeling tools as this assessment is finalized.

COMMENT: The groundwater exposure concentrations should be compared to the Maximum Concentration Limits (MCLs) for PFOS and PFOA. Having a risk assessment that evaluates the drinking water pathway without mention of MCLs seems to be missing a critical piece of the USEPA risked-based regulatory framework for managing PFOS and PFOA.

RESPONSE: The commenter appears to have confusion regarding the definition of the MCL, which is not a health-based value. Maximum Contaminant Levels (MCLs) are the highest level of a contaminant that is allowed in drinking water. MCLs are set as close to the health-based Maximum Contaminant Level Goals (MCLGs) as feasible using the best available treatment technology and taking cost into consideration. The biosolids risk assessment compares modeled exposure concentrations to health-based values, resulting in risk estimates for a suite of potential exposure pathways. Any future risk mitigation/management actions would consider detection thresholds for PFOA and PFOS in sewage sludge (based on the data provided in Table 9 in EPA Method 1633, the limit of quantification for sewage sludge could be expected to range from 1.6-4 ppb and the method detection limit is estimated to be 0.7 ppb, however, the exact values will be determined by each laboratory) and other relevant factors.

COMMENT: I recommend that this risk assessment address the uncertainty in the current USEPA toxicology calculations by briefly describing other regulatory and scientific viewpoints for the toxicity parameters shown in Tables 4 and 5.

RESPONSE: It is unclear what the commenter is referring to by "uncertainty in the current USEPA toxicology calculations." The EPA is relying on the conclusions of the agency's *Final Human Health Toxicity Assessment for Perfluorooctanoic Acid (PFOA) and Related Salts* (US EPA, 2024a) and *Final Human Health Toxicity Assessment for Perfluorooctane Sulfonic Acid (PFOS) and Related Salts* (US EPA, 2024b). These documents represent the best available science on PFOA and PFOS human health toxicity and were written in accordance with longstanding EPA policies and guidance on toxicity assessment. These final toxicity assessments for PFOA and PFOS reflect revisions made to respond to consensus recommendations from the

Science Advisory Board peer reviewers and thousands of public comments.

The EPA's final human health toxicity assessment for PFOA (US EPA, 2024a) considered all publicly available human epidemiological, animal toxicological, mechanistic and toxicokinetic evidence relevant to studies that evaluated health effects after oral PFOA exposure. Overall, the available evidence indicates that PFOA exposure is likely to cause hepatic, immunological, cardiovascular, and developmental effects in humans, given sufficient exposure conditions (*e.g.*, at levels in humans as low as 1.1 to 5.2 ng/mL and doses in animals as low as 0.3 to 1.0 mg/kg/day). These judgments are based on data from epidemiological studies of infants, children, adolescents, pregnant individuals, and non-pregnant adults, as well as short-term (28-day), subchronic (90-day), developmental (gestational), and chronic (2-year) oral-exposure studies in rodents. The EPA derived and considered multiple candidate reference doses (RfDs) from both epidemiological and animal toxicological studies across the four non-cancer health outcomes that the EPA determined had the strongest weight of evidence (*i.e.,* immune, cardiovascular, hepatic, and developmental). Decreased serum anti-tetanus and anti-diphtheria antibody concentrations in children (Budtz-Jorgensen and Grandjean, 2018), decreased infant birth weight (Wïkstrom et al., 2020), and increased total cholesterol in adults (Dong et al., 2019) were selected as the co-critical effects for the overall oral RfD of 3×10^{-8} mg/kg/day (US EPA, 2024a). With respect to uncertainty, this RfD was derived by applying a total uncertainty factor (UF) of 10 to account for intraspecies variability.

Consistent with EPA's Guidelines for Carcinogen Risk Assessment (US EPA, 2005a), the EPA reviewed the weight of the evidence across epidemiological, animal toxicological, and mechanistic studies and concluded that PFOA is *Likely to Be Carcinogenic to Humans* via the oral route of exposure. Epidemiological studies provided evidence of kidney and testicular cancer in humans and some evidence of breast cancer in susceptible subpopulations. Chronic oral animal toxicological studies in Sprague-Dawley rats reported Leydig cell tumors (LCT), pancreatic acinar cell tumors (PACT), and hepatocellular tumors. PFOA exposure is associated with multiple key characteristics of carcinogenicity. Available mechanistic data suggest that multiple modes of action (MOAs) could be involved in the renal, testicular, pancreatic, and hepatic tumorigenesis associated with PFOA exposure in humans and animal models. The EPA derived and considered multiple candidate cancer slope factors (CSFs) for PFOA from both epidemiological and animal toxicological studies across multiple tissue types and organ systems (*i.e.,* kidney, liver, pancreas, testes). The oral slope factor of 0.0293 $(\text{ng/kg/day})^{-1}$ (29,300 $(\text{mg/kg/day})^{-1}$) for renal cell carcinoma (RCC) in human males from Shearer et al. (2021) was selected as the basis of the overall CSF for PFOA (US EPA, 2024a).

The EPA's final human health toxicity assessment for PFOS (US EPA, 2024b) considered all publicly available human epidemiological, animal toxicological, mechanistic and toxicokinetic evidence relevant to studies that evaluated health effects after oral PFOS exposure. Overall, the available evidence indicates that PFOS exposure is likely to cause hepatic, immunological, cardiovascular, and developmental effects in humans, given sufficient exposure conditions (*e.g.,* at levels in humans as low as 0.57 to 5.0 ng/mL and doses in animals as low as 0.0017 to 0.4 mg/kg/day). These judgments are based on data from epidemiological studies of infants, children, adolescents, pregnant individuals, and non-pregnant adults, as well as short-term (28-day), subchronic (90-day), developmental (gestational), and chronic (2-year) oral-exposure studies in rodents. The EPA derived and considered multiple candidate RfDs from both epidemiological and animal toxicological studies across the four non-cancer health outcomes that the EPA determined had the strongest weight of evidence (*i.e.*, immune, cardiovascular, hepatic,

and developmental). Decreased infant birth weight (Wikstrom et al., 2019) and increased total cholesterol in adults (Dong et al., 2019) were selected as the co-critical effects for the overall oral RfD of 1 x 10−7 mg/kg/day (US EPA, 2024b). With respect to uncertainty, this RfD was derived by applying a total UF of 10 to account for intraspecies variability.

Consistent with EPA's Guidelines for Carcinogen Risk Assessment (US EPA, 2005a), the EPA reviewed the weight of the evidence across epidemiological, animal toxicological, and mechanistic studies and concluded that PFOS is *Likely to Be Carcinogenic to Humans* via the oral route of exposure. Epidemiological studies provided evidence of bladder, prostate, liver, kidney, and breast cancers in humans, although evidence was limited or mixed for some cancer types. Animal toxicological studies supported findings from human studies. Bioassays conducted in Sprague-Dawley rats reported hepatocellular tumors, pancreatic islet cell tumors, and thyroid follicular cell tumors after chronic oral exposure. Some studies observed multisite tumorigenesis (liver and pancreas) in male and female rats. PFOS exposure is associated with multiple key characteristics of carcinogenicity. Available mechanistic data suggest that multiple MOAs play a role in pancreatic and hepatic tumorigenesis associated with PFOS exposure in animal models. The EPA derived and considered multiple candidate CSFs from animal toxicological studies across multiple tissue types or organ systems (i.e., liver and pancreas). The oral slope factor of 39.5 $(mg/kg/day)^{-1}$ for combined hepatocellular adenomas and carcinomas in female rats from Butenhoff et al. (2012) and Thomford (2002) was selected as the basis of the overall CSF for PFOS.

For more information, please see the Final Human Health Toxicity Assessment documents (US EPA 2024a;b), the EPA response to the related SAB review (US EPA 2023b), the Final PFAS National Primary Drinking Water Regulation Rulemaking (US EPA, 2023a), and the Responses to Public Comments on Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation Rulemaking (US EPA, 2024c).

COMMENT: Dioxin is a more potent carcinogen than either PFOS or PFOA. In 2003, the USEPA decided against regulating dioxin in sewage sludge after conducting a risk assessment. I recommend USEPA perform a quantitative comparison of the dioxin and PFOS/PFOA risk assessments to: 1) highlight similarities and differences between these chemical classes; 2) provide context for current regulatory decisions; and 3) ensure consistency in the risk assessment approaches. This comparison should be placed in or next to Section 5.3.

RESPONSE: While the EPA disagrees that information on Dioxins and PCBs should be added to the PFOA and PFOS Draft Risk Assessment, the EPA will discuss these three items in response to specific comments by Reviewer 4 in the Charge Question portion of this document.

Reviewer 5

COMMENT: The document provides a risk assessment of the potential human health and environmental risks associated with the land application and disposal of sewage sludge containing PFOA and PFOS. The accuracy of the information is supported by recent and well-documented data showing elevated concentrations of these contaminants in US sewage sludge, including comparing modeled concentrations and observed concentrations in Alabama and Michigan. The report authors built upon EPA or other agency's previous work when a relevant

report or assessment exists and conducted a literature search of peer-reviewed and grey literature when needed. For the fate and transport models, the inclusion of regional location-based parameters to model a wide range of climate conditions (dry, moderate, and wet) increased the applicability of this risk assessment to diverse settings across the nation.

The clarity of the presentation is strong, with a clear structure outlining the assessment process. The report effectively distinguishes between high-end conservative risk assessments and central tendency deterministic modeling. It details the scenarios modeled, including agricultural reuse and disposal practices, and explains the implications of these scenarios in terms of human health risks. The conclusions drawn are sound, based on conservative and median modeling results that indicate significant health risks even at low concentrations of PFOA and PFOS. The decision not to pursue further probabilistic modeling at this time, in favor of focusing on sharing current results and mitigation strategies, is consistent with the mission of protecting human health and the environment.

RESPONSE: Thank you for your comment. The EPA agrees that in this case the deterministic approach is sufficient to potential inform risk managment actions. We appreciate the feedback that the rationale for this approach, as written in the draft risk assessment, is clear and convincing.

III. EPA RESPONSE TO CHARGE QUESTION COMMENTS

QUESTION 1: Programmatic, statutory, and regulatory context

Programmatic, statutory, and regulatory context. The Clean Water Act and its implementing regulations directs EPA to assess and manage risks associated with the disposal or use of sewage sludge to protect public health and the environment. Please comment on the extent to which the description of EPA's Biosolids Program, including its statutory and regulatory authorities, provides the context and basis for the risk assessment (see Section 1).

Reviewer 1

COMMENT: The document clearly sets the stage for the risk assessment. Information is provided on the disposal of sewage sludge, land applications, and potential pathways of exposure. The background on previous rounds of regulations, namely regarding organic compounds like dioxins and PCBs helps put the current assessment in context.

RESPONSE: Thank you for your comment.

Reviewer 2

COMMENT: This Section provides a history of regulation for metals and chemical compounds in biosolids and sewer sludge. The text indicates the type of modeling structures that have been used and their results. In particular, the focus on specific metals, PCBs and related compounds were modeled using multiple scenarios (14 in all covering pathways encompassing 17 different scenarios). The authors then suggest in the final sentence that a similar assessment should be carried out for PFOS and PFOA in this assessment.

There appears to be sufficient regulatory support to consider PFOA and PFOS in this assessment and the section provides the context clearly under the Clean Water Act and its Amendments.

I note no specific comments on material in this section. However, I do expect follow-up on the use of deterministic modeling strategies only as compared with the Monte Carlo strategies implemented in the dioxins assessment.

RESPONSE: Thank you for your comment. The dioxins assessment used Monte Carlo modeling approaches to estimate the 50^{th}, 75^{th}, 90^{th}, 95^{th}, and 99^{th} percentile exposure levels. As described in section 2.9.1 of the draft risk assessment (modeling plan), the assessment of PFOA and PFOS started with a high-end screening risk assessment, assuming a reasonable maximum exposure scenario (*see* Appendix E in the draft risk assessment). Due to the high-risk estimates in the screening analysis, the EPA next conducted a deterministic modeling approach targeting "central tendency" exposures (the 50^{th} percentile) to better understand the potential scope and magnitude of potential risks under different use and disposal scenarios. As described in section 4.9, based on the results of these 50^{th} percentile modeling exercises, the EPA determined that further Monte Carlo modeling for PFOA and PFOS would not change the risk conclusions. The different modeling approaches for PFOA/PFOS and dioxins are appropriate due to the different risk findings in each case. Please see the EPA's responses to Reviewer 4 in this section for more information about the differences between the PFOA/PFOS and dioxin risk assessments.

Reviewer 3

COMMENT: The EPA's Biosolids Program is governed by the Clean Water Act (CWA) and its amendments, specifically Section 405(d), which mandates the establishment of regulations to manage sewage sludge (biosolids) and protect public health and the environment from potential adverse effects. This statutory framework requires the EPA to set numeric limits and management practices that mitigate risks associated with toxic pollutants in biosolids. The Program's regulations under 40 CFR part 503 outline the acceptable practices for land application, surface disposal, and incineration of biosolids, including criteria for pollutant concentrations and site management practices. This regulatory backdrop is essential for understanding the scope and objectives of the risk assessment for PFOA and PFOS.

The risk assessment process described in the document is designed to evaluate the potential health and ecological risks associated with the land application and disposal of sewage sludge containing PFOA and PFOS. The extent to which the description of the EPA's Biosolids Program informs this assessment is evident in the structured approach taken to evaluate different scenarios of biosolids use. These scenarios include land application on agricultural lands and reclamation sites, and disposal in surface disposal sites. The assessment considers various exposure pathways and populations, such as farm families, community-supported agriculture participants, and individuals consuming freshwater fish, reflecting the Program's comprehensive approach to managing potential risks associated with biosolids.

Moreover, the historical context provided by previous risk assessments under the Biosolids Program illustrates the evolution of the EPA's approach to managing chemical risks in biosolids. Past regulations and assessments focused on metals and other contaminants, with subsequent risk evaluations addressing additional pollutants such as dioxins and PCBs. The framework developed from these earlier assessments serves as a model for the current evaluation of PFOA and PFOS, incorporating lessons learned and methodological advancements. This continuity ensures that the risk assessment for PFOA and PFOS builds upon a solid foundation of regulatory and scientific understanding, adapting to the specific challenges posed by these persistent and bioaccumulative substances.

In conclusion, the description of the EPA's Biosolids Program, including its statutory and regulatory authorities, provides a crucial context for the risk assessment of PFOA and PFOS in biosolids. It outlines the regulatory framework within which the assessment operates, the historical evolution of risk management practices, and the structured approach to evaluating potential risks. This comprehensive context ensures that the risk assessment is both relevant and robust, addressing the specific challenges posed by these emerging contaminants while building on established regulatory practices and scientific methodologies.

RESPONSE: Thank you for your comment.

Reviewer 4

COMMENT: Recommend adding context about how many people are likely to impacted by the groundwater pathway modeling scenarios. This maybe only possible on an order of magnitude basis. For the specific current scenario, this analysis might start with the population of the

farming/ranching community in the U.S. and estimating how many farms: 1) applied biosolids, and 2) drink water from a domestic water well, and 3) have a well that immediately *downgradient* of the biosolids application area, and 4) have a well with a well screen that only draws water from the top two meters of the aquifer (i.e., not screened in deeper aquifers or at the bottom of their aquifer). The goal is to give the public a rough estimate for how common this scenario occurs.

RESPONSE: Unfortunately, the number of people potentially impacted by groundwater contamination sourced from sewage sludge reuse and disposal is larger than the universe of potentially impacted people suggested by this commentor. The number of sewage sludge use and disposal sites includes not only farms with biosolids land-application, but also unlined or clay lined lagoons, surface disposal sites, land reclaimed using biosolids, forestry sites, golf courses, playgrounds, and other sites where biosolids are land applied. The number, size, and location of these sites is currently unknown. Therefore, the number of homes with potentially impacted drinking water sources (whether these drinking water sources are groundwater or surface water) has not been quantified as part of this draft risk assessment.

The goal of this draft risk assessment is to determine if PFOA and PFOS may be present at concentrations in sewage sludge that may adversely affect public health or the environment (see the Clean Water Act section 405(d)). If the EPA decides it would be appropriate to develop risk mitigation measures, it would consider the scope and scale of the potential beneficial outcomes of each risk mitigation activity using the best available information.

COMMENT: Recommend USEPA provide additional context on the comparison of the dioxin sewage sludge vs. PFOS/PFOA in sewage sludge. This analysis could be presented in or near Section 5.3. There appear to be large differences in the overall risk in sewage sludge these chemicals. Was this due to the starting concentrations, toxicology, fate and transport, or exposure factors?

RESPONSE: Comments related to the biosolids risk assessment for dioxin are out of scope; nevertheless, the EPA is providing some information comparing the dioxin assessment to the current PFOA/PFOS assessment. There are many differences between PFOA and PFOS and dioxins that have resulted in different findings in their respective risk assessments. First, the concentrations of dioxin (expressed as toxic equivalent concentration or TEQ) was far lower in the 2001 National Sewage Sludge Survey (NSSS) than the 1 ppb value used here for PFOA and PFOS. Most of the samples in the 2001 NSSS had TEQ values between 7 and 55 ng/kg (part per *trillion* or ppt); these data were used to generate a distribution of concentrations for the 2003 dioxin risk assessment. There are currently no national survey data on PFOA and PFOS concentrations in U.S. sewage sludge; however, data from states and peer-reviewed journal articles indicate that many PFOS sludge concentrations are near 10 parts per *billion* (ppb) with an upper range value being above 100 ppb (see draft risk assessment, appendix A). In short, PFOS concentrations in sewage sludge appear to be about 1000 times higher than dioxin concentrations were at the time the EPA developed the dioxins risk assessment.

Second, PFOA and PFOS are more mobile than dioxins, resulting in greater plant uptake and transport to groundwater and surface water. This greater mobility of PFOA and PFOS resulted in

groundwater being included as a pathway for draft risk assessment whereas it was scoped out of the dioxin assessment entirely. Similarly, in the dioxins assessment, the uptake of dioxins to above grounds plants was limited to dioxins becoming airborne from the soil and then being absorbed or landing on the plant as particulates. For PFOA and PFOS, studies demonstrate that these chemicals are transported to plant vegetative tissue via the plant vascular system.

Third, the reviewer has focused on the toxicity of one congener (2,3,7,8-TCDD); however, many of the congeners found in sewage sludge have toxic equivalence factors much less than one, *i.e.*, a fraction of the toxicity of 2,3,7,8-TCDD. Specifically, TEQs range from 1 to 0.00001, see Table 2-2 of the 2003 dioxins assessment (US EPA, 2003). This makes it difficult to directly compare the hazard of PFOA or PFOS in sewage sludge to dioxins in sewage sludge. In the case of PFOA and PFOS, the EPA is relying on toxicity values (reference doses, cancer slope factors) that are specific to these two chemicals.

In summary, dioxins and PFOA/PFOS differ in their occurrence in sewage sludge, their fate and transport behaviors in natural systems, and their human health toxicity. These differences have resulted in differences between the risk conclusions for dioxins in biosolids and the preliminary risk conclusions for PFOA or PFAS in biosolids.

COMMENT: Recommend this risk assessment compare the Section 3 media groundwater (and surface water?) concentrations to the Maximum Concentration Limits (MCLs) for PFOS and PFOA for all drinking water ingestion scenarios. This comparison should be done in the tables and the text.

RESPONSE: The EPA disagrees that is it appropriate to compare surface water and groundwater concentrations to MCLs in the context of this risk assessment. As described previously (*see* page 9), the MCLs for PFOA and PFOS finalized under the PFAS Drinking Water Rule take into account best available treatment technology in drinking water and cost to drinking water systems.

Reviewer 5

COMMENT: The description of EPA's Biosolids Program, including its statutory and regulatory authorities, provides a helpful context and basis for the risk assessment. First, the text highlighted Section 405 of the Clean Water Act (CWA) as the primary legal authority under which the EPA is required to establish and review regulations to protect public health and the environment from the adverse effects of pollutants in sewage sludge. Then, it introduced the Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503).

The historical regulatory context is particularly important, as it shows the evolution of the EPA's approach to managing risks associated with sewage sludge. The document traces the development of the EPA's sewage sludge regulations from the first rule in 1993, which established pollutant limits and management practices for ten metals, to subsequent risk assessment around dioxins and dioxin-like PCBs. This historical context establishes a foundation for understanding the risk assessment of PFOA and PFOS by connecting it to previous regulatory actions and frameworks used by the EPA. Introducing prior work before discussing the risk

assessment of PFOA and PFOS in sewage sludge is helpful because it provides relevant background knowledge for understanding the assessment results, and helps the reader to appreciate the wide range of outcomes that can result from the risk assessment, including setting numeric standards if considerable risk is found, and not setting a numerical standards if there is considerable sufficient safety margin.

RESPONSE: Thank you for your comment.

QUESTION 2: Problem Formulation

Problem formulation. ***Please comment on the characterizations of the environmental fate, exposure, and toxicity of PFOA/PFOS in the problem formulation section of the risk assessment (see Section 2, Appendix A).***

Reviewer 1

COMMENT: The state of the science regarding factors influencing PFOA/PFOS partitioning in the environment is clearly described. Historical measurements of PFOA and PFOS in biosolids are presented, and the potential for precursors to contribute to PFOA/PFOS concentrations in biosolids is highlighted.

RESPONSE: Thank you for your comment.

Reviewer 2

COMMENT: As a screening tool the models used appear well formulated if somewhat simplified. The Box equations on pages 42 and 43 illustrate this. While including essential features of concentrations, exposures, and risk, certain nuances are left out. However, the effect of these details may be expected to be insignificant given the approaches, e.g., high-end and median estimates of exposure and risk discussed.

RESPONSE: Thank you for your comment. It is unclear what “certain nuances” the commenter is referring to.

Reviewer 3

COMMENT: The description of the processing of influent and sewage sludge at wastewater treatment plants (WWTPs) highlights an intriguing aspect of environmental toxicology. The breakdown of fluorinated precursors into perfluorooctanoic acid (PFOA) and perfluorosulfonic acid (PFOS) during wastewater treatment and sludge processing underscores a critical area of concern. This process is particularly relevant given that these chemicals are persistent and hazardous. Precursors such as perfluorooctane sulfonamidoethanol-based phosphate diesters, fluorotelomer alcohols, and polyfluorinated iodides are commonly transformed into PFOA and PFOS, which then accumulate in biosolids used in land applications.

The research into these transformations is of high priority in environmental toxicology due to the significant environmental and health implications. Laboratory studies and real-world observations indicate that biosolids' treatment and land application are crucial pathways through which these hazardous chemicals are introduced into soils and the broader environment. The presence of these precursors in consumer products and their subsequent release into wastewater emphasizes the need for a focused assessment on PFOA and PFOS.

Given the identified data gaps in understanding these precursors' occurrence, environmental fate, and degradation pathways, further research is necessary. The current risk assessment prioritizes PFOA and PFOS due to their established risks, but future assessments should consider the

broader scope of PFAS precursors and their impacts. The findings could lead to refined policy decisions regarding managing these substances, enhancing our ability to mitigate environmental and health risks.

RESPONSE: Thank you for your comment. The EPA agrees that research to better understand the environmental fate and effects of precursors to PFOA and PFOS is important.

Reviewer 4

COMMENT: Section 2.6.1.1 of the Risk Assessment provides a detailed, well-written, and thorough explanation of the USEPA's Human Health Toxicity results. Recommend providing the readers of the document with a brief mention of regulatory examples and human toxicity studies that result in alternative viewpoints of PFOS/PFOA safe doses. For example:

- Australia's PFOA drinking water guideline is 560 ng/L vs. a USEPA interim health advisory level of 0.004 ng/L and a USEPA MCL of 4 ng/L.
- Burgoon et al., 2023 summarizes the work of 24 scientists from 8 countries who concluded the PFOA safe dose is between 10-70 ng/kg/day vs. USEPA's 0.03 ng/kg/day RfD (Table 4). Burgoon et al. (2023) states: *"However, this range is well above the single values of both EFSA (2020) and EPA (2023). The principal reasons for the larger disparity between this provisional range with these latter two single values is the unanimous judgment of the international collaboration that the existing human cancer and noncancer data are not sufficiently credible as a basis of the PFOA safe dose in the absence of mechanistic data that are relevant to humans at serum concentrations seen in the general population. In this regard, Health Canada, the WHO and Food Standards of Australia and New Zealand are in agreement with the Collaboration—the use of human data is not sufficiently credible as the basis for the PFOA safe dose."*

Finally while this is likely be untenable for the purpose of this USEPA risk assessment, is it possible that the Australia /Burgoon et al. toxicity values above are closer to the goal of reporting a "Central Tendency" for a biosolids risk assessment than using the current USEPA toxicology factors in Tables 4 and 5? Were the USEPA toxicological values developed in part using data from unusual populations and therefore may not to represent a toxicological "central tendency" of the response to PFOS/PFOA exposure to the population in the U.S.?

RESPONSE: As described previously, the EPA is relying on the conclusions of the agency's Final Human Health Toxicity Assessments for PFOA and PFOS (US EPA, 2024a;b) because these documents represent the best available science on PFOA and PFOS human health toxicity and were written in accordance with longstanding EPA policies and guidance on toxicity assessment. See the EPA's prior response on this topic on page 9 of this document.

As to the differences between the EPA's toxicity assessments and similar documents from other sources, one explanation for differing conclusions between health agencies are the differing methods and guidance used to develop the assessments. The EPA uses established systematic review practices to identify, evaluate, synthesize, integrate, and quantify evidence in a chemical database (US EPA 2022). Other health agencies, including the WHO, do not follow these same practices and, as a result, may arrive at different conclusions. Notably, the WHO has recently

withdrawn their proposed drinking water guidelines for PFOA and PFOS. Additionally, the EPA followed agency guidance, such as the Guidelines for Carcinogen Risk Assessment to determine the cancer classifications for PFOA and PFOS (US EPA, 2005). The classification systems used by other agencies (*e.g*., IARC, UK COT, CalEPA) differ from those used by the EPA; the application of different systems may result in different conclusions by other agencies. However, CalEPA's final public health goals are also generally supportive of the EPA's cancer classifications for PFOA and PFOS (CalEPA, 2024). As a final example, some agencies, such as the WHO, have published guidance values that are not solely health based (*i.e*., they consider feasibility, analytical methods, *etc*.) and, therefore, cannot be directly compared to the EPA's MCLGs, which are based solely on health effects information.

Further, the EPA disagrees with comments stating that the epidemiological database for PFOA is too uncertain to support a classification of Likely to Be Carcinogenic to Humans. As described similarly in both the draft and final toxicity assessments for PFOA as well as the Maximum Contaminant Level Goals for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS) document (US EPA, 2024d), the available epidemiological data support an increased risk of both kidney and testicular cancers associated with PFOA exposure. There is also evidence that PFOA exposure may be associated with an increased breast cancer risk, based on studies in populations with specific polymorphisms and for specific types of breast tumors. Taken together, these results provide consistent and plausible evidence of PFOA carcinogenicity in humans. Additionally, while genotoxicity is one potential MOA for carcinogenicity, there is no requirement that a chemical be genotoxic for the EPA to classify it as either Carcinogenic to Humans, Likely to Be Carcinogenic to Humans, or Suggestive Evidence of Carcinogenic Potential according to the Guidelines for Carcinogen Risk Assessment. Importantly, the SAB PFAS Review Panel supported the rationale for the Likely to Be Carcinogenic to Humans designation for PFOA in its final report.

Reviewer 5
COMMENT: Section 2 provided a comprehensive characterization of the environmental fate, exposure, and toxicity of PFOA/PFOS, which offered helpful background information for the risk assessment.

Section 2.1 is about the general literature search strategy; it is good to see that the authors of the report also referenced "grey literature" in their search.

Section 2.2 is about the chemical and physical properties of PFOS and PFOA, and their environmental behavior including fate and transport. The discussions around the transformation and degradation of precursors are particularly important, as this process is responsible for a considerable proportion of PFOA and PFOS load in the sewage sludge.

Section 2.3 is about the sources to wastewater treatment plants and biosolids, in which the authors cited relevant literature to discuss the source of PFOS and PFOA despite the phase-out of domestic manufacturing of these compounds. Here I wish the authors expanded more on any quantitative information they can find regarding the contribution of different sources of PFOS/PFOA to WWTPs in various geographies across the country. This review activity can be

nicely combined with the literature summary in section 2.4, where the authors synthesized recent studies over the past 15 years on PFAS occurrence data in biosolids. An easy improvement is to add a column to Tables A and B in Appendix A, and list major source of PFAS to the WWTP included in the study, if the paper reported any.

RESPONSE: Thank you for the helpful comment. There is a varying level of information available in the studies on the sources of PFOA and PFOS to the monitored biosolids. The EPA included information in the text and Appendix A where studies highlighted the sources (*e.g.*, Michigan and Vermont). Since most studies do not pinpoint the PFOA and PFOS source, the EPA is planning the upcoming influent study to gather nationwide PFAS data on industrial and domestic sources and concentrations in POTW influent, effluent, and sewage sludge.

COMMENT: Section 2.5 is about PFOA and PFOS accumulation in animal and plants, and it is relevant for a few different purposes of the report: the discussion of PFOA/PFOS accumulation in human is relevant for understanding reference dose and potential health effects, as well as internal dose calculation; the discussion of other animals is relevant for the exposure pathway of fish consumption; the discussion of plants uptake is relevant for the exposure pathway of consuming contaminated produce. I find the discussions about phytoremediation interesting but not particularly relevant to the focus of this report.

Section 2.6 is about the effects on human and aquatic and terrestrial biota. For human toxicity, the authors discussed the health effects of different exposure pathways and included reference dose (RfD) as well as cancer slope factor (CSF) for PFOA/PFOS from the recent EPA toxicity assessment. For ecological effects, the authors included a helpful table comparing the freshwater aquatic life water quality criteria in Table 3. For terrestrial organisms, since the amount of data available is less, listing the reference doses equivalent in the paragraph is helpful to set the stage for the discussion in section 2.6.3.

Section 2.7 is about exposure pathways for humans and aquatic and terrestrial biota. Section 2.7.1 can be more strengthened with adding quantitative information about the contributions of various exposure pathways. This information likely differs for different geographical regions, so the authors can discuss a few scenarios such as communities with contaminated drinking water, general population, occupation exposure, and children.

RESPONSE: The EPA agrees that information about relative contributions of each exposure pathway in each sewage sludge use or disposal scenario is useful in the context of exposures from biosolids use and disposal; this information is currently available in Section 4 (Risk Estimation). This assessment does not include discussion of exposure scenarios where there may be sources of PFOA and PFOS exposure other than biosolids (*i.e.*, non-biosolids occupational exposures, communities with drinking water contamination from another source, consumer products) because this risk assessment is scoped to consider only risks from sewage sludge use and disposal.

COMMENT: Section 2.8 introduces the four modeling scenarios: crop farm scenario, pasture farm scenario, surface disposal scenario, land reclamation scenario, and other land application scenarios. For each scenario, the authors developed a conceptual model to describe the pathways from source to environmental media, to exposure pathways, and to receptors. These are helpful to set up the framework before getting into the model parameters in the subsequent sections. The last scenario has considerable uncertainties around the key parameters and processes, so they were assessed qualitatively.

Section 2.9 is the analysis plan, which walked through the progression of risk assessment models from high-end deterministic models, to central tendency deterministic models, and last to probabilistic models. This is a logical progression as it went from most conservative to more realistic scenarios. This section also includes the various models EPA selected for assessing the different steps of PFOS and PFOA fate and transport: including from soil to groundwater, from groundwater to surface water, from groundwater to drinking water wells, and leaching through lined or unlined surfaces. This section also has detailed information on how EPA obtained parameters for these models and their literature review strategy. When there is an existing assessment or report from EPA or another agency, those conclusions are prioritized over individual studies. For peer-reviewed studies, field studies are favored over lab studies, and studies with biosolids applications are favored over other sources of PFAS contamination.

RESPONSE: Thank you for your comment.

QUESTION 3: Ecological Risk Assessment

Ecological risk assessment. As described in Section 2.6.3, available data indicate that risk to aquatic and terrestrial life from land application of biosolids contaminated with PFOA and/or PFOS is expected to be lower than the potential risk to human health from same/similar biosolids applications. As a result, the quantitative risk assessment (risk estimates, risk characterization) is scoped to focus solely on human health. Please comment on the conceptual and technical basis for limiting the assessment of ecological risk and focusing on human health for PFOA/PFOS.

Reviewer 1

COMMENT: The rationale for limiting the assessment to human health is sound considering that human health-based thresholds are more stringent, which means that guidelines established based on risk to humans would be protective for the terrestrial and aquatic ecosystems. It could be noted that animal/plant toxicity experiments are typically conducted at much higher doses, which may not allow the observation of low-dose effects.

RESPONSE: Thank you for your comment that the rationale for limiting the scope of this draft risk assessment to human health is sound based on the relative stringency of potential human-health protective practices compared to the stringency of potential practices protective of aquatic or terrestrial wildlife.

The EPA disagrees with the statement that there are not experimental data available regarding the potential for low-dose effects in aquatic animals. The EPA's final Aquatic Life Criteria for PFOA and PFOS include summaries of many studies conducted over chronic exposure scenarios that include observations of sublethal and potentially sensitive endpoints (US EPA, 2024e;f). These studies are available for many species of fish and aquatic invertebrates. The aquatic life criteria found multiple studies to evaluate surface water concentrations protective of 95% of aquatic organisms. Even given these data, surface water concentrations with the potential to impact human health via drinking water or eating fish are much lower than surface water concentrations potentially harmful to aquatic life. For example, the PFOA and PFOS 2022 interim drinking water health advisories were well below 1 ppt and the 2024 final health-based MCLGs for PFOA and PFOS were each zero, whereas the final chronic aquatic life criteria are 250 ppt for PFOS and 100,000 ppt for PFOA. Risks associated with fish consumption also are expected to occur multiple orders of magnitude below the EPA's national recommended aquatic life criteria (see draft risk assessment section 2.6.3).

The EPA agrees that there are limited PFOA and PFOS toxicity data available for terrestrial organisms, such as birds and other wildlife. Toxicity data for terrestrial plants and soil invertebrates are also limited and primarily focus on acute (mortality) effects (see section 2.6.2.2 of the draft risk assessment). The EPA will continue monitor the available ecotoxicological literature for terrestrial organisms.

Reviewer 2

COMMENT: Data on non-human toxicity of PFOA and PFAS is limited with only a few studies done examining effects on plants, invertebrates, birds, and livestock/game. These limited data result in substantial uncertainty in expected health impact and ecological risk in these media.

They do, however, suggest that the impact on these classifications of living organisms may be substantially less than those observed in humans. However, these must be strongly tempered by the relative number of investigations on them compared to human studies.

It is my opinion that the data on non-human life forms is currently too sparse to consider ecological risk assessments. I do think this data gap compels EPA to fund or carry out in-house research programs evaluating these effects in order to obtain more reliable estimates of exposure and effect. Such data would be useful in parameterizing models to look at the effects of control strategies or likely impacts of current levels on ecological risk assessments. Further, such studies may suggest whether the need for control strategies focused on ecological risk are even necessary. The current values thought to be protective of ecological systems exceed- often far exceed- those values being considered protective of human health. Hence implementing values protective of human health likely would prove sufficient for protecting ecological health with a large margin of safety. Additional data collection on PFOA/PFOS in ecological systems is warranted but is unlikely to result in regulations that would place such systems under greater regulatory control than regulations based upon human protection.

In summarizing my view of the ecological risk evaluation work presented in this Report, I believe EPA has made a correct decision to focus on the human health outcomes but should follow the literature coming out currently focusing on ecological impact with an eye towards developing additional ecological risk parameters. At this point, I do not feel enough data are available to make reasonable estimates for modeling.

RESPONSE: Thank you for your comment that available data suggest impacts of PFOA and PFOS exposure to plants, invertebrates, birds, and livestock appear to be substantially less sensitive than the impacts observed to these exposures in humans. As stated previously, the EPA agrees that there are fewer studies available observing effects in non-human terrestrial animals and terrestrial plants than are available for humans, and that this lack of data warrants discussion in the draft risk assessment. The EPA has added such discussion. The EPA will continue monitor the available ecotoxicological literature for terrestrial organisms.

Reviewer 3

COMMENT: The conceptual and technical rationale behind limiting ecological risk assessment for PFOA and PFOS and focusing primarily on human health appears fundamentally flawed and potentially shortsighted. This approach underscores a troubling tendency to prioritize human health risks over broader ecological impacts, which could lead to inadequate ecosystem protection.

Firstly, the assertion that adverse effects on plants, invertebrates, fish, and birds occur at higher concentrations than those affecting humans does not necessarily justify minimizing ecological risk assessments. Ecosystems are complex and interconnected, and focusing narrowly on human health could ignore subtle yet significant ecological impacts. For instance, the health of plants and invertebrates can influence broader ecological functions, including nutrient cycling, food web dynamics, and habitat structure. Adverse effects in these species might reflect direct harm

and disrupt these essential ecological processes, ultimately affecting biodiversity and ecosystem resilience.

RESPONSE: As stated above, surface water concentrations with the potential to impact human health via drinking water or eating fish are much lower than surface water concentrations potentially harmful to aquatic life. For example, the PFOA and PFOS 2022 interim drinking water health advisories were well below 1 ppt and the 2024 final health-based MCLGs for PFOA and PFOS were each zero, whereas the final chronic aquatic life criteria are 250 ppt for PFOS and 100,000 ppt for PFOA. Risks associated with fish consumption also are expected to occur multiple orders of magnitude below the EPA's national recommended aquatic life criteria (see section 2.6.3).

The EPA agrees that there are limited PFOA and PFOS toxicity data available for terrestrial organisms, such as birds and wildlife. Toxicity data for terrestrial plants and soil invertebrates are also limited and primarily focus on acute (mortality) effects (see section 2.6.2.2 of the draft risk assessment). The EPA will continue monitor the available ecotoxicological literature for terrestrial organisms.

COMMENT: Moreover, there needs to be more adverse effects reported in livestock to equate to a comprehensive understanding of environmental impacts. Livestock health is only one aspect of the broader ecological system, and its absence from studies does not negate the potential for other wildlife or plant species to suffer from exposure to PFOA and PFOS. This narrow focus could overlook cumulative and indirect effects that may become apparent only after prolonged exposure or under specific environmental conditions.

RESPONSE: The EPA is confused by the suggestion that this assessment narrowly focuses on adverse effects to livestock. The EPA agrees that adverse effects in livestock would be a distinct concern from adverse impacts to terrestrial wildlife or ecosystems. Moreover, the EPA does not indicate in the draft risk assessment that the presence or absence of adverse effects in livestock gives significant indication of the potential for adverse effects terrestrial wildlife like insects, other mammals, or disruptions to ecosystems. As written, the assessment summarizes available data on terrestrial wildlife toxicity separately from the available data on livestock toxicity in section 2.6.2.2.

COMMENT: From a technical standpoint, the decision to base risk thresholds primarily on human health rather than ecological criteria overlooks significant concerns. The observed effect levels for soil and aquatic environments being in the range of 10's to 100's mg/kg for PFOA and PFOS, compared to much lower thresholds for protecting human health, suggests a substantial disparity in protective measures. This discrepancy indicates that current aquatic life criteria and soil thresholds may be insufficiently stringent to prevent ecological harm, potentially allowing harmful concentrations of these substances to persist in the environment.

Additionally, the notion that human health-based thresholds will inherently protect ecological systems is problematic. Ecosystems only sometimes respond straightforwardly to contaminants, and different species and environmental compartments can have varying sensitivities to pollutants. The assumption that setting stringent human health standards will automatically

ensure ecological protection is an oversimplification that needs to account for the diverse ways pollutants can affect the environment. For example, fish might accumulate PFOA and PFOS at levels that are not directly harmful to human health but could still have detrimental effects on fish populations and aquatic food webs.

Furthermore, the argument that more studies on wildlife effects could bridge the gap between ecological and human health thresholds is insufficient. The current reliance on human health criteria as a proxy for ecological protection risks inadequate safeguards for ecosystems. Immediate and rigorous ecological risk assessments are crucial to address potential gaps and to ensure that both human health and environmental health are comprehensively protected.

In summary, the approach of prioritizing human health over ecological risk for PFOA and PFOS, while understandable given the potency of these chemicals in human health contexts, needs to be revised. It fails to account for the complexities of ecological systems and the potential for indirect and cumulative environmental impacts. A more balanced approach that integrates both human and ecological health considerations is essential for effective and comprehensive risk management.

RESPONSE: The EPA disagrees with this comment. As described previously, the EPA's recently finalized Aquatic Life Criteria for PFOA and PFOS include chronic, low-dose studies with observations of potentially sensitive non-lethal effects (US EPA, 2024e;f). It is possible for chemicals to have larger effects (increased toxicity) on human health than on other organisms, or vice versa, which would result in a "disparity" in the observed effect levels and the resulting protective thresholds for humans as compared to other organisms. Given the currently available data, it appears that PFOA and PFOS have substantially longer half-lives in human beings and are more toxic to humans than to other terrestrial or aquatic organisms. That said, the EPA acknowledges that there are far fewer studies available on toxicity to terrestrial wildlife than are available on toxicity to humans. The EPA will continue to evaluate the available data on ecological effects.

Specifically with regards to fish, the draft biosolids risk assessment finds that fish accumulate PFOA and PFOS levels into the edible portions of their body that are potentially harmful to human health at very low concentrations of PFOA and PFOS in surface water (far lower than currently available detection limits; see sections 3 and 4 of the draft risk assessment). Even very low levels of PFOA or PFOS in fish tissue result in risks above the EPA's acceptable threshold for human health (1-in-1-million cancer risk level). These same levels of PFOA and PFOS in fish tissue do not exceed the EPA's final chronic tissue-based aquatic life criteria for PFOA and PFOS.

While the EPA agrees that there could be complicated ecosystem responses to chemicals, the reviewer has not provided any citations to quantitative data of these effects for use in this assessment of PFOA or PFOS. As described previously, the EPA finds that currently available data indicate that human health assessment will result in lower (more protective) media concentration thresholds than the terrestrial or aquatic ecological assessments. The EPA will continue to monitor the literature for ecotoxicity studies, particularly for plants and wildlife.

Reviewer 4
COMMENT: No comments.

Reviewer 5
COMMENT: The decision to limit the assessment of ecological risk and focus primarily on human health in the risk assessment of PFOA and PFOS is based on the observation that the toxicity thresholds for these chemicals are significantly lower in humans than in aquatic and terrestrial life. Specifically, the concentrations of PFOA and PFOS that pose risks to human health, particularly through ingestion, are much lower than the levels that cause adverse effects in plants, invertebrates, fish, and birds. For instance, soil and water concentrations protective of human health are orders of magnitude more stringent than those required to protect ecological systems. Given the more potent nature of PFOA and PFOS toxicity in humans, the EPA has chosen to prioritize human health endpoints in the biosolids assessment. This approach is conceptually and technically justified because protecting human health at such low thresholds is likely to also provide adequate protection for ecological receptors, even though the exact risk levels for wildlife may still need further investigation. This strategy ensures that human health is not compromised while still offering a degree of protection to the broader environment.

RESPOSE: Thank you for your comment that the EPA's approach is conceptually and technically justified, even with the understanding that risks to wildlife may require further investigation and research.

QUESTION 4: Pathway evaluation, model selection, model parameterization, risk estimation and risk discussion

Pathway evaluation, model selection, model parameterization, risk estimation and risk discussion. The draft risk assessment shows that human health risks associated with drinking water and diet are expected to be the greatest among modeled scenarios and pathways. Please comment on the technical basis and clarity of the following elements in supporting this interpretation. Be as detailed as possible about deficiencies and suggested improvements:

*a. **Models and parameters selected for these scenarios and pathways, including comment on the inclusion of relevant scenarios (e.g., pasture farm) and pathways (e.g., groundwater, fish consumption) – see Sections 2.9.2, 2.9.3, Appendix B and Appendix***

Reviewer 1

COMMENT: The exposure scenarios are reasonable given they pertain to the individuals most likely to be exposed to PFOS/PFOA present in biosolids, i.e., individuals living on farms where biosolids have been applied.

When reading the section on transport models, I was confused as to what approach was selected. On page 39, the text states that "no currently available transport models reliably predict the timing of PFOA and PFOS impacts to groundwater after surface application" and that "Consistent with previous sewage sludge risk assessments, this assessment will consider the peak groundwater concentrations when calculating risks". However, the following sections describe models (e.g., EPACMTP) that were used to calculate transport. I think the overall process could be clearer.

RESPONSE: Thank you for your comment. The EPA has revised the text for improved clarity (*see* Section 2.9.2). There are several aspects of subsurface fate and transport models that the EPA evaluated when deciding which model to use, including how well the model captures peak concentration in the aquifer and how well the model captures the timing of the chemicals arriving to groundwater. Based on this assessment of available models, the EPA concluded that the EPACMTP model was the best available for this portion of the draft risk assessment.

COMMENT: Although the data on parameters like BCFs and BTFs are relatively sparse, the values selected for the models seem reasonable. However, I'm unsure the 10-year exposure period is conservative enough for farm families who could potentially be exposed for longer. That being said, estimated risks would be more elevated if a longer exposure period is used, which wouldn't change the conclusions.

RESPONSE: The EPA disagrees that bioconcentration factor (BCF) and biotransfer factor (BTF) data are sparse for PFOA and PFOS. While additional scientific data could be useful to improve the understanding of plant and livestock uptake, the quantity and quality of studies measuring PFOA and PFOS uptake into plants and livestock are relatively robust. Empirical data were available for all of the uptake and accumulation parameters (BAFs, BTFs, BCFs) used for calculations in this assessment, which distinguishes this assessment from screening assessments that often included modeled or estimated parameters. The number of fish BAF studies is also large compared to other chemicals.

The EPA agrees that many farm families reside on their property for more than ten years; however, as noted by the commentor, a modeling scenario with a longer duration of exposure on the farm would likely increase the risk findings of this assessment and therefore not change the conclusions. The EPA selected a residency time of ten years consistent with the goal of targeting a "central tendency" exposure scenario.

COMMENT: Calculations were made using a 1 ppb PFOS/PFOA. Measured concentrations in biosolids often far exceed this value. Is the relationship between starting concentrations in biosolids and risk estimates linear? In other words, would risk estimates be 5 times higher if the starting PFOA concentration was 5 ppb? Adding this information would help readers estimate the risks at higher starting biosolids concentrations (e.g., average concentrations in Maine).

RESPONSE: Yes, the models currently have a linear relationship between the starting concentration of PFOA and PFOS in sewage sludge and the calculated risk levels for each pathway. As you describe, this means that a sewage sludge with a starting concentration of 10 ppb PFOA or PFOS would have a final risk level (hazard quotient or cancer risk level) 10 times the reported value in this draft risk assessment. The EPA has added a description of this linear relationship to the draft risk assessment (*see* Section 3.1 in the draft risk assessment).

COMMENT: Lactational exposure was not included in the assessment. Breastfed infants in farm families could potentially be receiving a much higher daily dose than their parents. I understand including breastfeeding as a route of exposure would add a layer of modeling (pharmacokinetic) in this assessment, and results would be difficult to interpret in this context, but I was surprised to see that only a small section (page 110) is dedicated to this. If the EPA decides not to include this route of exposure, I suggest adding a strong rationale for not doing so in one the previous sections.

RESPONSE: As the commentor mentions, this topic is currently described in Section 4.8 of the draft risk assessment. Because the draft risk assessment already finds that there are unacceptable risk levels using the lower drinking water intake value for non-pregnant or lactating adults, it was not necessary to add additional risk tables with risk results calculated specifically for pregnant and lactating women. Instead, as described in the draft risk assessment, risks to this population would be 14-71% higher than the risks presented for the drinking water pathways in each scenario. The EPA agrees that this population is important to consider when weighing risk reduction options and communicating with the public.

Reviewer 2

COMMENT: Pasture and crop farms are well visualized with appropriate modifications of scenarios. Land reclamation is modeled similarly to Pasture Farm but at a higher level of application.

The High-end Deterministic: The High-end Deterministic Risk Screening tool is very, very conservative using a series of 95th percentile estimates and exposure. As noted on Page 37 Line 8- "could result in excess risk". One may argue that there is more risk estimates are possible if one were to perform Monte Carlo models, but such seems unlikely given the compounding of low-probability, i.e., 95th percentile, values for several parameters. I disagree with "reasonable

maximum exposure" argument, however. I would think that compounding a 95th percentile concentration with a 2.4L/day intake rate, also a 95th percentile, puts one at something on the order of a 99th to 99.9th or even higher percentile level.

RESPONSE: The commenter appears to misunderstand the Biosolids Tool (BST) and how the results are interpreted for the purpose of screening. The purpose of the BST is to prioritize compounds for further risk assessment. Choosing conservative values for parameters like the biosolids concentration and the exposure factors is appropriate for this goal.

COMMENT: Central Tendency Deterministic: The Central Tendency Deterministic modeling approach offers a more realistic assessment of the exposure and risk than does the High-End Deterministic approach. However, it gives no real assessment of the risk in context of a population. Data showing that such an approach does lead to an estimate of, say, the median exposure and risk to some (or the general) population would be more compelling. The argument, however, is made heuristically, which is, of course, a weaker argument. Additional thought and justification for these assumptions is warranted.

RESPONSE: By parameterizing models with median values for each scenario, it is expected that the model will output a median risk level for the target population in each scenario. Section 2.9.3.8 provides more information about the targeted population. Importantly, this biosolids risk assessment is primarily focused on a potential risks to a farm family because that population is likely to have the highest exposure to PFOA and PFOS from land applied biosolids. This approach is consistent with past agency practice when conducting biosolids risk assessments under CWA section 405 (US EPA, 1992; US EPA, 2003).

Reviewer 3

COMMENT: The selection of independent models for the PFOA and PFOS assessment is highly appropriate for addressing the complex fate and transport of these contaminants. By employing a series of specialized models tailored to different environmental scenarios—such as crop farms, pasture farms, reclamation sites, and surface disposal sites—the EPA ensures a comprehensive evaluation of how PFOA and PFOS move through various environmental media. The initial models focus on the sorption and movement of these chemicals through soil and groundwater, which is crucial for understanding their potential pathways and concentrations in different settings. Subsequent models that track runoff, erosion, and leaching, and estimate concentrations in surface water and groundwater, provide detailed insights into the dispersion and potential impact on drinking water sources. The final step, using uptake factors to calculate concentrations in food products and subsequently assessing risk to human health, ensures that all relevant exposure pathways are considered. This multi-tiered approach allows for a thorough assessment of PFOA and PFOS across multiple environmental compartments and human exposure scenarios, providing a robust framework for evaluating risks and informing regulatory decisions.

The approach described is highly appropriate and adequate for the risk assessment of PFAS. Prioritizing exposure factors specific to home-produced foods for agricultural site models, and using the most current data from the EPA's Exposure Factors Handbook, ensures that the

assessment accurately reflects real-world conditions and exposure scenarios for farm families. Additionally, employing regionally representative parameters and default values from peer-reviewed EPA models enhances the reliability of the environmental fate and transport predictions. This thorough and up-to-date methodology provides a robust framework for accurately assessing PFAS risks, accounting for both specific and general environmental and exposure factors.

The selection and parameterization of the models for assessing PFOA and PFOS risks are executed with exceptional precision. The incorporation of specific fate and transport considerations, along with well-chosen models for surface water, groundwater, air dispersion, and plant and animal uptake, demonstrates a comprehensive and detailed approach. The model parameters, including toxicity values, sewage sludge concentrations, physical and chemical properties, and various uptake factors, are thoroughly vetted and aligned with the latest research and data. Additionally, the careful selection of studies to inform these models ensures robustness and reliability. This meticulous approach leaves no room for further comment on this section, as it is exemplary in its execution.

RESPONSE: Thank you for your comment.

Reviewer 4
COMMENT: No comments.

Reviewer 5
COMMENT: The selected modeling approach involves using several independent models to estimate the concentrations of PFOA and PFOS across different environmental media, such as soil, surface water, and groundwater, within various scenarios (e.g., crop farm, pasture farm, reclamation site, and surface disposal site). The scenario about sewage sludge incinerators is qualitatively discussed due to the uncertainties around PFOS and PFOA destruction in incinerators. The first two scenarios are discussed in more detail because they represent the higher exposure dosage from a human health perspective. This rationale is justified. Section 2.9.2 then walked through different PFOA and PFOS fate and transport models, including surface soil, surface water, groundwater, air dispersion, and plant and animal uptake. The choice of using existing EPA models is appropriate, such as using EPA's 3MRA model to assess soil surface processes and using EPA's VVWM model to assess surface water processes. The plant and animal update processes are described with several equations multiplying together soil concentration and bioconcentration factor. I don't have any critique for the equations used for plants and fish. However, for livestock, are we assuming the ingested PFOS/PFOA will be absorbed at 100%? Usually, there is a bioavailability factor for the amount of PFAS livestock can absorb from feed as well.

RESPONSE: As stated in the draft risk assessment in Section 2.9.3.6, "There are no data available on PFOA and PFOS bioavailability to livestock specifically from feed, water, or soil; this assessment assumes 100% is available when orally ingested." Though there are no studies available that specifically study the bioavailability of PFOA and PFOS in feed, this assumption is supported by closely examining the studies used understand accumulation in livestock. The studies used to derive BTFs for livestock include a variety of exposure scenarios for the

experimental animals. In some cases, the animals are exposed through water only, in other cases the animals are exposed feed only, and in other cases the animals are sampled from a pasture farm where they have exposure from feed, water, and soil. When comparing the PFOA BTFs dervied for chicken eggs from the Wilson et al. 2020 study (animals exposed only through water) and the Kowalzak et al., 2020 (animals exposed only through contaminated feed), the calculated BTFs are nearly identical. This indicates that if there is a reduced bioavailability of PFOA in chicken feed, that effect is likely negligible. In the case of dairy cows, the BTFs selected for this study (from Vestegren et al., 2013) were derived by calculating the exposure from feed and water combined. If there were a reduced bioavailability of PFOA or PFOS in feed in dairy cows, this would already be factored into the BTF calculation. For beef cattle, the BTFs were also derived using data from pasture-fed cows (Vestegren et al., 2013 and Drew et al., 2021), so these factors also inherently consider differences in bioavailability between feed and water in the calculated values. Note that part of the reason previous assessments included assumptions about reduced bioavailability in feed compared to water is because the BTFs in these assessments were modeled, not measured. By using BTFs derived from empirical experiments with multiple sources of livestock exposure, the uncertainty regarding bioavailability across livestock exposure pathways is reduced or eliminated.

COMMENT: In Section 2.9.3, the process to parameterize the models is explained. I agree with prioritizing existing assessments or reports from the EPA or another agency over individual peer-reviewed studies. The choice of using RfD from the most recent final human health toxicity assessments for PFOA and PFOS is appropriate. It is also very encouraging to see that EPA was able to obtain all the parameters from the first two higher tiers of the data hierarchy focusing on biosolids applications, this helps with strengthening the relevance of the parameters to this risk assessment.

RESPONSE: Thank you for your comment.

b. Modeling of groundwater behavior for PFOA and PFOS. (see Section 2.9.2 and Appendix C focused on groundwater modeling).

Reviewer 1

COMMENT: The modeling presented in this section is beyond my expertise. Nevertheless, I have found the text to be clear and understandable for a reader like me.

RESPONSE: Thank you for your comment.

Reviewer 2

COMMENT: My expertise in groundwater modeling is limited. For example, I am not familiar with the EPACMTP modeling system as the work I have done has used PRZM for vadose zone transport and MODFLOW for groundwater. That being said, my brief review of EPACMTP suggests a more simplified model when compared to MODFLOW with fewer parameters that

may be appropriate for this screening level survey. It is my experience that more parameters introduce more uncertainty due to the uncertainty in each parameter compounding the whole.

RESPONSE: Thank you for your comment. The EPA agrees that MODFLOW is a more complicated flow model than the EPACMTP. MODFLOW has many more parameters and given that this risk assessment is modeling hypothetical farms in various regions of the U.S., rather than actual sites with a large quantity of measured site-specific field data, EPACMTP is a more appropriate model for this work. Additionally, EPACMTP is more appropriate than PRZM for vadose zone modeling because EPACMTP is more flexible to the conceptual models used in the biosolids risk assessments. For example, EPACMTP allows for the drinking water well to be placed away from the field where the application occurs, while PRZM requires that the well be located on the field.

Reviewer 3

COMMENT: The approach outlined for assessing PFOA and PFOS risk through the use of the 3MRA and EPACMTP models is methodologically sound and reflects a thorough understanding of the contaminants' behavior. The 3MRA source modules effectively capture the maximum mass flux of PFOA and PFOS from the top layer of soil or surface disposal units during the application period, providing a comprehensive estimate over a 150-year timeframe. This long modeling period ensures that even delayed or residual leaching is accounted for.

The subsequent use of EPACMTP to model the transport of PFOA and PFOS through the vadose zone and into groundwater is also appropriate. By considering the variability in vadose zone depth and acknowledging the unique challenges posed by PFOA and PFOS—such as their surfactant properties and interaction with soil minerals—this approach demonstrates a nuanced understanding of these substances. However, the fact that EPACMTP has not traditionally been parametrized for air-water interface effects suggests a potential limitation. Given PFOA and PFOS's distinct behavior at this interface, it might be prudent to evaluate whether additional model adjustments or supplementary methods are needed to fully capture these effects. Overall, while the approach is robust, attention to the unique properties of PFOA and PFOS could further refine the risk assessment.

RESPONSE: Thank you for your comment. The EPA includes a discussion of air-water interphase effects in Appendix C, but new research continues to be published on this topic. The EPA will continue to evaluate sub-surface transport models to describe PFOA and PFOS contamination of aquifers as this risk assessment is finalized and acknowledges that EPACMTP was not designed to capture air-water interface effects. The EPA will also investigate which modeled environments are most impacted by air-water interface effects.

COMMENT: The procedure described in the model implementation is generally a good approach for protecting groundwater resources, particularly in the context of a national risk assessment. The assumptions made, such as placing drinking water wells at the center of the buffer and focusing on the highest concentration areas of the groundwater plume, are conservative. This ensures that even in worst-case scenarios, human health and the environment are protected. By assuming that exposures occur during the years with the highest media concentrations, the model effectively captures a maximum risk scenario, which is appropriate for

broad, national assessments. Although this approach may overestimate risks for individuals with wells located on the fringe of the plume or deeper below the water table, the overarching goal is to safeguard public health. Overestimation of risk, in this case, is justified as it ensures that potential dangers are not overlooked, thereby protecting groundwater as a crucial source of drinking water. However, while these assumptions are suitable for national assessments, they might not accurately reflect the risks at specific sites where conditions differ. Despite this, the precautionary nature of the procedure aligns with the fundamental aim of risk assessment, which is to ensure safety and protect environmental and public health resources.

RESPONSE: The EPA appreciates the support for the strategy used in the draft risk assessment to assess the potential for risks via the groundwater to drinking water pathway. As described previously, the goal of this draft risk assessment is to determine if PFOA and PFOS may exist in concentrations in sewage sludge which may result in adverse effects in humans or the environment. Because drinking water wells may intersect with the contaminated plume and may be present near the land-application site, the EPA finds that it is appropriate to assess levels and risks in groundwater in this scenario.

The EPA agrees that the current risks to those living near biosolids use or disposal sites who use groundwater as a source of drinking water are difficult to quantify at this time. Currently, the EPA does not have data on the number of biosolids land application sites, the PFOA and PFOS concentrations of sewage sludges that were land applied, the size of any resulting groundwater plumes, or the number of people who are currently, or may in the future, use the contaminated groundwater as a source of drinking water. Quantifying the size of this potentially impacted population is outside the scope of the risk assessment.

Reviewer 4

COMMENT: Page 41: *"The hypothetical drinking water well in EPACMTP is represented by four observation locations placed at 0.5, 1.0, 1.5, and 2.0 meters below the water table to ensure the maximum groundwater concentration is observed."*

Page 32 and 56 of Appendix C: *"The well depths were limited to the top 2.0 m below the water table (1) to be consistent with a residential well scenario (these wells are generally shallow because of the higher cost of drilling a deeper well) and (2) to produce a conservative estimate of risk (because the infiltration rate is generally lower than the groundwater seepage velocity, groundwater plumes tend to be relatively shallow). "*

Page 45: *"While these assumptions may overestimate risk to a specific person at a specific site, they are reasonable for the purpose of risk assessment since they serve to protect human health and the environment."*

This reviewer appreciates the complexity of the groundwater calculation and the difficulties in formulating and applying a representative modeling approach, particularly with regards to concepts of being conservative in certain calculations with the intention of protecting human health and the environment. However, the goal of this groundwater pathway calculation is to identify the potential scope and magnitude of risks under different biosolids use and disposal scenarios on a *central tendency (median) risk basis*. Applying an overly cautious approach even

in one step of the calculation may greatly overestimate risk and jeopardize the accuracy and applicability of the central tendency risk assessment. Overall it is important to strive for a balanced and scientifically accurate assessment of potential exposure and not apply multiple "conservative" (overprediction) calculation steps.

RESPONSE: Groundwater is an important resource that requires protection. It is appropriate to report modeled concentrations of groundwater that are within the plume originating from the biosolids application site, even though it is possible that a well is located above or below the region of most impacted groundwater. Of course, it is also possible that a homeowner has a well located upgradient from the land application site or below an aquitard; building in such assumptions that represent lower or no groundwater impacts to the risk assessment would not advance the EPA's goals of identifying potential human health impacts. Further, the commentor appears to assume that the concentration of PFOA or PFOS rapidly drops off below the water table, such that the median and maximum groundwater concentration are significantly different. The EPA has added modeled vertical profiles of groundwater concentration to the modeling discussion that illustrate PFOA and PFOS concentrations are relatively consistent with depth, whether the well is located 10 meters or 5 meters from the land application site. In this way, the median and maximum concentrations of groundwater would be similar over a wide range of well depths.

COMMENT: The method that is currently used in Section 2.9.2 and Appendix C to translate modeled groundwater concentration in the underlying aquifer to an exposure concentration is one such example of a highly conservative (overprediction) calculation step., e.g., the text explicitly states this step is a "conservative estimate." This step selects the *maximum modeled concentration value of PFOS in groundwater at one of four modeled depths between the water table and 2 meters depth in the aquifer*. The same approach is used for PFOA. Unfortunately, this conservative estimate is hydraulically incorrect and will significantly overpredict the actual risk for four reasons described below.

First, groundwater wells screened in a permeable geologic formation (aquifer) *average* the concentrations of any constituents of all the water that enters the well. It is physically impossible for well in an aquifer to selectively remove the highest concentration water in the aquifer and leave other lower concentration groundwater next to the well behind. Therefore, a simple adaptation of the existing approach is to average *all* of the modeled concentrations across the entire well screen and vertical capture zone. This is a simple, more accurate, and appropriate way to predict the impacts of groundwater plume on a water supply well and mirrors the well-established mass flux approach that is accepted both in the scientific literature (e.g., Einarson and McKay, 2001) and by environmental regulators (e.g., the Interstate Technology and Regulatory Council, an environmental coalition led by state-regulators, see their mass flux guidance document, ITRC, 2010).

To implement this screen-averaged approach, an estimated screen length for a domestic water well is needed. Fortunately, there are commonly accepted general guidelines and empirical data that can be relied upon to provide this screen length. The best example of guidelines is the *Groundwater & Wells* 2nd edition (Driscoll, 1985), perhaps the quintessential reference for well construction, design, and groundwater hydrology. In the "Design of Domestic Wells" section,

Groundwater & Wells specifies that *"..for farm wells, the screens should be 10 to 15 ft long, depending on the hydraulic characteristics of the aquifer and the yield requirement."* Other guidance documents may provide other general lengths for domestic wells, but none indicate that very short screens (a few inches) are ever used.

While conditions vary significantly across the country, *Groundwater & Wells'* assumed screen length is supported by several empirical studies of domestic water well construction. Pope et al. (2007) studied 2,846 domestic water wells in the Virginia Coastal Plain and determined the most common (mode) screened interval was 10 feet long and the median screened interval was 15 feet. A study of 3500 domestic well logs in the Central Valley, California showed that a typical domestic well screen interval was 8 meters long (26 feet) (Bremer and Harter, 2012).

Therefore overall for a central tendency calculation, a 10-15 foot screen length would likely be appropriate for a domestic farm well.

RESPONSE: The reviewer appears to have assumed that there is a sharp peak to the concentrations of the chemicals in the 2.0 meters of groundwater below the water table, such that a well would dilute contaminated water with non-contaminated water. The EPA has added a discussion to Appendix C of the draft risk assessment that shows that the modeled contamination through the first 6-8 m below the water table are fairly constant.

Vertical profiles of relative PFOA ground water concentrations are shown below for modeled locations representing the wet climate (Charleston, SC), and the moderate climate (Chicago, IL) for observations distances 5 and 10 meters down gradient from the edge of the field, and for low K_{oc} (left column) and high K_{oc} (note that the saturated thickness at Charleston, SC, is 7.6 m). These profiles show that contamination is roughly constant over the top 6-8 m of the aquifer and the effect that the reviewer is concerned with is likely small.

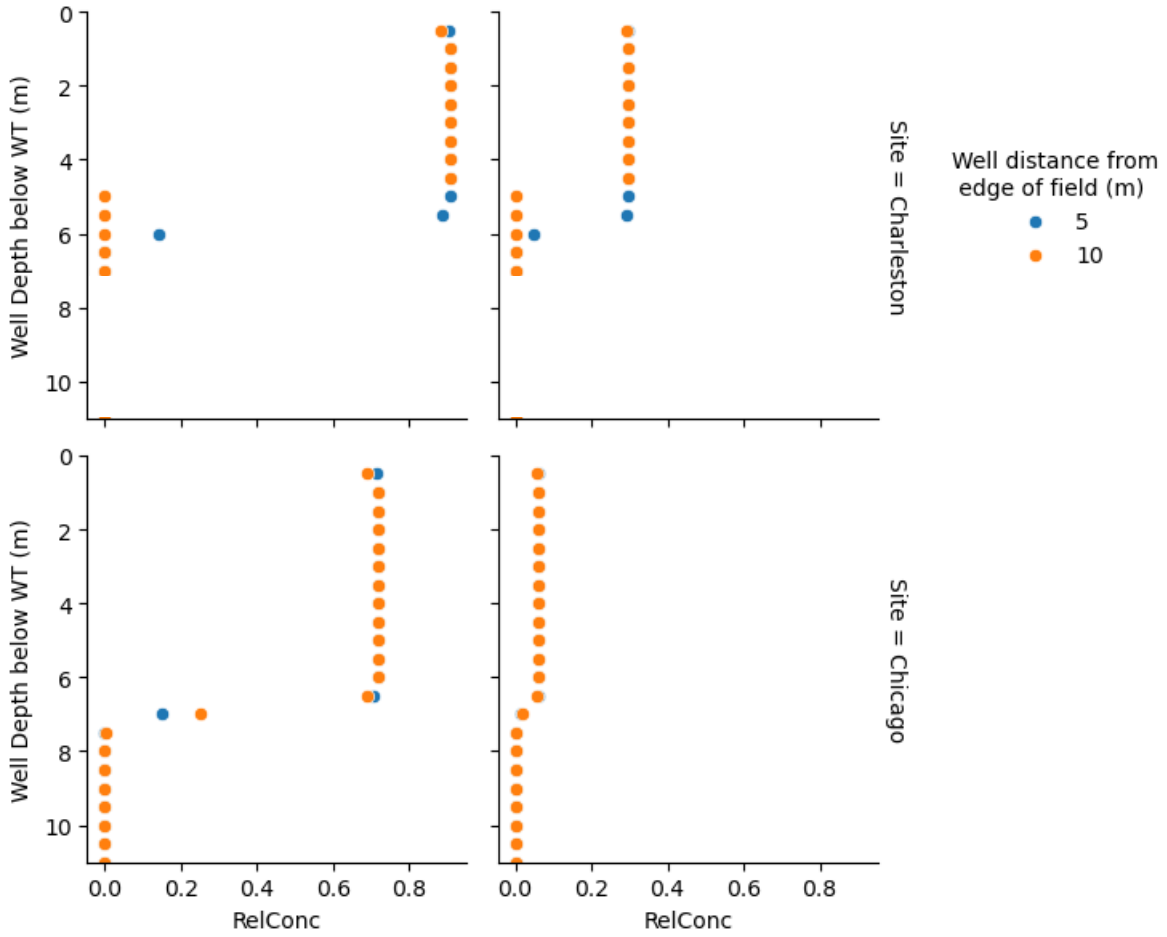


Figure 1. Modeled Relative Concentrations vs. Depth for CROP, PFOA at Charleston and Chicago at wells located 5 m and 10 m from the edge of the field.

The figure below presents vertical profiles of modeled relative concentrations as point observations and as concentrations averaged over 3 m in the first 10 m below the water table (again, the saturated thickness at Charleston, SC, is 7.6m). The dots in this figure represent individual concentrations at a specific depth in the groundwater profile while the x's represent the vertical averaged concentrations over ten feet. A comparison of point and averaged concentrations only diverge once the bottom of the plume is encountered. The additional modeling performed by the EPA indicates that averaging over a 10-foot length (< 3m) would have little impact on the concentrations of PFOA and PFOS extracted from the groundwater well that draws water from within the plume.

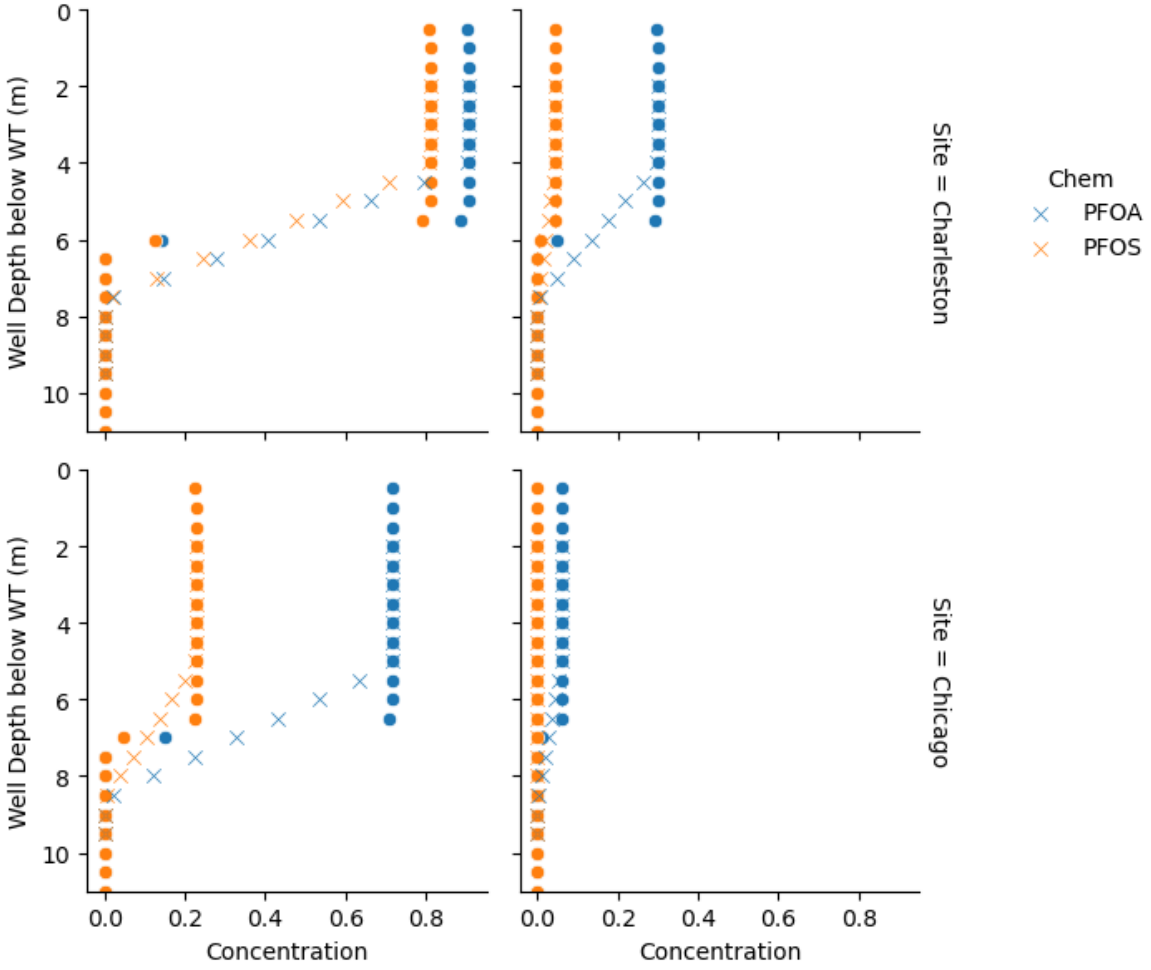


Figure 2 Well depth below water table (m) vs. Relative PFOA and PFOS Concentrations for point observations (solid circles) and 3m (10-feet) well screen average (cross symbol) for CROP, low Koc (left panels) and high Koc (right panels) at a well located 5 meters away from edge of field.

The EPA again notes that the Agency has made several assumptions and used modeling parameters that can be expected to lead to *underestimation* of risks. These include:

- Not summing any exposure pathways (*i.e.*, no aggregate exposure assessment) for the farm family and no use of a relative source contribution factor (RSC) to

account for other potential expsoures to PFOA and PFOS (e.g., dust, consumer products, dietary sources off the farm, etc.);
- No consideration of PFOS or PFOA precursors in sewage sludge;
- No consideration of dose additivity of PFOA and PFOS or PFAS of other chain lenghts (*i.e.*, no cumulative assessment); and
- Assuming a concentration of 1 ppb for PFOA and PFOS in sewage sludge when a central tendency value in the U.S. is likely higher.

COMMENT: **Second,** the existing approach assumes a well with 2-meter long screen that starts right at the water table. However, almost no domestic water wells that are constructed with short screens directly across the water table because:

- Potential water table fluctuations forces water well drillers to place well screens well below the water table (see left panel in the figure below from *Groundwater & Wells*, the accompanying text states *"The drilling contractor must insure that enough potential drawdown is available to meet present and future yield requirements").* Configuration C on the left panel below is described as being "constructed properly." *Groundwater & Wells* suggested positioning of the screens for domestic wells, shown on the right panel below, all have the top of the well screen well below the water table.

- Another classic groundwater publication from the USGS concurs, stating *"Because withdrawals from unconfined aquifers result in dewatering of the aquifers, wells in these aquifers are normally screened only in the lower part in order to obtain the maximum available drawdown."* (Heath, 1984). Water well construction guidance from USEPA (1975) states *"If the formation being screened is homogeneous and the ground water is unconfined (water table conditions) screen the lower one third of the formation."*

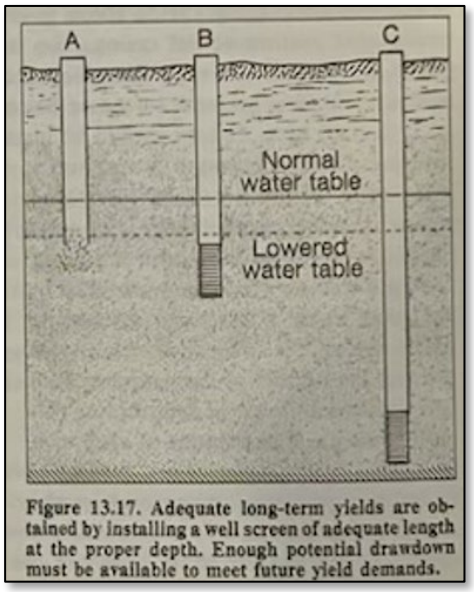


Figure 13.17. Adequate long-term yields are obtained by installing a well screen of adequate length at the proper depth. Enough potential drawdown must be available to meet future yield demands.

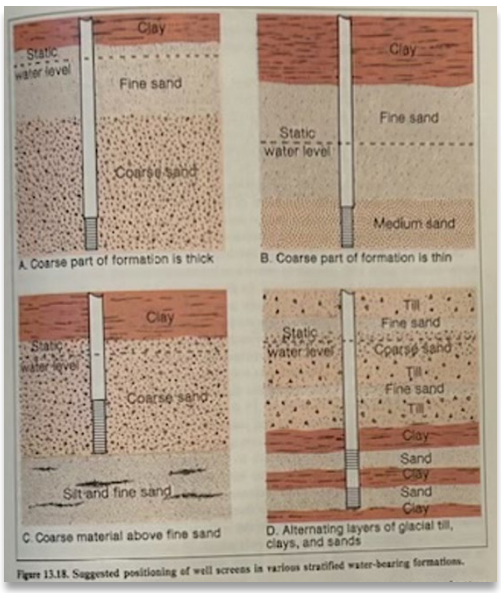


Figure 13.18. Suggested positioning of well screens in various stratified water-bearing formations.

- Drillers are also cognizant of geochemical problems that occur in wells that are screened

across the water table. For example Alberta's "Design and Construction of Water Wells" states:

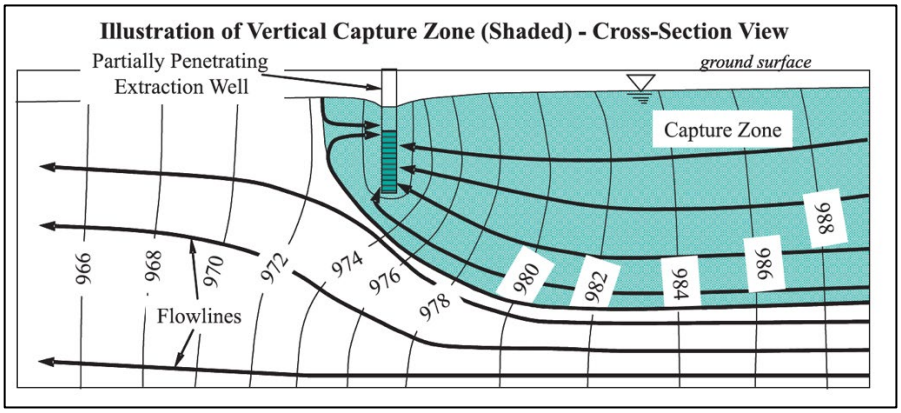
> ***Ensure that the pumping water level in the well never goes below the top of the slot openings or perforations. This will prevent oxygen exposure to the aquifer which would enhance bacterial growth and reduce well yield.***

RESPONSE: The figures presented above show that there is little difference between point or averaged concentrations from the first 2 m below the water table and the next 4 to 6 m until the bottom of the modeled contaminant plume is encountered. While it is possible that a deeper well would result in a lower exposure, that does not alleviate the impacts to the groundwater resource demonstrated by the modeled contamination. Deeper wells farther down gradient from the field may also draw from groundwater that is also contaminated (see schematic diagram figure C1-1 in appendix C).

COMMENT: **Third,** many domestic wells are do not extract water from the shallowest aquifer underlying the property, a key assumption in the current groundwater exposure scenario. For example, the USGS empirical database of domestic wells drilled in the Virginia Coastal Plain, state states that *"Contrary to widely held assumptions, only 22 percent of domestic wells in the Virginia Coastal Plain are completed in the shallow, unconfined surficial aquifer to which the water is returned directly by home septic systems. Fifty-three percent of the wells are completed in six deeper confined aquifers, and the remaining 25 percent are completed in the Potomac aquifer and confining zone, the deepest units in the confined system"* (Pope et al., 2007). This percentage will be different in different regions, but in general there are many domestic wells that are screened in deeper aquifers and do not extract groundwater from shallow surficial aquifers. Note that Bremer and Harter's (2012) paper does indicates significant risk of domestic wells pumping septic tank leachate, but it focuses on overlapping sources and wells on a regional scale, a scenario which does not seems to be the focus of this biosolids risk assessment. This paper might be useful if more detailed, regional risk assessments are performed.

RESPONSE: While there is empirical evidence that many domestic water wells in a region may be deeper than the those modeled here, the economics of well drilling tend to favor depths that provide sufficient supply in productive surficial aquifers for a residence without having to reach lower, confined units. For example, some states only require domestic wells to be greater than 10 feet below ground surface with limitations on maximum well depth based on casing size and materials used (North Carolina Administrative Code Title 15A Subchapter 2C, Section .0107 paragraph (b) (3) and (d)). Exposure to contamination in a surficial aquifer may not occur in all cases, however, focusing only on deeper sources of ground water ignores the potential impacts to the ground water resource that many in the U.S. rely on.

COMMENT: **Fourth,** any partially penetrating pumping well, even one with a very short screen, will draw water from a thicker part of the aquifer (e.g., see converging flowlines from USEPA, 2008 figure below). Therefore the water entering any well is not confined to streamlines directly horizontal to the well screen but draws water from a larger vertical interval in the aquifer than the well screen length as one moves upgradient.



RESPONSE: EPA agrees that an active well pulls ground water from above and below the well screen from a capture zone. In the schematic diagram the commentor provides, where the direction of groundwater flow is from right to left, the capture zone for a well located just downgradient of a field with biosolids land application would include the shallow aquifer directly below the field. This groundwater is likely to have relatively high concentrations of PFOA and PFOS. For this reason, including consideration of the entire capture zone in our drinking water modeling would likely not result in a lower groundwater risk finding, despite presenting a much more complicated modeling framework. At the location of the well, the vertical profile modeling presenting in the preceding figures indicate that there is not much differentiation in model concentrations throughout the first 6-8 m below the water table.

COMMENT: Overall, these four factors lead to the following recommendation. For the unusual cases where a near-water table, shallow, and downgradient well is used at a farm, the calculation should assume that it draws water from at least 20-30 feet thickness (or the entire assumed saturated thickness of the aquifer), accounting for 1) a typical screen length at a farm is likely to be around 10-15 feet long; 2) the typical well is likely to screened at a minimum of at least 5 to 10 feet below the water table, and 3) a partially penetrating well that captures flow from both above and below the screened interval. Therefore an *average* modeled PFOA and PFAS concentration in a 20-30 feet thick interval (to a maximum of the aquifer thickness minus about 5 feet) in the lower part of the aquifer should be used as the exposure concentration for drinking groundwater, not a single-depth maximum concentration in the top two meters of the aquifer.

RESPONSE: The EPA modeled saturated thickness ranging from 7.6 m at the wet climate site to 21.3 m at the dry climate site. The previous figures demonstrate that contamination of the first 6-8 meters of ground water below the water table whether averaged or not, are very constant until the bottom of the contaminant plume (or the bottom of the aquifer in the case of wet climate site) are reached. Additionally, it appears that the figure included by the reviewer demonstrates that the flow from deep in the aquifer is not entering the well, which appears to contradict the

reviewer's statement that the EPA should average over the entire "saturated thickness of the aquifer." Ignoring the shallower contamination below the water table would ignore potential exposures as well as impacts to the groundwater resource.

COMMENT: Page 42, Line 10: "*While EPACMTP estimates arrival times of aquifer contamination at the water table that are, in some cases, much longer than those that have been observed at biosolids application sites in Maine and Michigan, but closer to those observed breakthrough times than models that incorporate air-water interface effects and nonlinear adsorption. For this reason, EPACMTP was selected as being more appropriate for modeling vertical transport through the soil column."*

Appendix C, Page 29: "Overall, we observe that the vadose zone module in EPACMTP would produce higher (i.e., risk-conservative) PFAS concentrations at the water table because the model does not have the ability to address PFAS-specific retention behavior at the AWI."

The selection of the vadose zone model (EPACMTP vs. HYDRUS vs. ANALYTICAL) is a difficult modeling issue. On one hand one would want to include all of the PFOS/PFOA retention processes, including air/water partitioning, to provide the most accurate modeling results. One the other hands even EPACMTP appears to provide travel-time-to-groundwater results in some cases that do not much observed travel times at certain field sites. The difference between the AWI models (HYDRUS and ANALYTICAL) appear to be greatest for PFOS and the 10-m deep water table (Figure C1-13), but only after centuries of PFOS migration. While the EPACMPT solution is not technically pleasing, it appears to be adequate for this limited, specific application in the biosolids risk assessment. As indicated on page 92, I agree USEPA should continue to evaluate the availability of groundwater and vadose zone models as this assessment is finalized.

RESPONSE: Thank you for your comment that the analysis presented in Appendix C is sufficient to justify the EPA's choices for groundwater model and that the EPACMPT model is appropriate for the context of this national draft risk assessment.

<u>Reviewer 5</u>
COMMENT: The technical basis of using EPACMTP to estimate the subsurface transport of PFOA and PFOS is sound. EPACMTP has been used within EPA for a long time and has been used for modeling the vertical transport of other contaminants through the vadose zone to groundwater. The challenge of using EPACMTP is traditionally this model has not been parameterized to estimate air-water interface effects, which are important for PFOA and PFOS due to their surfactant properties. In Appendix C, EPA evaluated three models for their relevance to PFOA and PFOS vertical transport: EPACMTP, HYDRUS 1D with HD1 Pro Module, and Guo et al (2022) model. The strengths and limitations of EPACMTP have been discussed above. For Guo et al (2022) model, it is more specialized for PFAS and incorporates factors like air-water interface effects and nonlinear adsorption. These factors tend to result in longer delays in the transport of PFOA and PFOS to groundwater and lower peak groundwater concentrations. However, it is noted that this model may overestimate the time required for PFOA and PFOS to reach groundwater compared to real-world observations. HYDRUS model performed similar to the Guo et al model but in one of the tests the numerical solution became unstable (10m soil

column, dry environment). The choice of EPACMTP is defensible because it provides reasonable estimates of flow and transport under eight scenarios that reflect a broad range of hydrogeological conditions. In addition, EPACMTP's ability to provide estimates that are closer to observed breakthrough times at biosolid application sites in Maine and Michigan compared to other models justified its selection.

RESPONSE: Thank you for your comment in support of EPA's decision to use EPACMTP in this context.

c. Risk estimation and discussion, including clarity of results (see Sections 3 and 4) and description of variability, uncertainty, and sensitivity (see Section 5, Appendix D).

Reviewer 1
COMMENT: The risk estimations are relatively clear, but I felt like the document was missing some description/discussion. The risk calculations rely on cancer slopes and RfDs that are only briefly described. I would suggest adding a paragraph for each of these values, briefly detailing the critical study, modeling, uncertainty factors, limitations, etc.

RESPONSE: Section 2.6.1 includes numerous paragraphs describing the critical studies, health effects, and relevant target populations for PFOA and PFOS. The EPA finds that this information is the most relevant for contextualizing the results of the draft biosolids risk assessment. If the reader seeks additional information on these toxicity assessments, they are referred to the EPA's 2024 Final Toxicity Assessments.

COMMENT: It would also be important to put results into context. For example, exceedances were estimated for PFOA in groundwater at concentrations at or below 4 ng/L (the most recent MCL), which is a concentration that is likely to be observed in many municipal drinking water systems and private wells. Without estimates of aggregated exposures (and pharmacokinetic modeling to estimate serum concentrations), it is difficult to evaluate the extent of overexposure in farm family members in the scenario assuming 1 ppb PFOS/PFOA in biosolids.

RESPONSE: This draft risk assessment uses the RfDs and CSFs presented in the EPA's Final Toxicity Assessments for PFOA and PFOS as a comparator to exposures from each potential pathway of exposure. This assessment does not attempt to compare exposures to PFOA and PFOS from biosolids to exposures to PFOA and PFOS from all other sources. Converting the exposure values from this assessment to estimated serum levels that could be compared against measured serum levels in the general population would be complex and is outside the scope of this assessment.

Reviewer 2
COMMENT: In the Table found on Pages 77-78, one notes little difference between 1- and 10-year averages (Page 78). Further, Climate partitioned in Dry and Weet, is a stronger influence, especially Dry Climate/High Koc Groundwater (8 orders of magnitude). Can this be correct? About one order of magnitude for Moderate and Wet Climates. Larger disparities for PFOS (29 orders of magnitude for PFOS Dry Climate) and five for moderate while only 2 for Wet.

RESPONSE: It is expected that climate would have a significant impact of the groundwater results in each scenario. As described in Section 2.9.3.12 and Appendix B, there are many correlated parameters in the LAU model and EPACMTP that are related to climate/modeling location. Further, the sensitivity analysis presented in Appendix D indicates that depth from ground surface to water table (one of the parameters that is dependent on the climate/location) is highly sensitive in groundwater outcomes. The fate and transport of PFOA and PFOS applied to land varies significantly across the diverse geography of the U.S.

COMMENT: Crop Farm Results: The Media concentrations, developed in this model, which lead directly to exposures and risk, vary over 2-3 orders of magnitude. I expect these are skewed to the low end in real measurements, but most of the risk is in the group with substantial exposures possibly in more than one medium. How are these combined in the Deterministic models? It is here that Monte Carlo approaches may give more useful information.

RESPONSE: As described in sections 2.7.1 and 5.2.1, this draft risk assessment does not attempt to aggregate risks across multiple pathways. The risks reported in tables presented in section 4 represent only the risks from the designated pathway (*i.e.,* groundwater to drinking water). The EPA interprets these risks to approximate median risks to the exposed population from the stated pathway in each modeled scenario, assuming a starting concentration of 1 ppb PFOA and PFOS in sewage sludge.

COMMENT: I am concerned about the substantial variability in the model results varying over many orders of magnitude from essentially zero concentration and exposure resulting essentially no risk to much more substantial values. The dependency of Koc levels and Climate chosen calls into question the tole such modeling might have in regulation. If the model gives results that vary across a range from essentially zero to something near or above what may be concern, one might question their utility. Ground-truthing with more data is necessary, especially in light of the large differences noted for Koc and the lack of good data on conditions affecting this value in site-specific cases. Some expansion in Discussion would be warranted here.

RESPONSE: The EPA respectfully disagrees with the assertion that the modeling presented in this assessment has limited utility because it includes results from scenarios that represent wide variations in risks across various pathways. This modeling underpins the key conclusions of this assessment: across a wide range of hydrogeological settings and use or disposal settings, multiple pathways of exposure may result in exceedances of acceptable risk levels. For example, in hydrogeological settings where groundwater risks are low (such as areas with deep groundwater aquifers and little rain), risks through other exposure pathways (soil, surface water, fish) may be elevated. This is important information to understand the scope and scale of potential impacts in various regions of the US.

COMMENT: Pasture Farm Results: Similar criticisms of the Pasture Farm results as noted for Crop Farm results apply. The authors draw parallels between other scenarios not investigated and Pasture Farm results suggesting importance of identifying potential solutions to this problem. As

was the case for Crop Farm results, Pasture Farm results are strongly affected by assumed Koc. A series of papers by Shin, et al., modeled fate and transport of PFOA from an industrial site in West Virginia. In their complex model, they elected to use foc, the organic content of the soil, which changes depending on local conditions, as a free parameter to adjust the results to measured data. This may be generally applicable but suffers from a lack of site-specific data or sufficient general data to use this idea effectively and may seem arbitrary. However, EPA in this Report uses scenarios with substantial variance in Koc, which depends critically on foc. Thus the model used here reflects the same concerns as Shin, et al., attempted to account for in their work. EPA may wish to include discussion of ways of "fixing" some of these parameters or performing sensitivity analyses on their effects beyond the use of scenarios.

RESPONSE: The EPA has included a sensitivity analysis, see Appendix D. To clarify, K_{oc} does not depend on foc. K_d is calculated using K_{oc} and foc, as described in Appendix B and C.

COMMENT: Page 90 and 91 figures show that the model behavior displaying an roughly exponential increase in concentrations followed by a similar exponential decay after source removal. This is first-order Differential Equation behavior with Koc acting as a source dampener. The detailed structure of the model changes the results some to show the minor oscillatory behavior on the overlaying exponential, but a simple model gives results that are qualitatively similar to the more detailed model. Exposure over any time period can be inferred by integration of the differential equation solution to get "lifetime exposure" or exposure over an extended period, which may be associated with risk.

The groundwater concentrations reflect the delay associated with binding in the vadose zone. Essentially the PFAS move with different "speeds" through the vadose zone- a type of "chromatography" again- with PFOS progressing more slowly through vadose zone. Again, this can effectively be modeled as a first-order differential equation as might be done for "retention time" in chromatography.

The argument is made that, because both the median and 95th percentile deterministic models indicate unacceptable risks in many/most scenarios, it is unnecessary to perform Monte Carlo type analysis. I think more discussion is needed in this section. However, I do agree with their assessment that it is sufficient to perform these conservative, deterministic approaches in light of the results suggesting concern for nearly all scenarios.

RESPONSE: Thank you for the comment that the justification the EPA provided for proceeding with the central tendency modeling approach is clear and understandable. Comments regarding the potential to model the fate and transport of PFOA and PFOS in soil, surface water, and groundwater through simple mathematical equations is discussed when this issue is raised again under "specific editorial and technical comments."

COMMENT: There is clearly an introduction of bias in the estimates of risk due to zero concentration assumptions. Concentrations, exposures, and risk cannot be less than zero at other

locations. Thus, assumption of zero risk elsewhere can, at best, be accurate, but only in the unlikely event that any individual encounters no PFOA/PFOS or precursors in locations other than those associated with sewer sludge exposures. There is essentially no probability of such an event for any individual given the ubiquitous environmental distribution of these "forever chemicals." Additionally, lack of assessment of either aggregate exposures across multiple sources of PFPA/PFOS or cumulative exposure from simultaneous PFOA/PFOS/Pre-cursor exposure bias risk as well. While the authors address these issues in passing, I think the reader of the Report would be better served if these uncertainties were given more attention, perhaps is a separate section on such effects.

RESPONSE: As mentioned by the commentor, these items are identified as "systematic uncertainties resulting in underestimation of risks" in Section 5.2.1. These factors are also included in the executive summary as further support of the report's key finding that PFOA and PFOS exposures from biosolids use and disposal actions may result in unacceptable risks. The EPA finds that the existing discussion is sufficient for the purpose and scope of the draft risk assessment.

COMMENT: Discussion of overestimate of risk Page 112 Line 18-24 seems to be a stretch and quite speculative.

RESPONSE: The commentor is referring to the following text in the draft risk assessment:

> "The current modeling scenario assumes that a farm will receive yearly applications of biosolids for 40 consecutive years. This may be an overestimate of the loading for a farm, but the EPA does not have data to indicate the frequency of application at the same site across the country. The current biosolids regulations allow land application to happen yearly if the amount of biosolids land applied is consistent with the nutrient needs of the crops grown at the farm and this assessment attempts to reflect that part of the regulation. The regulatory framework also considers that a farm may receive biosolids for up to one hundred years."

Unfortunately, the EPA does not have data available on the typical duration of biosolids land application at a given site. Given this lack of data, the EPA will continue modeling the duration of biosolids land application used in prior risk assessments (US EPA 1993; 2003).

COMMENT: While the statement given in the last sentence of the first paragraph of Section 5.2.3 may, indeed, be valid, the justification for it given earlier in the paragraph is somewhat opaque and gives this reviewer no strong sense that it might be the case beyond the assertion made by the EPA authors. However, the EPA authors are indeed experts in this field and have spent substantial amounts of time thinking about this specific problem. Thus, I am reluctant to attempt to override their statements. Nevertheless, some discussion to justify this conclusion is warranted.

RESPONSE: The commentor is referring to the following text in the draft risk assessment:

> "Most of the random uncertainties included in this report stem from modeling parameters where there are data limitations, resulting in an over or underestimation of the "true" conditions. For example, exposure factors used in this assessment (drinking water intake, fish intake, intake of various types of foods) are based on surveys conducted at various times in the US. These surveys vary in sample size and methodology and may be imperfect measurements of "true" consumption behavior. These surveys also do not capture all potentially relevant consumption behavior, like the consumption of animal livers, which are known to have higher levels of PFOA and PFOS than muscle tissues. As a result, the mean or median of the survey may be over or underestimating reality. Despite these uncertainties, the EPA believes this assessment relies on the best available datasets for exposure factors."

The EPA considers the most recent edition of the Exposure's Factor Handbook to represent the best available information for exposure assessment.

COMMENT: The discussion Random Uncertainties is important, but limited (Page 112 Lines 26-41). While quite brief, the authors touch upon some of the essential details. The discussion of parameters uncertainty need not be limited to the Koc values as many of the parameters are uncertain. For example, the acid dissociation constant for PFOA is not really calculable due to surfactant effects, as noted early in the report. Often there is a chain of assumptions- Kow → … → Koc that, for there surfactants is not an easy ask. The binding to soil is likely to span orders of magnitude depending upon environmental conditions.

The discussion on Page 110 Line 23ff is about bias rather than a strict uncertainty as exposures cannot be less than zero and, thus, exposure s underestimated as long as there is any PFOA/PFOS present in the individual's exposome that is not accounted for by Sludge/biosolid exposure. One may consider it a model uncertainty, but also a parameter uncertainty. This bias is acknowledged implicitly in P111/L24ff. It is not clear that there is sufficient data for many parameters to identify these uncertainties as systematic, random, or model specification. Such is often the case in highly parameterized, complex models.

RESPONSE: Thank you for your comment. To clarify, the acid dissociation constant is the pKa, not the K_{ow}. K_{ow} was not used to determine the K_{oc} for PFOA or PFOS in this assessment.

Reviewer 3

COMMENT: This section discusses the results of modeling the concentration and exposure of PFOA and PFOS through three individual exposure pathways within various biosolids use or disposal scenarios. The concentrations in different media (such as milk, soil, water, and beef) are modeled assuming an initial concentration of 1 ppb in sewage sludge. The sensitivity of these results is influenced by climate conditions (dry, moderate, wet) and the Koc values, with exposures presented for both low (10th percentile) and high (90th percentile) Koc scenarios.

Crop: The discussion presented in the paragraph is generally good, as it provides a detailed and comprehensive analysis of the modeled concentrations of PFOA and PFOS in various environmental media within the crop farm scenario. It effectively highlights the key findings, such as the differences in concentrations across groundwater, surface water, soil, fish tissue, and

crops, while also considering the impact of different variables like climate, Koc values, and plant uptake factors. The discussion also acknowledges the limitations and uncertainties in the data, particularly in the uptake factors for fruits and vegetables, which adds transparency and credibility to the analysis. However, the paragraph is quite dense, and the flow of information could be improved by organizing the content into more clearly defined sections or bullet points to enhance readability. Overall, the discussion is informative and well-supported by the modeling results, but it could benefit from better structure and a more concise summary of the key points.

RESPONSE: Thank you for this comment. The EPA has revised the text in this section to enhance readability.

COMMENT: *Pasture farm:* The discussion in this paragraph is well-structured and thorough, providing a clear comparison between the pasture farm scenario and the crop farm model, particularly in terms of PFOA and PFOS concentrations across various media, such as soil, groundwater, surface water, and animal products. It effectively highlights the impact of the absence of soil tilling in the pasture model, which leads to higher soil and surface water concentrations, subsequently increasing fish tissue contamination. The analysis of exposure pathways for dairy cows and chickens, along with the implications of different Koc settings on contaminant levels in milk, beef, and eggs, is detailed and informative. However, the paragraph could be improved by being more concise and focusing on the most critical findings, as it currently presents a lot of data that might overwhelm the reader.

RESPONSE: Thank you for this comment. The EPA has edited this section for clarity.

COMMENT: *Reclamation site:* The reclamation scenario models the concentrations of PFOA and PFOS in various environmental media, including groundwater, surface water, soil, fish, milk, beef, eggs, and chicken. The scenario, which involves a single application of biosolids at a higher rate than the pasture farm scenario, generally results in lower concentrations of PFOA and PFOS across all media compared to the pasture farm model, which assumes annual applications over 40 years. Groundwater concentrations are particularly low, especially in soils with low sorption capacity, such as sandy soils or those with high pH. While most media concentrations are below detectable levels, PFOS in fish and eggs remains consistently detectable due to its high bioaccumulation potential. Overall, this scenario suggests that a single application of low concentration biosolids poses minimal risk of significant groundwater contamination but highlights the persistent presence of PFOS in certain media.

Sewage sludge disposal site: This assessment of the surface disposal scenario is very well done. It effectively models groundwater concentrations across unlined, clay-lined, and composite-lined disposal sites, accurately identifying the highest contamination levels in unlined sites, with PFOA concentrations ranging from 0.024 to 25 ng/L and PFOS up to 2.2 ng/L. The analysis correctly notes that clay-lined sites result in slightly lower concentrations, while composite-lined sites show minimal infiltration, with PFOA concentrations up to 0.014 ng/L and negligible PFOS infiltration. The discussion also thoughtfully considers the impact of different climate conditions on groundwater concentrations, including factors such as water table depth, infiltration rates, and rainfall-induced dilution.

The analysis in this section effectively outlines and categorizes the different types of uncertainties—systemic and random—present in the assessment, providing a clear and thorough discussion of their potential impact on risk estimations. The description of systemic uncertainties is particularly well done, highlighting how certain assumptions, such as low starting concentrations of PFOA and PFOS or the exclusion of precursor chemicals, could lead to an underestimation of risks. The analysis also acknowledges how these factors might not fully capture the complexities of real-world scenarios, such as long-term exposure or background contamination levels.

Additionally, the discussion of uncertainties that could lead to overestimation of risks, such as the use of greenhouse study data for plant uptake and assumptions about biosolids application frequency, is well-articulated. The explanation of random uncertainties, particularly those related to variability in site conditions and consumption behaviors, further enhances the credibility of the analysis by acknowledging the limitations of the data and models used. Overall, the discussion is very well done, and I do not have further comments on this section.

RESPONSE: Thank you for your comment.

Reviewer 4

COMMENT: Recommend that the text compares the drinking water concentration results groundwater concentrations to the MCLs for PFOS and PFOA and explain from a risk perspective what it means if groundwater or surface water concentration is above the MCL, and what it means if the concentration is below the MCL.

RESPONSE: As described previously, MCLs are not health-based values. See prior responses on this topic on pages 9 and 22.

COMMENT: For Sections 4.3, 4.4, 4.6, and 4.7, recommend that the drinking water pathways values that exceed the acceptable threshold (yellow-shaded values) also have some type of indication if the MCL is also exceeded.

RESPONSE: As described above, MCLs are not health-based values and are, therefore, not appropriate comparators for this risk assessment. See prior responses on this topic on pages 9 and 22.

COMMENT: Recommend re-evaluating if $1x10^{-6}$ risk level out of the 10^{-5} to 10^{-6} range is faithful to the goal of performing a central tendency calculation. Again, the key to this type of calculation is not to have any intentional over-conservative (overestimation) of risk or intentional underestimation of risk.

RESPONSE: It is the EPA's longstanding scientific judgment across its programs that, unless data indicate otherwise, human carcinogens exhibit linear "non-threshold" dose-responses, which means that there is no level without risk. The target cancer risk level used in determining if there is an unacceptable risk level is a policy decision. Prior EPA risk assessments in the biosolids program have indicated that when small populations are expected to be exposed to the chemical

of concern, it is appropriate to use a higher (less protective) target cancer risk level than 1 in 1 million ($1x10^{-6}$). For example, the Guide to Biosolids Risk Assessment (US EPA, 1995) states that a higher target cancer risk level is appropriate if meeting that higher target would result in "only a fraction of a person to several persons being at risk out of the total U.S. population." Given that the population of people with exposures to PFOA and PFOS via sewage sludge use or disposal is potentially large and the cancer slope factor is high, the EPA takes the policy position that a 1 in 1 million target risk level is appropriate for this draft risk assessment. Using a cancer risk level of 10^{-6} is health-protective and consistent with other Agency actions, *e.g.*, national recommended ambient water quality criteria for the protection of human health (US EPA, 2000). Protecting public health includes protection of humans with increased cancer risk due to greater susceptibility. The 10^{-6} risk level has been generally considered to be public-health protective for a range of susceptibilities based on interindividual differences among humans, although this risk level may not completely account for all susceptible individuals, including those with certain diseases, genetic polymorphisms, co-exposures to other chemicals, and/or exposed during especially sensitive life stages (US EPA, 2005). The EPA and other Federal agencies often use a cancer risk level of 10^{-6} to guide the development of management actions in polices involving cancer risk (Castorina & Woodruff, 2003). Additionally, this long-standing practice of using a cancer risk level of 10^{-6} is consistent with national efforts to eliminate cancer as a leading cause of death in the U.S. by decreasing cancer cases.[1]

Reviewer 5

COMMENT: Section 3.1 presents the modeled concentration and exposure results for individual exposure pathways in each of the four scenarios. In each scenario, a table is used to summarize the modeled concentrations in environmental media, followed by a discussion of the strength of the evidence and source of uncertainty. In general, these environmental media concentrations are consistent with both the mechanistic understanding of PFOS and PFOA's environmental behavior (such as PFOA is more abundant in water, and PFOS adsorb more strongly to soil and bioaccumulates more). The authors compared estimated concentrations across different scenarios and provided mechanistic explanations, such as the one-time application of biosolids in the reclamation scenario typically resulted in lower concentrations than the pasture farm scenario. When appropriate, the authors also pointed out the source of uncertainties and areas of future research to reduce those uncertainties, for example, the data limitation on the uptake factors of fruits and vegetables are mentioned in the crop farm scenario, and the lack of BTF on PFOA uptake in cows raised for beef is mentioned in the pasture farm scenario. Besides the four detailed scenarios, the authors also discussed qualitatively how sewage sludge could impact environmental concentrations of PFOS and PFOA in other uses of biosolids including home gardening, low-public contact use cases, and incineration.

Section 3.2 provides information on how modeled concentration varies over time for moderate climate scenarios. One limitation of this section is that the effect of precursors transforming into PFOS and PFOA over time was not considered. The reason has been clearly stated and can be understood. Due to the high sensitivity of modeled concentrations in Koc values, the authors correctly chose to present the results for high Koc and low Koc separately. In section 3.2.3, when the breakthrough time (the time it takes for PFOS/PFOA to reach nearby wells after biosolids application) is estimated by the groundwater model, it is clear that they were extremely

[1] *See* https://www.whitehouse.gov/cancermoonshot/.

overestimated by the model. I think the reason is likely because precursors are not explicitly accounted for in the model and they play an important role in groundwater transport of PFAS. The authors listed a few other reasons for why the model overestimated this time, such as microbial weathering, leaching due to freeze-thaw cycles, and macropores. However, I think the role of precursors needs to be added to page 92's discussion as well.

RESPONSE: Thank you for this comment. Though it is possible that precursors to PFOA and PFOS may have fate and transport characteristics that lead to faster migration to groundwater, most PFOA and PFOS precursors also contain carbon-fluorine alkyl chains of equal length or longer than PFOA and PFOS. Because these precursors also contain long chains of fluorinated carbons, it is unlikely that these precursors will move more quickly through the soil column than PFOA and PFOS (*see* Brusseau, 2023 "Influence of chain length on field-measured distributions of PFAS in soil and soil porewater). The presence of precursors is more likely to increase the magnitude of the groundwater concentration than it is to increase the time it takes for PFOA and PFOS to reach the groundwater. More data on the fate and transport characteristics of PFOA and PFOS precursors in the vadose zone would be useful in better understanding their transport behaviors.

COMMENT: Section 4 presents quantitative results from the risk characterization for the four scenarios, and then discusses qualitative considerations for the other scenarios. The lifetime cancer risk is calculated by multiplying the lifetime average daily dose with the cancer slope factor. For non-cancer risk, the average daily dose is compared to the reference dose. I understand the need to separately show each exposure pathway so that their individual contributions can be made clear, however, I don't think it is prudent to compare the reference dose for the aggregate exposure to the average daily dose of each exposure pathway, because this could lead to under-estimation of the risk. Take the table on page 96 as an example, under the high Koc and dry climate conditions, for adults even though the HQ for individual exposure pathways does not exceed one, the sum of them has exceeded one, representing considerable health risks. Section 4.9 listed reasons why EPA is not conducting additional modeling exercises at this time, which I completely agree with. I think from the central tendency modeling results, it is clear that considerable health risks from biosolids application exist, and therefore the more urgent next step is to identify actions for mitigating such risks.

RESPONSE: Thank you for your comment. The EPA agrees that when exposures are added from multiple pathways, risk increases. The EPA also acknowledges that there are scenarios in which one person could be exposed through multiple pathways. For example, some farm families with biosolids land application on their property may be largely self-sufficient, sourcing nearly all of their produce, animal products, and water from their property. These families would have biosolids-related exposures from multiple pathways. Other farm families may source some, but not all, of their food products from potentially contaminated sources (*i.e.*, they may drink milk from cows on their farm, but not grow any vegetables or fruits impacted by biosolids land application). Still more individuals may be impacted by a single pathway of biosolids-related exposures, such as a person who fishes from an impacted waterbody but has no other sources of biosolids-related exposures, or an individual whose drinking water source is impacted, but otherwise sources food from non-impacted sources. By presenting risks for each pathway, it is easier to conceptualize risks to other populations with biosolids-related exposes from one or

more pathways of exposure. For example, by presenting exposures by pathway, risk levels are presented that can be used to estimate the size of the populations who may have drinking water exposures of PFOA or PFOS from biosolids-impacted groundwater, but no other biosolids-related exposure. This universe of potentially exposed individuals is larger than the population of farm families living on farms with biosolids land application. Because there are potential exceedances of acceptable risk levels in individual pathways, it is important to consider the total population with biosolids-related exposures, acknowledging that individual exposures within this group will vary.

COMMENT: Section 5 discusses variability, uncertainty, and sensitivity. It also compared modeled results with observed results in three states. I think organizational-wise, section 5.3 should be its own section as it does not fit in the discussion of model uncertainties.

RESPONSE: The EPA agrees with this suggestion and has reorganized this section of the draft risk assessment.

COMMENT: The discussion of variability in section 5.1 is very general and does contribute much information, so I would suggest removing this section.

RESPONSE: The EPA believes that discussion of variability is important to include even though data are not available to quantify the variability expected that this time.

COMMENT: Section 5.2 organizes model uncertainty into systemic uncertainty (which then divides into uncertainties that result in underestimating and overestimating risks) and random uncertainty. The authors had a comprehensive discussion of the uncertainties that may result in underestimating the risks. As mentioned above, I think the last point about this assessment does not quantify aggregate exposures is not an uncertainty, but more of a modeler's choice. EPA has been using aggregate exposures for other chemicals in the past, which is why the relative source contribution term is coined. I would encourage the authors to think about developing RSCs for the four quantitative scenarios as the average daily doses from different exposure pathways have been estimated.

RESPONSE: The EPA has edited this section of the draft risk assessment to better explain the rationale for presenting individual risks per pathway, which includes added discussion of the uncertainties and variabilities that we believe exist around knowing how many pathways are relevant to various potentially-impacted populations. Due to the fact that single pathways of exposure may result in exceedances of acceptable risk levels and that there are currently unknowns in the scope and scale of the potentially impacted population, the EPA finds that presenting pathway-specific risks is this most efficient way of presenting risks at this time, even though this presentation does not quantify the total risks to people exposed to multiple sources of biosolids-related exposures.

d. Comparison of modeled results to biosolids investigations conducted in Michigan and Alabama (see Section 5.3).

Reviewer 1

COMMENT: The document indicates there is no complete dataset to evaluate modeled concentrations in different media after biosolids application. In the absence of adequate data to evaluate the model (e.g., PFAS concentration in biosolids and application rate), EPA used incomplete input data from Michigan and Alabama and compared modeled to measured concentrations. These comparisons provide some qualitative indication that the model generates reasonable outputs (e.g., PFOA being more mobile in water than PFOS, PFOS more likely to be detected in milk than PFOA). Quantitatively, the comparisons suggest that modeled concentrations are in the same ballpark as measured concentrations, but uncertainty is substantial. Overall, these comparisons provided some support for the modeling described in the document, but it is unclear whether the model is accurate at sites with lower sludge concentrations (e.g., 1 ppb) for which data is unavailable.

RESPONSE: Thank you for this comment. The EPA has added a discussion of a biosolids investigation in Ottawa, Canada, which had a land application scenario with PFOA and PFOS concentrations closer to those modeled in this assessment (*see* section 6.1 in the draft risk assessment).

Reviewer 2

COMMENT: Decatur, Alabama values are close to what is modeled and are likely sufficiently so to in some sense "validate" the screening-level model. The Michigan modeling results, although perhaps giving modeling results a bit further from these measured values is also of utility. However, the data are very limited. Only two locations are noted and the monitoring occurs over only a brief time. The modeling was done to simulate many years- up to 1000 years in some cases- with assumptions made that parameters do not change. Further, the discussion regarding these differences would be of interest to the readers of the Final Report.

RESPONSE: Thank you for your comment. The EPA has added an additional case study to this section and additional discussion on the differences between the case studies and the scenarios included for modeling in the draft risk assessment.

Reviewer 3

COMMENT: The comparison of modeled results to biosolids investigations conducted in Michigan and Alabama is very well described and thoroughly executed. From 1990 to 2008, the Decatur Utilities Dry Creek WWTP in Alabama processed wastewater containing PFAS from local industries, resulting in significant contamination across approximately 2,000 hectares of farmland. Studies by 3M and the EPA revealed substantial PFAS contamination in groundwater, surface water, and soils, with PFOA being more mobile in water and PFOS more strongly bound to soils. The observed trends, such as PFOS being more likely to be detected in milk than PFOA, align with the higher uptake factors modeled for PFOS. The assessment's modeled results suggest that if biosolids applied at these sites had similar PFAS concentrations to those reported in the 3M study, the expected contamination levels would be within observed ranges for PFOA but higher for PFOS, highlighting the complexities of accurately modeling PFAS contamination.

In 2018, a similar investigation in Michigan revealed high concentrations of PFOS (2,150 ppb) and lower levels of PFOA (1-5 ppb) in biosolids applied to several land application sites. Subsequent sampling showed significant contamination in soil, surface water, and beef tissue, with PFOS levels in soil ranging from 2,480 to 96,700 ppt and PFOA up to 1,530 ppt. Although the observed PFAS concentrations in Michigan were higher than expected, likely due to the higher concentrations of PFAS in the biosolids, the study's findings align broadly with the modeled scenarios. This comparison demonstrates that, despite some uncertainties, the models provide a reasonable approximation of real-world contamination scenarios, effectively capturing the challenges in assessing the long-term environmental impacts of PFAS in biosolids.

RESPONSE: Thank you for your comment that the comparison of modeled and observed concentrations was effective and informative.

Reviewer 4

COMMENT: Recommend comparing the PFOS/PFOA biosolids risk assessment results with the dioxin sewage sludge risk assessment, which concluded the regulation was not warranted. I believe the cancer slope factor for 2,3,7,8-TCDD is much higher than PFOS or PFOA. What are the significant differences in risk, and if so, are they due to the starting concentrations, toxicology, fate and transport, or exposure factors?

RESPONSE: See prior responses to comments regarding the differences between dioxins and PFOA/PFOS for biosolids risk assessment.

Reviewer 5

COMMENT: Section 5.3 compares modeled results to real-life observations of PFOA and PFOS in Decatur, Alabama, and Wixom, Michigan. I would recommend dropping section 5.3.3 because there are no results available from Maine to be discussed.

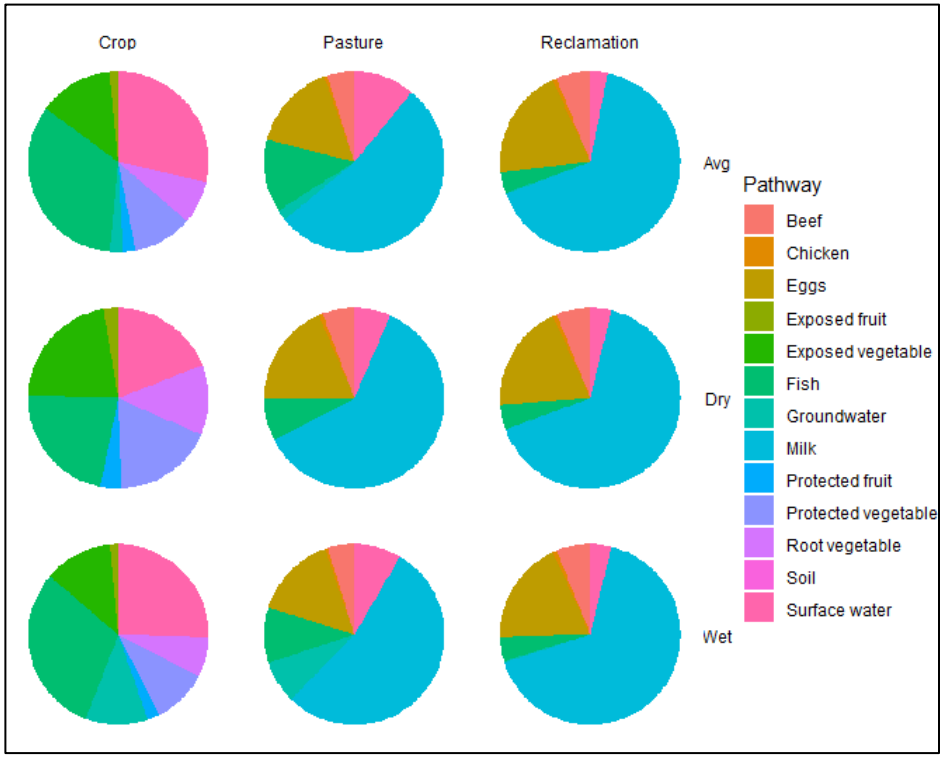
RESPONSE: Given that there is widespread awareness of agricultural contamination in Maine, the EPA finds that it is important to explain that the site-specific data from these sites are not publicly available at this time.

COMMENT: This ground-truthing exercise is helpful to support the range of the model estimates with observational data. When interpreting the results, it is important to keep in mind that these two cases represent the high-end contamination scenarios and there is considerable uncertainty around the concentrations of PFOA and PFOS in the biosolids being applied. Due to the retrospective nature of the comparison, the authors could not find all the data they needed to compare model estimates to the various studies of PFOA and PFOS impact around biosolids land application sites. For the Alabama example, they drew some general observations but, in my opinion, these trends are so general that you don't need to go through a sophisticated modeling exercise to know, such as "PFOA is more mobile in water and PFOS is more strongly sorbed to soil". For the Michigan example, some more quantitative comparison was made between the observed data and the model estimates, but since there is a considerable difference in the biosolids PFAS concentration and the application practice, the comparison reads very hand-wavy. I would encourage the authors to dig a little deeper and think about what other interesting

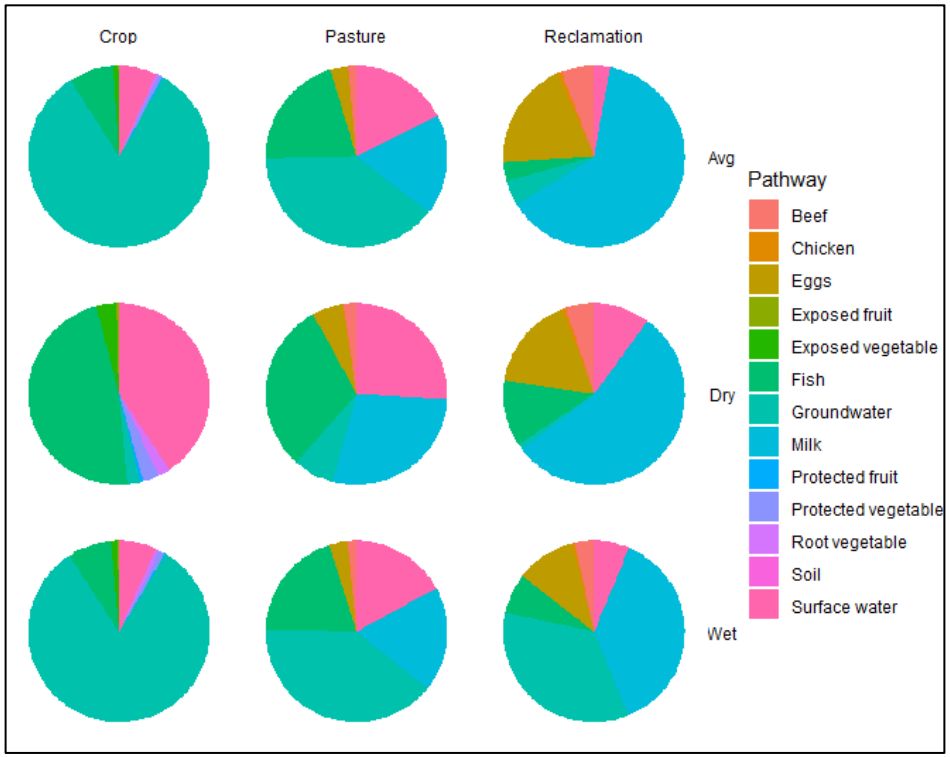
comparisons can be made. One idea is to look at the relative ratios of environmental concentrations in different compartments such as soil, water, milk, etc., and compare those ratios between the real-life observations and model estimates. This will generate insights into the relative importance of various exposure pathways.

RESPONSE: The EPA agrees that it is difficult to compare the data presented on existing biosolids site assessments for PFOA and PFOS due to missing information. Though the suggestion to compare modeled and measured ratios of environmental concentrations is an interesting one, this approach would also be plagued by site-specific conditions potentially dominating the observed conditions. Below are sets of plots showing the relative non-cancer risk contributions for PFOA for each pathway of exposure, as calculated for scenario, climate, and K_{oc} setting (low vs high K_{oc} conditions). These plots show that the percent contribution of risk for each pathway varies significantly by K_{oc} condition, and also varies per scenario and climate setting. Lacking information on soil composition and sorption potential in each of these existing sites, it is difficult to use our model to understand relative ratios of concentrations in various media.

PFOA, high K_{oc}, relative non-cancer risk contribution



PFOA, low K_{oc}, relative non-cancer risk contribution



Specific editorial and technical comments

III. SPECIFIC OBSERVATIONS

Reviewer 1

Pg.	Paragraph	Comments or Questions	Response
Sum.	4	The summary states that "that there are significant human health risks derived from land-applying sewage sludge that contains 1 ppb of PFOA and PFOS". The use of "significant" lacks specificity, and could be confused with statistical significance. An option would be to describe risks as "human health risks above what is considered to be acceptable".	The EPA agrees and has made these edits.
1	4	The usual terminology for PFAS is per- and polyfluoroalkyl substances	The EPA agrees.
15	2	The long half-lives of PFOA and PFOS are also due to reabsorption in the kidney. I would suggest adding a sentence or two describing this process.	The EPA agrees and has added this information.
15	3	There are some data on serum PFAS concentrations in individuals living on farms where biosolids have been used (https://pubmed.ncbi.nlm.nih.gov/38941944/). I suggest adding some information in this section.	The EPA has added this information.
18	3	When discussing sufficient exposure conditions (sentence on lines 13-16), the data for humans should be presented as "serum concentrations" rather than "doses".	The EPA agrees and has made these edits.
18	3	I would suggest adding accelerated puberty and altered ossification in the sentence on lines 28-30 given that these were used for the previous PFOA risk assessment.	See discussion on these endpoints in the PFOA Toxicity Assessment, pg 5-12: "For the current assessment, EPA preferentially selected endpoints for which there were a greater number of studies supporting the observed effect. For example, for the 2016 PFOA HESD, EPA derived a candidate RfD based on the co-

Pg.	Paragraph	Comments or Questions	Response
			critical effect of accelerated male puberty reported by Lau et al. (Lau et al., 2006). Results of the current assessment's literature search showed that no *high* or *medium* confidence studies supporting that observed effect have been published since 2016. As Lau et al. (Lau et al., 2006) was also the only study identified in 2016 that reported an acceleration of male puberty (a second study reported a delay in male puberty (Butenhoff et al., 2004a) and there were several other developmental endpoints (*e.g.,* reduced offspring weight and survival, delayed eye opening) that were supported by multiple studies), EPA did not further consider this endpoint from Lau et al. (Lau et al., 2006) for POD derivation in the present assessment. Similarly, upon further evaluation during the current assessment of the co-critical effects of reduced forelimb and hindlimb ossification in pups reported by Lau et al. (Lau et al., 2006), it was determined that an unexplained non-linear dose-response trend adds uncertainty to selection of the LOAEL as the POD. As reduced ossification was only observed at the highest dose tested (10 mg/kg/day) by the one other study (Yahia et al., 2010) that tested dose levels close to the LOAEL from Lau et al. (Lau et al., 2006) (1 mg/kg/day) and because no studies identified during literature searches for the current assessment reported this effect, EPA relied on other endpoints from Lau et al. (Lau et al., 2006) that were amenable to BMD modeling, exhibited dose-dependent response trends, and were supported by at least one other study in the available literature."
19	1	Same comment as above, i.e., "doses" should be replaced by "serum concentrations" for the human data.	The EPA agrees and has made these edits.

Pg.	Paragraph	Comments or Questions	Response
20	Section 2.6.1.3	There is some experimental data on dermal absorption in humans (https://pubmed.ncbi.nlm.nih.gov/36191486/). It could be briefly summarized, although it does not necessarily apply to dermal absorption through soil or water.	Given that this information has not yet been incorporated into an existing toxicity assessment from the EPA or ATSDR, we are hesitant to reference this single study (see the literature hierarchy described in section 2.9). Given that this study finds low rates of dermal absorption consistent with existing assessment conclusions, this study will not be added to the risk assessment.
28	Figure 2	Looks like there's a missing arrow going from Pathway 14 to Adult, Child.	The EPA agrees and has made these edits.
31	Figure 3	Same comment as for Figure 2	The EPA agrees and has made these edits.
35	Figure 7	Same comment as for Figure 2	The EPA agrees and has made these edits.
45-46	Tables 4-5	These Tables are presented earlier in the document.	Given that many readers flip through the assessment sections, we find that the redundancy of key information is acceptable in this context.
90	Figure 5 (and other figures reporting water results)	I suggest using ppt (ng/L) for water concentrations. Readers are going to be most familiar with these units given recent guidelines.	The EPA agrees and has made these edits.
91	Figure 12	The figure number jumps from 5 to 12.	The EPA has corrected the table and figure numbers.
94	Equation A1-24	Why are units different for the PFOA oral cancer slope factor? I suggest using the same unit for PFOS and PFOA (i.e., (mg/kg-day)-1) to be consistent with the equation	The EPA agrees and has made these edits.
101	1	On line 5, fish should be included as one of the highest risk pathways for PFOA.	The EPA agrees and has made these edits.
101	2	The last sentence of the paragraph states that "there may be significant risk posed by PFOA levels in milk from farms with biosolids land application that fall below detectable limits". I suggest toning down as exceeding an acceptable threshold does not necessarily mean that there is	The EPA agrees and has made these edits.

Pg.	Paragraph	Comments or Questions	Response
		a "significant risk", only that we don't consider risk to be acceptable/tolerable.	

Reviewer 2

Page	Paragraph	Comments or Questions	Response
Executive Summary Page 1	Line 20ff	I think the Executive Summary should contain some discussion of likely effects on regulations resulting from this document in	The goal of this document is to focus on the risk assessment – potential risk mitigation options will be discussed in other documents and forums.
2	Line 18ff	Perhaps the highlighted missing discussion would address the issue noted in the previous comment. However, I do not know this at this time. If there were no plans to include discussion of regulatory impact, I would urge the authors to include one here.	The goal of this document is to focus on the risk assessment – potential risk mitigation options will be discussed in other documents and forums.
13	Line 6ff	The authors discuss dividing 110 available samples into five composite samples as done by Venkatesan and Halden. More discussion needed as to how this was done in order to determine whether the methods lead to realistic assessments of concentrations in these media. On the surface, these seems like too few composites to give a meaningful assessment of central tendency and variability, especially noting the variability in these composite samples themselves for PFOA and PFOS. More discussion may be of interest to readers of this document. However, this reference may itself include such discussion that could then be alluded to.	For the Venkatesan and Halden 2013 study, the authors generated 5 composite samples by randomly dividing the 110 available samples from the 2001 National Sewage Sludge Survey (NSSS). Each composite sample encompassed 21 to 24 discrete samples (Venkatesan and Halden, 2013). According to the Venkatesan and Halden 2013 study, the purpose of the technique was to create national baseline levels for the 13 PFAS with the composite samples, and this methodology was utilized in previous studies (McClellan and Halden, 2010; Chari and Halden, 2012; Venkatesan and Halden, 2013b). The next NSSS that the EPA is currently planning in

Page	Paragraph	Comments or Questions	Response
			collaboration with the POTW Influent PFAS Study will focus on obtaining current national concentration data on PFAS in sewage sludge. Collecting and analyzing PFAS in individual samples of sewage sludge from 200 to 300 POTWs throughout the United States will help in better understanding the variability across the nation.
15	Line 33	Am I to assume that the publication is "in press" or it would not have been referenced in an EPA assessment?	Yes, this had been pending release from the EPA, but is now available. The draft assessment has been edited accordingly.
17	Line 13	Why is "evidence indicates" bold? Emphasis or typo?	This formatting was copied from the original toxicity assessments for PFOA and PFOS. The formatting has significance in these documents per the systematic review process, so the EPA elected to maintain the formating for this document.
21	Line 17	Reference to EPA document missing. Highlighted.	The EPA has made these edits.
26	Lines 34-36	Repetitive with earlier text. Is this intentional so that those reading only this section get the specific definition of aggregate (and later cumulative) exposure?	Yes, this information was intentionally repeated. While there was a goal to minimize repetition, many readers jump around the document rather than reading from beginning to end.
27-34	Figures	Both cartoons and flow diagrams are well visualized.	Thank you for your comment.
49ff	Lines 1ff	There is uneven treatment here. This section appears as an annotated literature review with sections associated with each paper while other sections discuss the references in a written-text manner. This was a bit jarring to me as a reader.	We will edit to ensure literature is cited in a consistent fashion.

Page	Paragraph	Comments or Questions	Response
78	Table	There is a large range of media concentrations. This suggests to me there would be substantial difference in exposures and thus risks associated with various potential media → exposure → dose → effects continuum. Is this discussed? Koc is a big factor that likely depends on various other hard-to-measure factors. This will contribute to model uncertainty.	Discussed in response to question 4.
81	Table	Groundwater and Chicken vary substantially by Climate. Some explanation of this "correlation" is of interest. Does it come later?	The EPA has added discussion on this topic.
85	Line 23	There is a high degree of uncertainty in uptake rates of PFOA and PFOS due to lack of data. This is a substantial data gap for this modeling exercise. One could argue that this, and potentially other data gaps, calls into question the results. Can some sensitivity analyses be done to assure the reader that this effect is negligible or important in this analysis? This can guide further data collection.	It is not clear if the commentor is referring to the uptake into edible plants, feed plants, livestock, or fish. All of these factors vary linearly with risk. See Appendix D for the sensitivity analysis.
88	Line 10ff	I am concerned about the "known artefact in the numerical modeling of 3MRA's Land Application Unit…" It would seem that this artefact needs to be explained more fully. From what I can gather, it is caused by the shutoff of land use of sludge at this time. However, some of the modeling work goes out as much as 1000 years. The assertion that this artefact has negligible effect on the risk calculations, but I do not see a defense of the assertion here, which gives me pause.	The existing text explains clearly the cause of the "artifact" and why it does not influence the final risk calculations.
88	Line 18	Is this not simply "chromatography" in the soil column with the end of the "column" being	The reviewer is referring to the following sentence in a paragraph

Page	Paragraph	Comments or Questions	Response
		groundwater, the media of interest, or the time scale of interest?	describing the mechanics of the soil column model used in this assessment: "The advective component of the transport equation moves contaminant mass down to the next layer (and ultimately, out the bottom of the LAU) at discrete time intervals equal to the time it takes for dissolved contaminants to traverse a layer via convective transport." This sentence is discussing the details of how the model manages advective vs convective transport of material over time, which is not analogous to chromatography.
89-90	Figures	I have a thought here: These figures all look like exponential growth towards a saturation level followed by exponential decline after source is "turned off"- a simple time-dependent solution to a first-order differential equation. From the point of view of a screening tool, would it not be similar to just assume such a model? The little wiggles, etc., would not appear to be major perturbations that would change the risk estimates in a manner that would affect the conclusions of little long-term risk, or higher risk for certain choices of parameters. Occam's razor may suggest this; the simplest model sufficient for the purpose is likely the best.	It is not possible to predict the outcome of the complex set of fate and transport models simply by observing that sometimes, the output of these complex models takes the shape of a common mathematical form. The models selected for this draft risk assessment are the standard peer-reviewed models for these scenarios used by the EPA. This draft risk assessment is not a screening assessment.
89-93		I have another thought here.: Given the large time span modeled, The 40-year offset depositing PFOA and PFOS coupled with the greater Koc value for PFOS is "lost" in the "mists of time." The curves are very similar, just offset by about 80 years which has	This draft risk assessment displays risk conclusions for the maximum measured groundwater concentration over time, consistent with the policy

Page	Paragraph	Comments or Questions	Response
		little significance over the 1000-year modeling period. Further, there is no effect after about 400 years for groundwater as all of the PFOA/PFOS makes it through the soil column to the groundwater in that time span. These "forever chemicals" will be around "forever" and will impact the groundwater far into the future. I suppose if one were an individual alive during the intervening period where PFOA has propagated, but not PPFOS these offsets would matter. But, to paraphrase Keynes, in the long run we someone will get the exposure. See Figure 13 Page 92 compared to Figure 14 Page 93.	goal of protecting groundwater resources for future use.
94	Table	The CSF Description has units of $(mg/kg/dy)^{-1}$ but the Value column lists the units as $(ng/kg/dy)^{-1}$,	This has been corrected for consistency.
96	Table	The Row labels are misaligned as are some of the data values using exponential notation. Perhaps three separate tables would be more readable.	The EPA agrees and has made these edits.
106	Table	Observation: No risk at all for PFAS and no risk for Composite Liner for PFOA. I believe this is discussed later. There are row label misalignments in these two tables.	The EPA assumes the commenter is referring to PFOS, not PFAS. The EPA has corrected table formatting issues.
109	Lines 24ff	The discussion of why Mone Carlo analysis is not warranted is hard to follow and seems, at points, to be self-contradictory. I urge the authors to re-read it and, perhaps, re-work the description. If they feel it is clear enough, then perhaps it is my inability to decipher that is suspect.	The EPA has edited the discussion of Monte Carlo analysis for clarity.
110		I agree that EPA should consider the effects of precursors on risk going forward and incorporate into these models as data becomes available and of significant number to merit selection of parameters for decomposition.	Thank you.

Page	Paragraph	Comments or Questions	Response
114	Line 13	The Washington, et al., 2010 reference is not called here but rather appears inline in the text.	The EPA agrees and has made these edits.
116	Line 33	The colloquial term "~2000 times less" is not an appropriate term as it is ill-defined. Use 1/2000th if that is what is meant.	The EPA agrees and has made these edits.

Reviewer 3

No specific revisions or changes are required. The risk assessment does not require just the conceptual visualization of farm scenarios.

Reviewer 4

Page	Line	Comments or Questions	Response
ES-1	18	"Both chemicals are amongst the most potent carcinogens assessed by the EPA to date." Recommend adding that this toxicity is only one factor in the risk assessment and give the example that the while one other chemical, 2,3,7,8-TCDD dioxin, is a more potent carcinogen that PFOS or PFOA, it was not deemed to be a significant enough risk in biosolids to warrant regulation by USEPA.	The cancer assessment for 2,3,7,8-TCDD dioxin was not finalized by the EPA, as the IRIS program determined that the non-cancer RfD would be protective of cancer effects. As described to prior comments, there are many differences between dioxins and PFOA/PFOS that result in different risk findings or tentative risk findings in biosolids.
13	13	Recommend showing the reduction in PFOS and PFOA concentrations in biosolids over time more clearly in a table or graph. Is it possible these concentrations will continue to decline over time?	The EPA presents a discussion of current PFOA and PFOS sources in section 2.3, and occurrence information is summarized in section 2.4 and Appendix A. Note that peer-reviewed studies in the tables in Appendix A are shown in chronological order. Recent U.S. studies on industrially impacted biosolids have shown high levels of PFOS despite the phase-out. The EPA is planning a National Sewage Sludge Survey to obtain PFAS occurrence information in sewage

Page	Line	Comments or Questions	Response
			sludge from 200-300 of the largest POTWs in the U.S., which will help elucidate potential industrial and domestic PFAS sources nationwide.
15	31	Recommend reporting if any elevated serum populations have reported any significant health impacts and if so, what they are.	For a detailed review of human epidemiology studies for PFOA and PFOS please refer to the EPA's 2024 final toxicity assessments for PFOA and PFOS.
27 30	17	In the Farm Scenarios "Conceptual Visualization" recommend showing conceptual groundwater flow direction, a shallow plume at the top of the aquifer, and the assumed vertical configuration of the downgradient well screen (Minor point: check Figure numbers on page 30)	This detail is not included in the conceptual model diagram, which is meant to be schematic, but is rather included in Appendix C. Thank you for the comments on figure numbers; the EPA has corrected these typos.
30	2	Same comment as for Figure 1.	See above.
38	38	Some additional explanation would be helpful for the Bumb et al. (1992) reference. Is the point that this soil moisture curve paper provides an expression of capillary pressures in the capillary fringe?	Additional description has been added to this paragraph to explain that AWI retention may also be relevant to the saturated zone because there may be air entrained in pore spaces, as discussed in Bumb et al. 1992.
39	5	"Most of the mass of PFOA and PFOS can remain in the vadose zone for decades, centuries, or longer." The authors should report what percent of the modeled PFOA and PFOS mass that was applied in the biosolids remained in the biosolids after 150 years; do those results match this statement above about "most of the mass"?	Thank you for this comment. The text has been edited to clarify that the specific percentage of mass retained in the vadose zone may vary by location. However, modeling in this draft risk assessment does find that most of the mass (>50%) is retained in the vadose zone in the modeled locations and the EPA has additionally added a citation to a publication that has the same finding.
39	28	Agree with the observation that some of the simple PFAS leaching screening models appear to overestimate the	Thank you.

Page	Line	Comments or Questions	Response
		time to reach groundwater for certain scenarios.	
39	29	Agree with the text that describes how the simplest, screening version of these models appear to overestimate vertical PFAA travel time for some cases. A site-specific calibrated version of more sophisticated AWI-types model would not have the overestimation problem but this is not helpful to this risk assessment.	Thank you.
39	32	*"Consistent with previous sewage sludge risk assessments, this assessment will consider the peak groundwater concentrations when calculating risks, regardless of the timing of their occurrence, to avoid underestimating risks through this pathway."* USEPA should confirm that no model runs great than 150 years were used to assess risk results shown in Section C.3.. Note that Figure 13 on page 92 extends to 600 years.	While the land application unit model is run for 150 years, the groundwater model (EPACMTP) runs until the peak concentrations are observed. The EPA has edited this text for clarity.
41	13	Recommend providing information on the transport of PFOS/PFOA out of the hypothetical reservoir: does VVWM account for PFOS/PFOA in the reservoir outflow?	VVWM includes a first-order dissipation rate due to flow moving contaminant out of the water body – See Equation D.1 in Appendix D. To maintain a steady depth in the reservoir, the flow rate out of the reservoir equals the flow rate in – (*e.g.*, runoff) – that rate is a function meteorology and field scenario (see Table D-3).
41	41	This approach of using the maximum value in the top 2 meters may significantly overpredict the actual risk in some cases. Any users of a drilled groundwater well will not be drinking water with the highest concentration in the formation but an average concentration across the entire screened interval and capture zone.	See the EPA responses to comments in Question 4.
46	31	To following underlying objective a "central tendency", recommend using a mid-range Kd for sorption (the geometric mean of low and high Kd/s) rather than	Given the sensitivity of K_d, reporting high and low values is more valuable than a single median value.

Page	Line	Comments or Questions	Response
		breaking out the low/high results. This would greatly simplify the data presentation in the results tables in Section 3, and more importantly provide a central tendency result.	
55	9	The dispersivity values in Table B-7 seem appropriate for this modeling effort.	Thank you.
77 78 81 83		Recommending reporting the MCL for PFOS and PFOA (4 ppt) in all of the different exposure tables in Section 3.1 for the drinking water pathways.	See responses to prior comments.
77	26	Recommend that the text explains from a risk perspective what it means if groundwater or surface water is above the MCL, and what it means if it is below the MCL.	See responses to prior comments.
99 100 102 103 106		For Sections 4.3, 4.4, 4.6, and 4.7, recommend that the drinking water pathways values that exceed the acceptable threshold (yellow-shaded values) also have some type of indication if the MCL is also exceeded.	See responses to prior comments.
87	37	Minor point: check figure numbers in this section. Are Figures 6-11 are missing?	The EPA has corrected these figures.
94	14	Recommend re-evaluating if $1x10^{-6}$ risk level, which was selected out of the 10^{-5} to 10^{-6} range, is faithful to the goal of performing a central tendency calculation. Again the key to this type of calculation is not to have any over-conservative (overestimation of risk) or underestimation of risk assumptions, calculation steps, input data.	See response to prior comment.

Reviewer 5

Page	Paragraph	Comments or Questions	Response
5	2	The list of 14 exposure pathways is helpful but it will be easier to understand if this list is turned into a graphic. It is also not clear to me the difference	These pathways were identified in historic assessments and are slightly modified for the purpose of PFOA and PFOS draft risk

Page	Paragraph	Comments or Questions	Response
		between pathway 1 (sludge-soil-plant-human) and pathway 2 (sludge-soil-plant-home gardener). Pathway 1 seems to encompass pathway 2.	assessment, as explained in the text. The graphics are provided for the pathways relevant to PFOA and PFOS, which are the focus of this assessment.
39	5	The header "soil surface modeling" should have its own numbering.	The EPA has revised accordingly.
53	table	This table needs a number and a title. Also, it will be helpful to sort the table by parameter so that it is easy to compare between PFOA and PFOS. For example, BCF for forage and silage have the same value for these two chemicals, but BCF Veg for PFOA is a lot higher than that for PFOS.	The EPA re-configured the table to sort the table by crop types.
67	Bottom table	Can you explain why the BAF for TL4 is lower than that of TL3?	Yes, unlike other organic compounds that typically have higher BAFs in higher trophic level fish, the empirical data for PFOA and PFOS show that these chemicals do not follow the same trend.
69	last	Typo in the last sentence, it should say "the adult **un**protected vegetable intake equates to one serving of unprotected vegetables every day."	Thank you; the EPA corrected this typo.
70	first	Typo in the last sentence, it should say "the adult **root** vegetable intake equates to five servings of root vegetables a week."	Thank you; the EPA corrected this typo.
73	1	Why does the exposure factor for dust ingestion have different units for adults, children 12-19, children 6-11, and children 1-5. Shouldn't it be all in the unit of mg/kg/day?	The data sources for soil and dust ingestion available in the EPA Exposure Factors Handbook report these intake rates in units of mg/day. The bodyweight parameter (2.9.3.11) is used to convert these ingestion rates to mg/kg-day when calculating risk.
73	2	Typo in the NHANES survey years, it should say 1999-2006. I also wonder if a more recent figure should be used instead?	Thank you for identifying this typo. This data represents the most up-to-date edition of

Page	Paragraph	Comments or Questions	Response
			the bodyweight chapter of the EPA's exposure Factors Handbook.

References

CalEPA. (2024). Public Health Goals for Perfluorooctanoic Acid and Perfluorooctane Sulfonic Acid in Drinking Water. Available on the Internet at: https://oehha.ca.gov/media/downloads/air/public-health-goal-document/pfoapfosphgfinaldraft040524.pdf

Castoria, R. & Woodruff, T.J. (2003). Assessment of Potential Risk Levels Associated with U.S. Environmental Protection Agency Reference Values. *Environmental Health Perspectives, 111, 10,* 1318-1325.

US EPA (US Environmental Protection Agency). (1992). Technical Support Document for Land Application of Sewage Sludge. Office of Water, Office of Science and Technology. EPA 822/R-93-001a.

US EPA. (1995). A Guide to the Biosolids Risk Assessments for the EPA Part 503 Rule. EPA/832-B-93-005. https://www.epa.gov/sites/default/files/2018-11/documents/guide-biosolids-risk-assessments-part503.pdf

US EPA. (2000). Methodology for deriving ambient water quality criteria for the protection of human health (2000). EPA-822-B-00-004. Office of Water, Washington, DC. https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf

US EPA. (2003). Exposure Analysis for Dioxins, Dibenzofurans, and Coplanar Polychlorinated Biphenyls in Sewage Sludge. Technical Background Document. https://www.epa.gov/biosolids/exposure-analysis-dioxins-dibenzofurans-and-coplanar-polychlorinated-biphenyls-sewage

USEPA. (2022a). ORD Staff Handbook for Developing IRIS Assessments. EPA 600/R-22/268.

US EPA. (2023a). Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation. https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0027

US EPA. (2023b). EPA Response to Final Science Advisory Board Recommendations (August 2022) on Four Draft Support Documents for the EPA's Proposed PFAS National Primary Drinking Water Regulation. https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0043

US EPA. (2024a). Office of Water Final Human Health Toxicity Assessment for Perfluorooctanoic Acid (PFOA). 815R24006.

US EPA. (2024b). Office of Water Final Human Health Toxicity Assessment for Perfluorooctane Sulfonic Acid (PFOS). 815R24007.

US EPA. (2024c). Responses to Public Comments on Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation Rulemaking. 815R24005. https://www.epa.gov/system/files/documents/2024-04/pfas-comment-response-document_final-508_v2.pdf

USEPA. (2024d). Per- and Polyfluoroalkyl Substances (PFAS) Occurrence and Contaminant Background Support Document for the Final PFAS National Primary Drinking Water Regulation. 815R24013.

US EPA. (2024e) Final Freshwater Aquatic Life Ambient Water Quality Criteria and Acute Saltwater Aquatic Life Benchmark for Perfluorooctanoic acid (PFOA). 842R24002.

US EPA. (2024f) Final Freshwater Aquatic Life Ambient Water Quality Criteria and Acute Saltwater Aquatic Life Benchmark for Perfluorooctane sulfonate (PFOS). 842R24003.