



Responses to Select Science Advisory Board Comments Relevant to the Draft Sewage Sludge Risk Assessment for PFOA and PFOS

January 2025

**U.S. Environmental Protection Agency Office of Water, Office of
Science and Technology, Health and Ecological Criteria Division**

Washington, D.C.

INTRODUCTION

In 2023, the U.S. Environmental Protection Agency (EPA) presented the Science Advisory Board (SAB) with the Biosolids Program's proposed framework for 1) prioritizing chemicals found in sewage sludge, 2) conducting screening-level human health and ecological risk assessments using the Biosolids Tool (BST), and 3) conducting refined risk assessments for those chemicals that pose the greatest potential risk to human health and the environment. In October of 2023, the SAB provided a report with feedback on all three items in the proposed framework. The EPA's proposed framework, the charge questions to the SAB, and the final SAB report are available on the EPA's [SAB webpage](#).

The EPA is in the process of responding to all feedback provided by the SAB and revising the general framework for prioritizing, screening, and conducting refined risk assessment for chemicals found in sewage sludge. Although the focus of the SAB review was on the general framework rather than on any particular chemical, some comments provided by the SAB are relevant to the EPA's 2025 *Draft Sewage Sludge Risk Assessment for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS)* ("Draft Risk Assessment"). For thoroughness, the EPA is responding to these comments below. The EPA expects to publish responses to the rest of the SAB's comments later in 2025.

The SAB prioritized their recommendations to indicate relative importance and were defined by the SAB as follows:

- **Tier 1: Key Revisions** – Actions that are necessary to improve the critical scientific concepts, issues, and/or narrative within the assessment/document/model/guidelines.
- **Tier 2: Suggestions** – Actions that are encouraged to strengthen the scientific concepts, issues, and/or narrative within the assessment/document/model/guidelines, but other factors (e.g., EPA need) should be considered by the EPA before undertaking these revisions.
- **Tier 3: Future Considerations** – Useful and informative scientific exploration that may inform future evaluations of key science issues and/or the development of future assessments/documents/models/guidelines. These recommendations are likely outside the immediate scope and/or needs of the current review.

The EPA typically uses the term "biosolids" to mean sewage sludge treated to meet the requirements in Title 40 of the *Code of Federal Regulations* (CFR) part 503 and intended to be applied to land as a soil amendment. This document contains comments from SAB panel members who used the terms interchangeably, so for the purposes of this document, "biosolids" should be interpreted as "sewage sludge."

SAB Comment	Tier Level	EPA Response
<p>While the role of air-water interfacial sorption may not impact most of the chemicals on the list to be evaluated, PFAS transport to groundwater is known to be greatly impacted by this process in the vadose zone. Given the significance of PFAS in the current regulatory framework, the SAB urges EPA to consider how to address this transport process.</p>	<p>Tier 2</p>	<p>The EPA considered models that include air-water interfacial sorption for the PFOA and PFOS risk assessments for these chemicals. A detailed discussion of the model selection process is included in the Draft Risk Assessment under Section 2 and Appendix C. Additionally, the Draft Risk Assessment underwent independent, external peer review by five experts, and the EPA requested feedback specifically on model selection for PFOA and PFOS. The external peer reviewers agreed with the EPA's model selections (<i>see</i> question 4 on EPA Response to External Peer Review Comments on the Draft Sewage Sludge Risk Assessment for PFOA and PFOS). These air-water interfacial sorption models may also be considered during refined risk assessment for other chemicals with similar physical and chemical properties. See the Draft Sewage Sludge Risk Assessment for PFOA and PFOS and responses to peer-review comments for additional information.</p>
<p>The SAB recommends that EPA consider occupational exposures to chemicals in biosolids for dedicated workers who may be responsible for their application.</p>	<p>Tier 2</p>	<p>Under CWA section 405, the EPA is directed to periodically identify pollutants and on the basis of toxicity, persistence, concentration, mobility, or potential for exposure, may be present in sewage sludge in concentrations which may adversely affect human health and the environment. The EPA considered how existing pathways of exposure for farm families may compare to potential exposures for biosolids land appliers (<i>see</i> Section 2.7 of the Draft Risk Assessment), but several significant data limitations on worker exposures were identified. The Draft Risk Assessment concludes that there is insufficient information available to model occupational exposures for workers that repeatedly apply biosolids at different farms throughout the year or to determine whether the farm family or farm worker exposures will exceed the exposures of these professional biosolids applicators. The assessment acknowledges that if this type of worker is repeatedly spray applying biosolids on farm fields, this could lead to airborne exposures over many days of the year and this type of exposure is not represented within the modeled pathways for the farm family. However, the EPA does not currently have survey or other data to estimate the behavior patterns of these types of workers with missing information including amount of biosolids mass aerosolized during</p>

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		<p>application, time spent per day applying biosolids, and number of days worked per year. Should this information become available, the EPA would consider adding this receptor group and the appropriate pathways of potential exposure to the BST and future refined risk assessments. Additionally, PFOA and PFOS are expected to occur primarily in their ionized phase in most farm soils due to the chemicals' acid dissociation constant (pKa) values and are not expected to volatilize; thus, inhalation is not included as a relevant exposure pathway.</p>
<p>The SAB recommends EPA review the data regarding fish consumption rates for an adult farmer to confirm the correct values are used corresponding with trophic level 3 and 4 fish consumption.</p>	Tier 1	<p>In revisiting the fish consumption rate and trophic level assignments used for the BST and risk assessments, the EPA has elected to use a fish consumption rate (FCR) that reflects surveys targeted at consumers of home-produced foods because this group is most representative of the agricultural settings in the US where biosolids are often land applied. Specifically, the EPA is now using fish consumption rate values from the EPA's Exposure Factors Handbook Chapter 13, Table 13-20. The Exposure Factors Handbook also includes information on the species of fish consumed by freshwater fishers in the US (Chapter 10, Table 10-74); this data was used to apportion the trophic level-specific consumption patterns specific to freshwater fishers. See the EPA's Draft Sewage Sludge Risk Assessment for PFOA and PFOS, Section 2.9.3.8.1 for more information on these datasets.</p>
<p>The SAB recommends EPA consider using the adult farmer fish consumption exposure scenario for fish consumption of trophic levels 3 and 4 fish at a central tendency consumption rate (e.g., 50th percentile consumption rate).</p>	Tier 2	<p>See above response. Note that in the Draft Risk Assessment for PFOA and PFOS, for reasons explained in Section 2.9, the EPA selected the 50th percentile values from the Exposure Factors Handbook Chapter 13, Table 13-20.</p>
<p>The SAB recommends that at the refined risk assessment stage, EPA consider models that can differentiate between the total chemical concentration and bioavailable concentration in biosolids (i.e., the biosolids matrix).</p>	Tier 1	<p>The refined risk assessment stage accounts for bioavailable fraction in soils in that the models are parameterized using field-based biosolids-specific studies, when available. Using field-based biosolids-specific studies for plant uptake, groundwater leaching, and animal uptake parameters implicitly considers only the "available" fraction of the chemical in biosolids-amended soil and in the other exposure media like feed and water for livestock. However, in some cases, these biosolids-specific field</p>

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		<p>data are not available. This topic of how to consider total as compared to bioavailable concentrations of chemicals when data specific to soils are not available was discussed extensively in the process of developing the 1993 regulations that included numeric limits for metals in land-applied biosolids. As stated in the preamble to Part 503 "Recent data from long-term field studies have shown that sewage sludge properties influence pollutant bioavailability through binding of the pollutants by the sewage sludge itself. However, the research data base on the fate of many sewage sludge-borne pollutants is still extremely limited. As a result, uncertainties about the health effects and threshold exposures of these pollutants has made the risk/exposure assessment for these pollutants difficult. Therefore, the Agency has decided to continue to use RE [relative effectiveness of exposure] values equal to one for those pollutants with limited data but has revised its RE values where sufficient scientifically defensible information was available indicating the bioavailability of the pollutant was less than 100 percent. The Agency recognizes that in some cases this may result in numerical limits that may be more protective than necessary; however, EPA believes that it is prudent to have a balance of mid-range and bounding parameters in order to protect highly exposed individuals" (Preamble to 40 C.F.R. § 503 (58 FR 9295 (Feb 19, 1993))). The EPA plans to continue to follow this longstanding practice of assuming 100 percent bioavailability of the pollutant in biosolids in the absence of data indicating otherwise.</p>
<p>The SAB recommends that EPA model land reclamation scenarios that reflect the use of large one-time biosolids application rates (i.e., > 100 dry tons/acre) and its potential impact on public health and ecological risks (Pepper et al., 2013).</p>	<p>Tier 1</p>	<p>The risk assessment framework submitted to the SAB and the Draft Risk Assessment for PFOA and PFOS include a land reclamation scenario with a one-time application of biosolids at a rate of 50 dry tons per acre. This value is five times the expected agronomic rate (see Appendix E.1 of the BST User Guide Appendixes and Draft Risk Assessment, Section 2.9.3). Though it is possible for biosolids to be land-applied at rates higher than five times a typical agronomic rate, the EPA anticipates that these scenarios do not frequently occur. A probabilistic risk assessment could consider a range of application rates for a reclamation scenario (note that as described in Section 2.9 of the Draft Risk Assessment, the EPA will not be</p>

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		developing a probabilistic risk assessment for PFOA or PFOS, but probabilistic approaches would be considered for risk assessments of other chemicals).
<p>The SAB recommends that EPA consider the following to inform future evaluations/revisions of the refined assessment: Land reclamation is currently limited within the refined assessment to the restoration of mining sites. There are several other potential land reclamation scenarios where biosolids could be utilized including being employed to restore vegetation on wildfire-damaged land, sand dunes, construction sites, and over-grazed rangelands (McFarland et al., 2009). The potential contribution of domestic septage land application on human health and ecological chemical exposure within the model farm scenario should be considered. While domestic septage applied to non-public contact sites (i.e., private farms or ranches) does not have numerical pollutant limits, domestic septage applied to public contact sites (i.e., parks, cemeteries, home gardens, etc.) must meet the same numerical pollutant limits as land-applied sewage sludge.</p>	Tier 3	<p>There is considerable variability in the scale and types of land reclamation projects that use biosolids to improve soil conditions. In the Draft Risk Assessment, the EPA considered additional reclamation scenarios in the refined risk assessment phase to better understand what reasonably anticipated scenarios may present risks.</p> <p>Regarding domestic septage, in support of Part 503, the EPA compared the concentration of chemical pollutants in domestic septage to municipal sewage sludge and found that an application rate based on nitrogen content was protective of the risk derived chemical pollutant limits (Technical Support Document for Land Application of Sewage Sludge Volume II, 1992). The EPA will continue to evaluate whether domestic septage application rates based on nitrogen are protective of human health and the environment; however, data related to management practices and concentrations of chemicals in domestic septage are often sparse.</p>

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<p>Artificial drainage enhancements of agricultural fields are not accounted for in any models despite their prevalence, especially in the US Midwest (USDA, 2019). Subsurface, tile drainage involves placement of a perforated tile approximately 1-m below the soil surface to improve field drainage, thus reducing runoff, but allowing for direct transport from immediately below the rooting zone to streams. Therefore, the role of runoff in these cases will be overpredicted, thus impacting exposure estimates of more highly retained compounds of interest, but possibly underestimating the impact to streams of more mobile/soluble chemicals. For addressing tile-drain networks, it could be plausible to use the Multimedia, Multi-Pathway, Multi-Receptor Exposure and Risk Assessment (3MRA) to 1 meter (vs 2 m) and then direct discharge to stream coupled with the Variable Volume Water Model versus the dilution-attenuation factor (DAF).</p>	<p>Not Tiered</p>	<p>The EPA agrees that the use of tile drains would impact the fate and transport of chemicals being land applied on agricultural fields. In general, tile drainage systems would be expected to increase risks observed in surface water-related exposure pathways (surface water as a source of drinking water, fish consumption, aquatic life ecological receivers). In the Draft Risk Assessment, the modeling of tile drained agricultural fields would not change the overall risk conclusions because the Draft Risk Assessment models many pathways with risk levels above acceptable thresholds (<i>i.e.</i>, fish consumption, surface water used as a source of drinking water, milk consumption) that would likely result in the same or higher risks if tile drainage were modeled. If a refined risk assessment finds that tile drains would be key risk drivers, the EPA would consider modeling this hydrological setting.</p>